

SMLOUVA O PARTNERSTVÍ

uzavřená podle § 1746 odst. 2 zák. č. 89/2012 Sb., občanského zákoníku, ve znění pozdějších předpisů.

I. Smluvní strany

Kraj Vysočina,

se sídlem: Žižkova 57, 587 33 Jihlava
IČO: 70890749
zastoupený: XXX
kontaktní osoba: XXX
bankovní spojení: Sberbank CZ, a. s. Jihlava
číslo účtu: XXX

a

Česká republika - Státní ústav pro kontrolu léčiv, organizační složka státu

se sídlem: Šrobárova 48, 100 41 Praha 10
IČO: 00023817
zastoupený: Mgr. Irenou Storovou, MHA, ředitelkou
kontaktní osoba: XXX
bankovní spojení: Česká národní banka
číslo účtu: 35-623101/0710

(dále též společně jako „partneři projektu“)

se společně shodli na vytvoření národního projektového konsorcia za účelem realizace projektu „**Deployment of Cross Border eHealth Services in the Czech Republic – NIX-ZD.CZ II (ePrescription/eDispensation)**“ („Zavedení přeshraničních služeb eHealth v České republice – NIX-ZD.CZ II – ePreskripce / eDispenzace“) v rámci pracovního programu CEF TELECOM a uzavřeli níže uvedeného dne, měsíce a roku tuto smlouvu o partnerství a vzájemné spolupráci (dále jen „Smlouva“):

II.

Předmět a účel smlouvy

1. Předmětem této smlouvy je úprava postavení projektových partnerů, jejich úlohy a odpovědnosti, jakož i úprava jejich vzájemných práv a povinností při naplňování účelu této smlouvy.
2. Účelem této smlouvy je zajištění realizace projektu „**Deployment of Cross Border eHealth Services in the Czech Republic – NIX-ZD.CZ II (ePrescription/eDispensation)**“ („Zavedení přeshraničních služeb eHealth v České republice – NIXZD.CZ II – ePreskripce / eDispenzace“) – dále jen „**NIX-ZD.CZ II**“ podpořeného finančními prostředky z fondu **CEF (Connecting Europe Facility)**

TELECOM a z rozpočtů projektových partnerů. Tento projekt je realizován v rámci koordinovaného přístupu spolupracujících zemí EU.

Datum zahájení realizace projektu:	1. července 2018
Datum ukončení realizace projektu:	30. června 2022
Celkové plánované náklady projektu:	710.169,- EUR
Maximální dotace CEF TELECOM (75 %):	532.627,- EUR

- Partnery projektového konsorcia jsou Kraj Vysočina jako vedoucí partner projektu a přímý příjemce finančních prostředků z pracovního programu CEF a Státní ústav pro kontrolu léčiv.
- Za účelem realizace projektu NIX-ZD.CZ II uzavřel Kraj Vysočina jako koordinátor projektu Dohodu o udělení grantu („Grant Agreement under the CEF Telecommunications Sector“ – Příloha č. 3) v rámci fondu Connecting Europe Facility (CEF) – TELECOM s Innovation and Networks Executive Agency (INEA) jako organizací pověřenou Evropskou komisí k technické a finanční implementaci fondu CEF-TELECOM. Tato dohoda stanoví základní pravidla a podmínky pro implementaci projektu, reportování a čerpání přidělených finančních prostředků.
- Státní ústav pro kontrolu léčiv jako partner projektu NIXZD.CZ II pověřil Kraj Vysočina k podpisu výše uvedené Dohody o udělení grantu a k vykonávání veškerých povinností koordinátora projektu v souladu s obecnými podmínkami pro udělení finanční podpory v rámci fondu CEF-TELECOM.

III.

Předmět a cíl projektu

- Předmětem projektu NIXZD.CZ II je implementace přeshraniční služby pro přeshraniční předávání elektronické preskripce, včetně odesílání dispence, prostřednictvím Národního kontaktního místa pro eHealth pro Českou republiku.
- Cílem projektu je navržení, implementace, testování a ostrý provoz přeshraniční služby ePreskripce/eDispence prostřednictvím Národního kontaktního místa pro eHealth v České republice.
- Provozovatelem infrastruktury NIXZD.CZ a organizací pověřenou Ministerstvem zdravotnictví ČR provozem informačního systému Národního kontaktního místa pro eHealth pro ČR je Kraj Vysočina jako koordinátor projektu.

IV.

Práva a povinnosti partnerů projektu

- Smluvní strany se dohodly, že se budou spolupodílet na realizaci projektu uvedeného v čl. II odst. 2 této smlouvy. Partneři projektu se zavazují v rámci projektu NIXZD.CZ II provádět dále uvedené činnosti.
- Při realizaci projektu se budou partneři projektu řídit podmínkami této smlouvy, jakož i podmínkami stanovenými v Dohodě o udělení grantu v rámci fondu CEF TELECOM, jejíž kopie tvoří Přílohu č. 3 této smlouvy.
- Kraj Vysočina jako koordinátor projektu se zavazuje plnit zejména následující činnosti:

- a) plnění funkce koordinujícího partnera projektu, projektového a finančního managementu,
 - b) komunikace s INEA/Evropskou komisí jako implementačním orgánem,
 - c) účast na koordinačních schůzkách pracovní skupiny eHMSEG (eHealth Member State Expert Group),
 - d) koordinace prací a jednotlivých aktivit dle Přílohy č. 1 této smlouvy,
 - e) kontrola dodržování cílů a harmonogramu projektu dle Přílohy 1 a 3 této smlouvy,
 - f) zajištění technické části a technologického prostředí informačního systému Národního kontaktního místa pro ČR (dále jen „NCPeH“), příprava a úprava stávajícího systému pro službu přeshraniční ePreskripce/eDispenzace,
 - g) implementace služby ePreskripce /eDispenzace do NCPeH, ustanovení organizačních podmínek a procesů v rámci NCPeH,
 - h) součinnost při přípravě legislativních návrhů, sekundárních předpisů, bezpečnostních požadavků a národních standardů,
 - i) zajištění sémantické interoperability,
 - j) zajištění integračních testů a auditu,
 - k) součinnost při seznamování odborné veřejnosti s výstupy projektu a propagace projektu,
 - l) organizování seminářů a kongresů
 - m) vyúčtování vynaložených prostředků a zpracování zpráv o činnosti konsorcia v dohodnutých termínech a v souladu Dohodou o poskytnutí grantu,
 - n) příjem dotací od poskytovatele finanční podpory a následné přeúčtování Státnímu ústavu pro kontrolu léčiv dle schváleného rozpočtu projektu (Příloha č. 2).
4. Státní ústav pro kontrolu léčiv jako partner projektu se zavazuje plnit následující činnosti:
- a) připomínkování a oponenturu veškerých výstupů projektu (analýz, návrhů atd.),
 - b) zajištění nutných úprav Centrálního úložiště elektronických receptů pro zajištění implementace služby přeshraničního předávání elektronických receptů,
 - c) součinnosti při zajištění návrhů úprav legislativy, sekundárních předpisů, bezpečnostních požadavků a národních standardů,
 - d) součinnost s Krajem Vysočina při zajištění sémantické interoperability,
 - e) součinnost s Krajem Vysočina při zajištění integračních testů a auditu,
 - f) součinnost s Krajem Vysočina při seznamování odborné veřejnosti s výstupy projektu a propagací projektu,
 - g) součinnost s Krajem Vysočina při organizování seminářů a kongresů, zejména těch s celonárodním rozsahem,
 - h) vyúčtování vynaložených prostředků a zpracování zpráv o své činnosti v dohodnutých termínech.
5. Přehled jednotlivých fází projektu a související přehled aktivit a jejich rozdělení mezi partnery projektu tvoří Přílohu č. 1 této smlouvy.
6. Partneři projektu nesou plnou odpovědnost za realizaci činností, které mají vykonávat dle této smlouvy tak, aby byl splněn účel smlouvy nejpozději do data ukončení realizace projektu.
7. Partneři projektu jsou povinni jednat způsobem, který neohrožuje realizaci projektu a zájmy projektového partnera.

8. Partneri projektu mají právo na veškeré informace týkající se projektu, zejména jeho finančního řízení, dosažených výsledků projektu a související dokumentace.
9. Partneri projektu se zavazují se vzájemně informovat o svých aktivitách a projektech, které mají nebo mohou mít vztah k realizaci předmětu této smlouvy
10. Kraj Vysočina se jako koordinátor zavazuje pravidelně v průběhu realizace komunikovat se svými partnery a informovat je o postupu projektu, především formou telekonferencí a pravidelných porad. Za tímto účelem se ustavuje projektový tým složený z určených zástupců každého účastníka smlouvy:

Kraj Vysočina	XXX	XXX
	XXX	XXX
	XXX	XXX
	XXX	XXX
	XXX	XXX
Státní ústav pro kontrolu léčiv	XXX	XXX
	XXX	XXX
	XXX	XXX
	XXX	XXX
	XXX	XXX

11. Při plnění předmětu smlouvy se partneri projektu zavazují:

- a) provádět činnosti, které realizují v rámci projektu, v souladu s harmonogramem jednotlivých aktivit projektu, který tvoří Přílohu č. 1 této smlouvy,
- b) naplňovat během realizace projektu monitorovací indikátory vztahujících se k činnostem, které realizují v rámci projektu a které jsou uvedené v Příloze č. 1 této smlouvy,
- c) vytvořit podmínky k provedení kontroly vztahující se k činnostem, které realizují v rámci projektu, poskytnout oprávněným osobám veškeré doklady vážící se k těmto činnostem, umožnit průběžné ověřování souladu údajů o realizaci projektu uváděných v monitorovacích zprávách se skutečným stavem v místě jeho realizace a poskytnout součinnost všem osobám oprávněným k provádění kontroly,
- d) informovat bez zbytečného odkladu druhou stranu o veškerých skutečnostech, které mohou mít vliv na povahu nebo podmínky provádění projektu, zejména se jedná o změny, které mohou nastat ve vztahu k projektu nebo změny souvisejících s činnostmi, které realizují dle této smlouvy.

V.

Financování projektu, rozpočet

1. Rozpočet projektu (Příloha č. 2 – Rozpočet projektu), který stanoví výši spoluúčasti jednotlivých partnerů projektu, tvoří nedílnou součást této smlouvy.
2. Kraj Vysočina nese jako koordinátor projektu plnou odpovědnost za celkový rozpočtový a finanční management projektu. Kraj Vysočina bude odpovědný za přeposílání finančních prostředků Státnímu ústavu pro kontrolu léčiv, jakož i za

provádění změn v rozpočtu spočívajících v přesunu finančních prostředků mezi jednotlivými položkami.

3. Kraj Vysočina jako koordinátor projektu zajistí správné vedení účetnictví a veškerých finančních dokumentů v souladu s dohodou o udělení grantu a s příslušnými právními předpisy.
4. Každý partner je odpovědný za svůj rozpočet až do výše částky, kterou se podílí na projektu a zavazuje se uvolnit svou část spolufinancování v souladu s Přílohou č. 2 této smlouvy (Rozpočet projektu).

VI.

Další práva a povinnosti partnerů projektu

1. Partneři projektu jsou povinni zdržet se jakékoliv činnosti, jež by mohla znemožnit nebo ztížit dosažení účelu této smlouvy.
2. Partneři projektu jsou povinni vzájemně se informovat o skutečnostech rozhodných pro plnění této smlouvy.
3. Partneři projektu jsou povinni jednat při realizaci projektu eticky, korektně, transparentně a v souladu s dobrými mravy.
4. Partneři projektu jsou v rámci plnění aktivit projektu povinni provést příslušná organizační a technická opatření k zabezpečení ochrany osobních údajů ve smyslu platné legislativy.

VII.

Trvání smlouvy

Smlouva se uzavírá na dobu určitou, a to do doby dosažení účelu dle článku II. smlouvy, nejméně však do doby ukončení realizace projektu a jeho závěrečného vyúčtování.

VIII.

Ostatní ustanovení

1. Jakékoliv změny této smlouvy lze provádět pouze na základě dohody projektových partnerů formou písemných dodatků podepsaných oprávněnými zástupci partnerů.
2. Tato smlouva nabývá platnosti a účinnosti dnem podpisu oprávněných zástupců jednotlivých partnerů projektu.
3. Vztahy smluvních stran blíže neupravené se řídí zákonem č. 89/2012 Sb., občanským zákoníkem a příslušnými právními předpisy České republiky.
4. Tato smlouva je vyhotovena ve dvou vyhotoveních, z nichž každý partner obdrží po jednom vyhotovení.
5. Partneři projektu jsou povinni řídit se při realizaci projektu ustanoveními následujících příloh, které tvoří nedílnou součást této Smlouvy:

Příloha č. 1 – Aktivity a harmonogram projektu

Příloha č. 2 – Rozpočet projektu

Příloha č. 3 - Grant Agreement Under the Connecting Europe Facility (CEF) –
Telecommunications Sector

6. Smluvní strany prohlašují, že tato smlouva byla sepsána na základě jejich pravé a svobodné vůle, nikoliv v tísní ani za jinak nápadně nevýhodných podmínek.
7. O uzavření této Smlouvy rozhodla Rada Kraje Vysočina dne 26. 6. 2018 usnesením č. 1155/19/2018/RK.

V Jihlavě dne 2. 7. 2018

Za Kraj Vysočina:

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XXX

V Praze dne 22. 6. 2018

Za Státní ústav pro kontrolu léčiv:

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Mgr. Irena Storová, MHA, ředitelka

Monitorovací období			7/2018 - 7/2019					7/2019 - 6/2020					7/2020 - 6/2021					7/2021 - 6/2022												
CEF - Deployment of Cross Border eHealth Services in the Czech Republic - NIXZD.CZ - eP / eD			Infrastruktura a zařízení	Číslo (eur)	Kraj Vysočina	person-months	SUKL (+ upr. test kraje)	person-months (konkr.)	Infrastruktura a zařízení	Číslo (euro)	Kr.Vys	person-months	SUKL	person-months	Infrastruktura a zařízení	Číslo (euro)	Kr.Vys	person-months	SUKL	person-months	Infrastruktura a zařízení	Číslo (euro)	Kr.Vys	person-months	NZ	person-months	SUKL	person-months		
ACTIVITIES	TERMIN	TASKS																												
1. Preparation and implementation	7/2018 - 1/2020	T.1.1 Plánování a monitoring aktivit vedoucích k provozu nové služby eP/eD v NCPeH (preparation and implementation plan, adopt and localize monitoring tools - in line with other MS, monitor overall progress of A.1 tasks)			Plánování a monitoring	1	Plánování a monitoring	2	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
		T.1.2 Návrh národní architektury - současný stav, analýza současné architektury a návrh úprav (včetně vazeb na e-government, eDAS, zdravotní registry; EU interoperabilita...). Analýza národního konektoru a návrhy jeho úprav. Adaptace národních eP/eP dokumentů do EU-friendly.			Analýza stávající SW SUKL vůči OpenNCP z pohledu NCP	2	Analýza stávajícího stavu (SW včetně datasetů) a návrh výsledné architektury	6		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.1.3 Ustanovení organizačních podmínek a procesů - návrh organizačního zajištění eHNCP + NIXZD, návrh use-case (scénáře a zapojené subjekty), Country A services and country B services.			Návrh úprav org. struktury eHNCP a NIXZD.CZ, specifikace use-case, návrh úprav systému monitoringu a podrobn.	3	Analýza a návrh procesů souvisejících s ePreskripcí	4		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.1.4 Stanovení legislativních a bezpečnostních požadavků a požadavků za ochranu osobních dat - legislativní ukotvení, soulad s bezpečnostními normami ČR (analýza rizik, dokumentace dle pravidel ISMS/ISO 27001), stanovisko ÚOOÚ k návrhu architektury, Podpis Agreementu.			Návrh legislativních a organizačních požadavků, úprav.	3	Návrh legislativních a organizačních změn, zejména z hlediska ochrany osobních údajů a bezpečnosti	4		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.1.5 Zajištění sémantické interoperability eP - klinické dokumenty ve standardu HL7 CDA V2 Level 3, strukturované dle guidelines EK, definice terminologií v MVC, překlady a namapování dle národních standardů (MTC)			Návrh úpravy sémantické interoperability vůči eP/eD, úpravy MVC/MTC, jazykové překlady.	6	Návrh úpravy openNCP a IS eRecept pro zajištění interoperability eP/eD a návrh úprav nomenklatury a standardů	3		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.1.6 OpenNCP - lokalizace, implementace, integrace a testování OpenNCP localisation implementation, integration and testing - národní konektor			Úpravy stávajícího prostředí OpenNCP, validace, testování.	4	Implementace národního konektoru a úpravy IS eRecept dle předchozích bodů	10		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.1.7 Unit a integrační testy - pre-production testing, technical and functional testing.			Integrační testy, PPT testing.	4	Integrační testy, PPT testing	4		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
2. Service testing, Approval and Deployment	2/2018 - 1/2020	T.2.1 Provedení testů k zajištění kvalitního provozu - pre-PPT conformance tests			Příprava a provedení testů. Následné úpravy prostředí.	2	Spolupráce při provedení testů.	4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x		
		T.2.2 Pre-Production Testing and Project-a-thon - eHDSI Test Framework - testing phases (Bootcamp, Projectathon, Preparation for PPT testing, PPT testing)			Provedení testovacích aktivit. Následné úpravy prostředí.	3	Spolupráce při testovacích aktivitách.	4		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
		T.2.3 Perform Security audit - MS overall service readiness and MS service initial audit = audit framework. Readiness checklist (annex of audit framework)			Bezpečnostní testy a audit dle audit framework.	2	Spolupráce při auditu.	6		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.2.4 Country readiness approval processes - objective evidence of the technical and semantic readiness (projectathon), legal, organizational, security readiness (audit). Results to the eHMSEG and eHN - formal authorization.			Příprava auditních podkladů pro schválení	2	Spolupráce při přípravě podkladů pro schválení.	2		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.2.5 Spuštění ostrého provozu - Service deployment - implement operational environment for servers, security assets, connection with NI and central config. Services. Deployment of NCPeH, portal and national connector. Configuration of system toward the Central config. Services, synchronization of the Local terminology service.			Spuštění ostrého prostředí.	2	Spuštění ostrého prostředí.	2		x	x	Spuštění ostrého provozu	2	x	2	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		T.2.6 Non regression testing - defined by European Competent Body			Provedení non-regression testů.	2	Spolupráce při non-regression testing.	2		x	x	Provedení non-regression testů.	2	x	2	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3. Operation	11/2019 - 6/2022	T.3.1 Provoz služby a monitoring - release plan, service levels.			x	x	x				Provoz služby a monitoring	2	x	2	x	x	Provoz služby a monitoring	2	x	2	x	x	Provoz služby a monitoring	2	x	2	x	2		
		T.3.2 Maintenance služby a změny v provozu - incident management, change requests. Sémantické uprady. Zajištění provozu služby během plánovaných i neplánovaných odstávek.			x	x	x		x	x	Maintenance and change management, sémantické uprady.	1	?	1	x	x	Maintenance and change management, sémantické uprady.	1	x	1	x	x	Maintenance and change management, sémantické uprady.	1	x	1	x	1		
		T.3.3 Vyhodnocení služby - automatický sběr dat, dotazníky - spokojenost uživatelů, hodnocení pohovory s odbornými uživateli, vyhodnocení validity předávaných klinických dat.			x	x	x	x	x	x	Vyhodnocení funkčnosti služby	1	Vyhodnocení funkčnosti.	1	x	x	Vyhodnocení funkčnosti služby	1	x	1	x	x	Vyhodnocení funkčnosti služby	1	x	1	x	1		
4. Dissemination, Training and Support	10/2018 - 6/2022	T.4.1 Marketing a propagace služby pro lékaře - e-learning, semináře, letáky, využití stávajících info kanálů ve zdravotnictví			Marketing a propagace - organizační zajištění	1	Marketing a propagace	1	Pořízení e-learningového kurzu, propagační a edukační materiály		Marketing a propagace	1	Marketing a propagace	1	Propagační materiály		Marketing a propagace.	1	Marketing a propagace - ?	1	Propagační materiály		Marketing a propagace.	1	Spolupráce při marketingu a propagační službě.	x	Marketing a propagace - ?	1		
		T.4.2 Marketing a propagace pro odbornou veřejnost a zainteresované subjekty ("decision-makers") - organizace seminářů, účast na konferencích, "vnitřní" marketing			x	x	x		Propagační a edukační materiály		vnitřní marketing	1	1	1	Propagační materiály		vnitřní marketing	1	1	1	Propagační materiály		vnitřní marketing	1	x	x	1	1		
		T.4.3 Marketing a propagace pro občany a širokou veřejnost/koncové uživatele - reklamní kampaň, video spoty, atd...			x	x	x		Propagační a edukační materiály		info kampaň		Info kampaň pro veřejnost	1	1	Propagační a edukační materiály		info kampaň		1	1	Propagační a edukační materiály		info kampaň	x	x	1	1		
		T.4.5 Help Desk a Support			x	x	x		Rozšíření licencí HelpDesk systému KrV		Obsluha HelpDesk, podpora uživatelů.	2	podpora uživatelů	2	2	x	x	Obsluha HelpDesk, podpora uživatelů.	2	podpora uživatelů	2	2	x	x	Obsluha HelpDesk, podpora uživatelů.	2	x	x	2	
5. Governance and management	7/2018 - 6/2022	T.5.1 Reportování a management - dle organizační struktury eHDSI (lead partner)			Acting and reporting.	1	x	x	x	x	Acting and reporting.	1	x	x	x	x	Acting and reporting.	1	x	1	x	x	Acting and reporting.	1	x	x	x	x		
		T.5.2 Management projektových aktivit - downfit státu			Project management.	1	Management projektových aktivit.	1	x	x	Project management.	1	Management projektových aktivit.	1	x	x	Project management.	1	Management projektových aktivit.	1	1	x	x	Project management.	1	x	x	1	1	
			0		39		55		0		14		14		0		10		10		0		10		0		10			

Kraj Vysočina - člověkoměsíce	73
SÚKL - člověkoměsíce	89
CELKEM člověkoměsíce	162
CELKEM mzdy - euro	567000
Nákup - HW, SW, equipment - euro	
Subcontracting - externí audit - euro	30000
CELKEM NÁKLADY euro	597000
CZK	15522000

Application Form Part A



EUROPEAN COMMISSION

CONNECTING EUROPE FACILITY:
TELECOM

A3.2

TENtec proposal number

DRAFT (27765281)

Financial information on the Action

Indicative breakdown of estimated eligible costs by activity

Co-financing rate

75.00

Activities	Personnel costs	Subcontracting costs	Other costs	Total costs	Indirect eligible costs	Total eligible costs	Estimated CEF contribution
Preparation and Implementation	185,500	0	22,750	208,250	14,578	222,828	167,121
Vysočina Region	70,000	0	11,200	81,200	5,684	86,884	65,163
State Institute for Drug Control	115,500	0	11,550	127,050	8,894	135,944	101,958
Service Testing, Approval and Deployment	143,500	30,000	17,920	191,420	11,299	202,719	152,040
Vysočina Region	59,500	30,000	9,520	99,020	4,831	103,851	77,889
State Institute for Drug Control	84,000	0	8,400	92,400	6,468	98,868	74,151
Operation	84,000	0	10,920	94,920	6,644	101,564	76,173
Vysočina Region	42,000	0	6,720	48,720	3,410	52,130	39,098
State Institute for Drug Control	42,000	0	4,200	46,200	3,234	49,434	37,076
Dissemination, Training and Support	112,000	0	11,200	123,200	8,624	131,824	98,868
Vysočina Region	56,000	0	5,600	61,600	4,312	65,912	49,434
State Institute for Drug Control	56,000	0	5,600	61,600	4,312	65,912	49,434
Governance and Management	42,002	0	5,880	47,882	3,352	51,234	38,425

Activities	Personnel costs	Subcontracting costs	Other costs	Total costs	Indirect eligible costs	Total eligible costs	Estimated CEF contribution
Vysočina Region	28,002	0	4,480	32,482	2,274	34,756	26,067
State Institute for Drug Control	14,000	0	1,400	15,400	1,078	16,478	12,359
Total	567,002	30,000	68,670	665,672	44,497	710,169	532,627

Sources of Financing

Applicants	Applicant budget(s)	State budget(s)	Regional/local budget(s)	Other sources	Requested CEF financing	Total
Applicant 1	85,883	0	0	0	257,650	343,533
Applicant 2	91,659	0	0	0	274,977	366,636
TOTAL	177,542	0	0	0	532,627	710,169

Exchange rate

If applicable, please indicate the exchange rate used for preparing the application: CZK

Related actions

If the proposed Action is part of a larger project previously supported through EU funding, please specify all related Actions:

Action title	Funding programme	Grant Agreement / Decision number	Amount
Deployment of Cross Border eHealth Services in the Czech Republic - NIXZD.CZ	CEF TELECOM	2015-CZ-IA-0067	358,107



Innovation and Networks Executive Agency

Department C - Connecting Europe Facility (CEF)

**GRANT AGREEMENT
UNDER THE CONNECTING EUROPE FACILITY (CEF) -
TELECOMMUNICATIONS SECTOR**

AGREEMENT No INEA/CEF/ICT/A2017/1529838

The **Innovation and Networks Executive Agency (INEA)** ("the Agency"), under the powers delegated by the European Commission ("the Commission"), represented for the purposes of signature of this Agreement by the Head of Department C of the Agency, Andreas Boschen,

on the one part,

and

1. Vysočina Region (Kraj Vysočina)

-
Registration No N/A
Žižkova 57
58733 Jihlava
Czech Republic
VAT No N/A,

hereinafter referred to as "the coordinator", represented for the purposes of signature of this Agreement by President of Vysočina Region, Jiri Behounek

and the following other beneficiaries:

2. State Institute for Drug Control (SUKL) - established in Czech Republic duly represented by the coordinator by virtue of the mandates included in Annex IV for the signature of this Agreement,

hereinafter referred to collectively as "the beneficiaries", and individually as "beneficiary" for the purposes of this Agreement where a provision applies without distinction between the coordinator or another beneficiary,

on the other part,

HAVE AGREED

to the Special Conditions (hereinafter referred to as “the Special Conditions”) and the following Annexes:

- Annex I Description of the action
- Annex II General Conditions (hereinafter referred to as “the General Conditions”)
- Annex III Estimated budget of the action
- Annex IV Mandate provided to the coordinator by the other beneficiary
- Annex V Model technical report(s)
- Annex VI Model financial statement(s)
- Annex VII Model terms of reference for the certificate on the financial statements

which form an integral part of this Agreement, hereinafter referred to as "the Agreement".

The terms set out in the Special Conditions shall take precedence over those set out in the Annexes.

The terms of Annex II "General Conditions" shall take precedence over the other Annexes.

SPECIAL CONDITIONS

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- ARTICLE 2 – ENTRY INTO FORCE OF THE AGREEMENT AND DURATION OF THE ACTION
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- ARTICLE 5 – BANK ACCOUNT FOR PAYMENTS
- ARTICLE 6 – DATA CONTROLLER AND COMMUNICATION DETAILS OF THE PARTIES
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- ARTICLE 12 – OBLIGATION TO CONCLUDE AN INTERNAL CO-OPERATION AGREEMENT
- ARTICLE 13 – INAPPLICABILITY OF THE NO-PROFIT PRINCIPLE
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- ARTICLE 15 – SPECIAL PROVISIONS ON ELIGIBLE COSTS
- ARTICLE 16 – WAIVING OF THE OBLIGATION TO PROVIDE CERTIFICATES ON THE FINANCIAL STATEMENTS
- ARTICLE 17 – FINANCIAL SUPPORT TO THIRD PARTIES
- ARTICLE 18 – IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING
- ARTICLE 19 – SETTLEMENT OF DISPUTES WITH NON EU BENEFICIARIES
- ARTICLE 20 – BENEFICIARIES WHICH ARE INTERNATIONAL ORGANISATIONS
- ARTICLE 21 – JOINT AND SEVERAL FINANCIAL LIABILITY FOR RECOVERIES
- ARTICLE 22 – IMPLEMENTATION OF ACTIVITIES NOT FINANCIALLY SUPPORTED UNDER THE AGREEMENT

ARTICLE 1 – SUBJECT MATTER OF THE AGREEMENT

The Commission has decided to award a grant, under the terms and conditions set out in the Special Conditions, the General Conditions and the other Annexes to the Agreement, for the action entitled "**Deployment of Cross Border Services in the Czech Republic - NIX-ZD.CZ II. (ePrescription/eDispensation)**" ("the action"), action number **2017-CZ-IA-0110** as described in Annex I.

With the signature of the Agreement, the beneficiaries accept the grant and agree to implement the action, acting on their own responsibility.

ARTICLE 2 – ENTRY INTO FORCE OF THE AGREEMENT AND DURATION OF THE ACTION

2.1 The Agreement shall enter into force on the date on which the last party signs.

2.2 The action shall run from 01/07/2018 ("the starting date") until 30/06/2022 ("the completion date").

ARTICLE 3 - MAXIMUM AMOUNT AND FORM OF THE GRANT

The grant for the action shall be of a **maximum amount of EUR 532,627**.

The grant shall take the form of:

- (a) the reimbursement of 75.00% of the eligible costs of the action ("reimbursement of eligible costs"), which are estimated at EUR 710,169 and which are:
 - (i) actually incurred ("reimbursement of actual costs")
 - (ii) reimbursement of unit costs: not applicable
 - (iii) reimbursement of lump sum costs: not applicable
 - (iv) for indirect costs declared on the basis of a flat-rate of 7% of the total eligible direct costs minus subcontracting costs within the meaning of Article II.10 and costs of financial support to third parties within the meaning of Article II.11 ("reimbursement of flat-rate costs");
 - (v) declared on the basis of an amount per unit calculated in accordance with the beneficiary's usual cost accounting practices ("reimbursement of costs declared on the basis of the beneficiary's usual cost accounting practices") for personnel costs
- (b) unit contribution: not applicable
- (c) lump sum contribution: not applicable
- (d) flat-rate contribution: not applicable

ARTICLE 4 – ADDITIONAL PROVISIONS ON REPORTING, PAYMENTS AND PAYMENT ARRANGEMENTS

4.1 Reporting periods and payments

In addition to the provisions set out in Articles II.23 and II.24, the following reporting and payment arrangements shall apply:

4.1.1 Reporting periods

The action is divided into the following reporting periods:

- One single reporting period from the starting date to the completion date of the action.

4.1.2 Payments

Upon entry into force of the Agreement, the Agency shall make the pre-financing payment of EUR 266,314 (two hundred sixty-six thousand three hundred fourteen euros) to the coordinator in accordance with Article II.24.1.

At the end of each reporting period, except the last reporting period, the Agency shall make an interim payment to the coordinator in accordance with Article II.24.2.

At the end of the last reporting period, the Agency shall make the payment of the balance to the coordinator in accordance with Article II.24.3.

4.2 Time limit for payments

The time limit for the Agency to make the payment of the balance is 90 days.

4.3 Language and submission means of requests for payment, reports and financial statements

All requests for payments, reports and financial statements shall be submitted in English.

Those documents or, if applicable, scanned copies of the original signed paper versions and electronic files, shall be sent via e-mail to the e-mail address specified in Article 6.2.

ARTICLE 5 – BANK ACCOUNT FOR PAYMENTS

All payments shall be made to the coordinator's bank account as indicated below:

Name of bank: Sberbank Cz a.s.

Precise denomination of the account holder: Kraj Vysočina

Full account number (including bank codes): CZ7868000000004200112590

SWIFT code: VBOECZ2X

ARTICLE 6 - DATA CONTROLLER AND COMMUNICATION DETAILS OF THE PARTIES

6.1 Data controller

The entity acting as a data controller according to Article II.6 shall be the Director of the Agency.

6.2 Communication details of the Agency

Any communication addressed to the Agency by post or e-mail shall be sent to the following address:

Innovation and Networks Executive Agency (INEA)
Department C - Connecting Europe Facility (CEF)
Unit C5 Telecommunications

B-1049 Brussels

Fax: +32(0)2 297 37 27

E-Mail addresses:

For general communication: inea@ec.europa.eu

For the submission of requests for payment, reports and financial statements: INEA-CEF-ICT@ec.europa.eu

Any communication addressed to the Agency by registered mail, courier service or hand-delivery shall be sent to the following address:

Innovation and Networks Executive Agency (INEA)
Avenue du Bourget, 1
B-1140 Brussels (Evere)

6.3 Communication details of the beneficiaries

Any communication from the Agency to the beneficiaries shall be sent to the following addresses:

For Vysočina Region:

Klara Jirakova

Project manager

Žižkova 57, 58733 Jihlava, Czech Republic

E-mail address: jirakova.k@kr-vysocina.cz

ARTICLE 7 – ENTITIES AFFILIATED TO THE BENEFICIARIES

Not applicable.

ARTICLE 8 - IMPLEMENTING BODIES DESIGNATED BY THE BENEFICIARIES

Not applicable.

ARTICLE 9 - MONO-BENEFICIARY GRANT

Not applicable.

ARTICLE 10 – ADDITIONAL PROVISIONS ON REIMBURSEMENT OF COSTS DECLARED ON THE BASIS OF THE BENEFICIARY'S USUAL COST ACCOUNTING PRACTICES

In addition to the conditions set out in Article II.20.5, where, in accordance with point (v) of Article 3(a) the grant takes the form of the reimbursement of unit costs, lump sum costs or flat-rate costs declared by the beneficiary on the basis of its usual cost accounting practices, the beneficiary shall ensure that the cost accounting practices used are also in compliance with the conditions laid down in Commission Decision C(2016)478 of 3 February 2016.

ARTICLE 11 – ADDITIONAL PROVISIONS ON USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

In addition to the provisions of Article II.8.3, the beneficiaries shall warrant that the Agency has the rights to:

- summarise the results of the action and distribute the summary;
- extract a part (e.g. audio or video files) of, divide into parts or compile the results of the action.

ARTICLE 12 – OBLIGATION TO CONCLUDE AN INTERNAL CO-OPERATION AGREEMENT

Not applicable.

ARTICLE 13 - INAPPLICABILITY OF THE NO-PROFIT PRINCIPLE

Not applicable.

ARTICLE 14 - INELIGIBILITY OF VALUE ADDED TAX

By way of derogation from point (h) of Article II.19.2, amounts of value added tax (VAT) paid are not eligible for the following beneficiaries: Vysočina Region and State Institute for Drug Control.

ARTICLE 15 - SPECIAL PROVISIONS ON ELIGIBLE COSTS

Not applicable.

ARTICLE 16 – WAIVING OF THE OBLIGATION TO PROVIDE CERTIFICATES ON THE FINANCIAL STATEMENTS

Not applicable.

ARTICLE 17 - FINANCIAL SUPPORT TO THIRD PARTIES

Article II.11 is not applicable.

ARTICLE 18 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

Not applicable.

ARTICLE 19 – SETTLEMENT OF DISPUTES WITH NON EU BENEFICIARIES

Not applicable.

ARTICLE 20 – BENEFICIARIES WHICH ARE INTERNATIONAL ORGANISATIONS

Not applicable.

ARTICLE 21 – JOINT AND SEVERAL FINANCIAL LIABILITY FOR RECOVERIES

Not applicable.

ARTICLE 22 – IMPLEMENTATION OF ACTIVITIES NOT FINANCIALLY SUPPORTED UNDER THE AGREEMENT

Not applicable.

SIGNATURES

For the coordinator

For the Agency

Jiri Behounek

Andreas Boschen

Done at Jihlava, on

Done at Brussels, on

In duplicate in English

ANNEX I DESCRIPTION OF THE ACTION

ARTICLE I.1 – SCOPE AND OBJECTIVES OF THE ACTION

The aim of the Action is to prepare, test, deploy, and operate the cross-border service for the exchange of ePrescription / eDispensation via the National Contact Point for eHealth (NCPeH). The Action complements the on-going CEF funded Action 2015-CZ-IA-0067, which focuses on preparation, testing, deployment and operation of the NCPeH for the provision of the Patient Summary as Country A and B.

This Action will allow Czech Republic's to become part of a secure peer-to-peer network allowing the exchange of ePrescriptions across Europe, contributing to patient safety and provide medical personnel with essential medical patient data.

The NCPeH will streamline nationwide service provision of ePrescription/eDispensation endorsed by the eHealth Network and governed by the eHealth Operational Management Board.

Vysočina Region acts as mandated by the Ministry of Health of the Czech Republic, in cooperation with the State Institute for Drug Control, to assure the seamless provision of cross border service.

The Action will also broaden the level of care provided to European citizens visiting the Czech Republic, in line with the 2011/24/EU directive, as well as to better support Czech citizens' health information needs while travelling in European countries.

ARTICLE I.2 – LOCATION OF THE ACTION

I.2.1 Member State(s): Czech Republic

I.2.2 EEA country(ies): not applicable

I.2.3 Third country(ies): not applicable

ARTICLE I.3 – ACTIVITIES

I.3.1 Activities timetable

Activity number	Activity title	Indicative start date	Indicative end date	Milestone number
1	Preparation and Implementation	01/07/2018	31/01/2020	1, 2
2	Service Testing, Approval and Deployment	01/02/2019	31/01/2020	3, 4, 5
3	Operation	01/11/2019	30/06/2022	6, 7, 8
4	Dissemination, Training and Support	01/10/2018	30/06/2022	9

I.3.2 Activities description

Activity 1: Preparation and Implementation

This activity aims at designing a national deployment plan and at performing national preparatory and implementing activities towards the provision of cross-border eHealth services for the exchange of eP/eD according to the defined Service Level Agreement (SLA). Czech Republic will prepare, test, deploy eP/eD in 2020 and operate the National Contact Point for eHealth (NCPeH) regarding the provision of eP/eD.

This activity is broken down into the following tasks:

Task 1.1 – Plan and monitor progress activities towards service operation

During this task, the activities forming the Action will be planned and their progress will be monitored to ensure service operation of a new service eP/eD in NCPeH

This task is comprised of the following steps:

- define the detailed preparation and implementation plan;
- adopt and localize the monitoring tools, in line with the other Member States;
- monitor the overall progress of the tasks related to activity 1.

Task 1.2 – Design National architecture

This task aims at designing the National architecture. It is comprised of the following steps:

- analysis of the current architecture of the National Infrastructure and how to connect with the NCPeH;
- assess how Portal B can be implemented (connected with an Identity Provider service for Health Professional);
- design the overall architecture and specify the National Connector;
- specify the transformation of the eP documents into the EU-Friendly documents (and further updates accordingly to the EU guidelines).

Task 1.3 – Establish Organisational requirements and procedures

This task aims at establishing the organisational requirements and procedures in line with the eHN Organisational Framework for NCPeH. Roles, procedures and tasks will be identified and assigned to the specific actors, including the involvement of institutions relevant for the provision of Country A services (i.e. patient consent management) and Country B services.

Task 1.4 – Establish Legal, security and privacy requirements and procedures

This task aims at establishing legal, security and privacy requirements and procedures. The "Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services" will be signed by Czech Republic relevant authorities. It will allow the Czech NCPeH to be part of the CBeHIS and with the criteria set in the Agreement.

This task is comprised of the following steps:

- compliance with national legislation;
- compliance with relevant security standards (risk analysis, documentation in line with ISMS/ISO 27001).

Task 1.5 – Assure Semantic interoperability of eP/eD

This task will assure semantic interoperability of eP/eD. The main outcomes of the semantic assets management will be:

- the clinical documents in HL7 CDA V2 Level 3 structured and coded according to the European Commission Guidelines and the associated implementation Guides;
- The common terminologies, defined in the Master ValueSet Catalogue (MVC) and their translation and transcoding according to national requirements (Master Translation/Transcoding Catalogue: MTC).

Task 1.6 – OpenNCP localisation implementation, integration and testing

This task includes the OpenNCP localisation implementation, integration and testing regarding the service provision of eP/eD. The OpenNCP will be localized and implemented towards the national infrastructure and the country B portal. This task may contain modifications of the national connector regarding the National Contact Point for eHealth in order to allow the service provision of eP/eD. These modification will include new functionalities relevant to the service provision of eP/eD..

Task 1.7 – Perform unit, integration testing

During this task, unit and integration testing will be performed. Following the unit tests, the OpenNCP localisation will be tested for National usage of eP/eD. The complete system will be deployed in the Pre-production Testing environment, to perform technical and functional integration tests, according to the Test Framework, adopted by the eHDSI Member State Expert Group (eHMSEG). The integration and testing process will be repeated and fine-tuned for each wave, and every time a new OpenNCP release has to be adopted.

Activity 2: Service Testing, Approval and Deployment

The purpose of this activity is to test (nationally and internationally) the IT service implemented, carry out security audits and provide evidence on the Member State readiness level towards the provision of services.

This activity will be broken down into the following tasks:

Task 2.1 – Perform Testing to Quality Assure service provision

During this task testing to Quality Assurance service provision will be performed. Pre-production conformance tests will be performed and documented in order to be admitted to the Projectathon conformance and clinical testing (in compliance with the Conformance Gate). The pre-production environment will comply with the same security requirements of the operational environment, including the adoption of the specified certificates for the VPN and security settings, the integration with the Test National Infrastructure and the connection to the Central Configuration and Terminology Services.

Task 2.2 – Undergo Pre-Production Testing and Project-a-thon

During this task pre-production Testing and Project-a-thon will be performed. The NCPeH and the Portal will be registered for the following events:

- Bootcamp in 2019;
- Projectathon in 2019 - The NCPeH and the portal will be registered as [NCP-A, NCP-B and Portal for ePrescription];

- Preparation of the Pre-Production Testing;
- Pre-Production Testing.

Task 2.3 – Perform Security audit

During this task security audit will be conducted. The NCPeH will be assessed against criteria listed in the technical documents provided by the eHealth DSI (eHDSI) Solution Provider. Czech Republic will facilitate and undergo necessary audits to confirm its readiness to join the EU Cross-Border eHealth Information Services (CBeHIS). Evidence of the audit results will be provided to the eHDSI Member State Expert Group (eHMSEG) and eHN, for the Member State approval to enter operation with Cross-border eHealth Information Services.

Task 2.4 – Prepare country readiness approval processes

This task aims at preparing country readiness approval processes. Evidence of the technical and semantic readiness, through the Projectathon test results, and legal, organizational and security readiness, through the audit results, will be provided to the HDSI Member State Expert Group and to the eHealth Network (eHN), in order to get the formal authorization by eHN. This process is repeated each time a new service is prepared to enter in operation.

Task 2.5 – Service deployment

This task aims at deploying the service. This task will allow all the technical, semantic and organisational components requested for the cross-border eHealth services of eP/eD to become operational.

This task is comprised of the following steps:

- implement the operational environment as for the servers, the security assets, the connection with the National Infrastructure and the Central Configuration Services;
- the deployment of the NCPeH, the portal and the National Connector components;
- the configuration of the system toward the Central Configuration Services and the synchronization of the Local Terminology Service.

Task 2.6 – Non regression testing

This task aims at performing non regression testing as defined by the EU Competent Body. The scenarios for non-regression testing will be designed by eHDSI Solution Provider, and approved by eHMSEG. These tests will be repeated for new services or as last action after change management which may result into minor or major releases of the NCPeH.

Activity 3: Operation

This activity aims at the provision of cross-border eHealth services regarding eP/eD according to the SLA and the defined Key Indicators (i.e. performance and success). It will also include the maintenance of assets necessary to the provision of cross-border eHealth services as well as Change and Risk management.

This activity is broken down into the following tasks:

Task 3.1 – Service provision and monitoring

During this task service will be provided and monitored. The approved and deployed services will be provided according to the release plan:

- 2020 ePrescription Country A and B

In agreement with other Member States, the aim will be to provide cross-border services 24h/day, 7 days a week. Service and performance monitoring will be adopted to be able to intervene in case of performance degradation or service interruption.

Task 3.2 – Service Maintenance and Change Management

During this task the aspects of service maintenance and change management will be dealt. A ticketing process will be put in place to manage incidents, problems, change requests. The process to manage changes, specified in eHDSI, will be applied. Any change in the operation environment has to be first validated in the Pre-Production environment, according to the approved change management procedures. Major changes will require the application of specific non-regression tests. Changes may refer to semantic upgrades (e.g. adoption of new version of the MVC/MTC) or changes in nationally used code systems (changes of the MTC) or fixing in the CDA documents, software patches, minor or major OpenNCP releases. During planned changes, the service may be temporarily suspended. These planned maintenances will be performed mainly during night. If explicitly requested by the Commission competent body, NCPeH redundancy may be applied, to guarantee the continuity of service during the planned or unplanned maintenance. Operation and change management indicators will be collected and reported on quarterly basis.

Task 3.4 – Service Evaluation

During this task the service will be evaluated. The evaluation process will follow three complementary approaches:

- automatic data collection, programming and activating the specific OpenNCP component (always guaranteeing the privacy of the patient);
- light questionnaires, provided to the Health Professionals and Patients, to assess the user satisfaction;
- thorough evaluation sessions with domain experts, to assess the clinical validity and collecting indications for service / clinical documents improvements.

Service evaluation results will be collected and reported on a semi-annual basis.

Activity 4: Dissemination, Training and Support

This activity will raise awareness and demand among citizens, health professionals like pharmacists and pharmacy information system vendors regarding the provision of cross-border eHealth services of eP/eD. During this activity, educational and training activities will be coordinated to empower and support end users as well as other Member States entering Operation.

The Activity will put in place and make use of different communication channels:

- Project Content Management System;
- Project Web Portal, co-ordinated with the Web Portals of the other Member States;
- On-line Training Tools;
- Social Media and web channels.

An overall communication strategy will be defined and as far as possible aligned with the other Member States.

This activity is broken down into the following tasks:

Task 4.1 – Health professional Dissemination, Education and Training

During this task dissemination, education and training activities of Health professional will

take place. Specific communication and educational sessions will be organized in order to inform and provide training to the Health Professionals (physicians who generate the ePrescription, emergency ward personnel, pharmacists). The training will cover the use of the system and the differences among the Member States approaches, e.g., to consent management, way of creating the ePrescription Document.

Task 4.2 – Member State and stakeholder involvement and engagement

During this task Member States and stakeholder will be involved and engaged. Overall strategies and action roadmap will be agreed with the other Member States and implemented according to national specificities. The goal of these activities will be to stimulate the triggering of the specific initiatives toward the Health Professionals and the Citizens.

Task 4.3 – Citizen and end-users dissemination and motivation

During this task, dissemination activities and motivation of the citizen and end-users will be carried out. While the ongoing Action 2015-CZ-IA-0067 focuses on informing the citizens about the existence of eHDSI and cross-border services, as well as their rights in cross-border care, the activities that will be carried out during this Action will be focused on the cross-border ePrescription/eDispensation service. Citizens will be made aware of availability of eHealth cross-border services in term of activities to be carried while still at home, to enable the use of these eHealth services (i.e. consent signature, request for their ePrescription Document to the General Practitioner) and about the activated Points of Care in the visited Countries. Specific mass communications and focused activities targeting tourists, students and business travellers will be designed and put in place.

Task 4.5 – Help Desk and Support

During this task a help desk and support service for the eP/eD will be set up and organised according to the typical three-level approach:

- Basic information to citizens and health professionals;
- Technical support to health professionals;
- Expert problem solving trouble tickets management.

The service levels for the three help desk services will be discussed and agreed with the other Member States participating in the eHealth initiative.

Activity 5: Governance and Management

The aim of this activity is to establish the link and the binding channel between the Member State, the eHealth DSI and other Member States providing the services as well as the appropriate national management structure to assure the provision of cross-border eHealth services.

This activity is broken down into the following tasks:

Task 5.1 – Acting and reporting according to the eHSDI Governance

This task aims at ensuring that participation and activities are carried out according to the procedures defined by the eHealth DSI governance model, namely by complying with eHDSI Operational Management Board (eHOMB) and the eHMSEG instructions and requests, as well as adopting eHealth Network decisions regarding policies, guidelines and approval to enter in Operation with eHealth Cross Border Services.

Taks 5.2 – Management of National activities

During this task a national governance and management structure will be established to guarantee the execution of the Action.

The beneficiary will identify within its organisation the persons responsible for the following NCPeH roles: Organisation; Contact person; Technical responsible; Security responsible; Help desk responsible.

ARTICLE I.4 – MILESTONES AND MEANS OF VERIFICATION

Milestone number	Milestone description	Indicative completion date	Means of verification
1	Definition of the service deployment schedule with activities, milestones and tasks completed.	31/12/2018	Approved service deployment plan.
2	Definition of the service dissemination, education and training plan for ePrescription completed.	31/12/2018	Approved service dissemination, education and training plan.
3	Compliance with the service requirements and recommendations for ePrescription/eDispensation achieved.	30/11/2019	Service Readiness Statement for ePrescription approved by the eHealth Network.
4	Completion of the preparation and implementation activity.	31/01/2020	Submitted progress report(s) on the preparation and implementation activity, containing Czech requirements and recommendations.
5	Planning of service support with responsibilities, workflow and stakeholder definition completed.	30/11/2019	Approved service provision support plan.
6	Start of operation of ePrescription (Country A and B).	31/03/2020	Issued Go-live statement.
7	Mid-term report on the operation activity.	31/03/2021	Submitted service provision report.
8	Completion of operation activity.	30/06/2022	Submitted service provision report(s).
9	Completion of the service dissemination, training and support activity.	30/06/2022	Yearly reports on dissemination, education and training, service provision and helpdesk performance.

10	Completion of governance participation and national activities management.	30/06/2022	Yearly reports on governance participation and national governance activities.
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ANNEX II

GENERAL CONDITIONS

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PART A – LEGAL AND ADMINISTRATIVE PROVISIONS

ARTICLE II.1 – GENERAL OBLIGATIONS AND ROLES OF THE BENEFICIARIES

II.1.1 General obligations and role of the beneficiaries

The beneficiaries shall:

- (a) be jointly and severally responsible for carrying out the action in accordance with the terms and conditions of the Agreement;
- (b) be responsible for complying with any legal obligations incumbent on them jointly or individually under applicable EU, international and national law;
- (c) make appropriate internal arrangements for the proper implementation of the action, consistent with the provisions of this Agreement; where provided for in the Special Conditions, those arrangements shall take the form of an internal co-operation agreement between the beneficiaries.

II.1.2 General obligations and role of each beneficiary

Each beneficiary shall:

- (a) inform the coordinator immediately of any events or circumstances likely to affect or delay the implementation of the action of which the beneficiary is aware;
- (b) inform the coordinator immediately of any change in its legal, financial, technical, organisational or ownership situation or of its affiliated entities and of any change in its name, address or legal representative or of its affiliated entities;
- (c) submit in due time to the coordinator:
 - (i) the data needed to draw up the reports, financial statements and other documents provided for in the Agreement;
 - (ii) all the necessary documents in the event of audits, checks or evaluation in accordance with Article II.27;
 - (iii) any other information to be provided to the Agency according to the Agreement, except where the Agreement requires that such information is submitted directly by the beneficiary to the Agency.

II.1.3 General obligations and role of the coordinator

The coordinator shall:

- (a) monitor that the action is implemented in accordance with the Agreement;

- (b) be the intermediary for all communications between the beneficiaries and the Agency, except where provided otherwise in the Agreement, and, in particular, the coordinator shall:
 - (i) immediately provide the Agency with the information related to any change in the name, address, legal representative as well as in the legal, financial, technical, organisational or ownership situation of any of the beneficiaries or of its affiliated entities, or to any events or circumstances likely to affect or delay the implementation of the action, of which the coordinator is aware;
 - (ii) bear responsibility for supplying all documents and information to the Agency which may be required under the Agreement, except where provided otherwise in the Agreement; this includes responsibility for submitting the deliverables identified in Annex I, in accordance with the timing and conditions set out in it; where information is required from the other beneficiaries, the coordinator shall bear responsibility for obtaining and verifying this information before passing it on to the Agency;
- (c) make the appropriate arrangements for providing any financial guarantees required under the Agreement;
- (d) establish the requests for payment in accordance with the Agreement;
- (e) ensure that all the appropriate payments are made to the other beneficiaries without unjustified delay;
- (f) bear responsibility for providing all the necessary documents in the event of checks and audits initiated before the payment of the balance, and in the event of evaluation in accordance with Article II.27.

The coordinator shall not subcontract any part of its tasks to the other beneficiaries or to any other party.

ARTICLE II.2 – COMMUNICATIONS BETWEEN THE PARTIES

II.2.1 Form and means of communications

Any communication relating to the Agreement or to its implementation shall be made in writing (in paper or electronic form), shall bear the number of the Agreement and shall be made using the communication details identified in Article 6.

Electronic communications shall be confirmed by an original signed paper version of that communication if requested by any of the parties provided that this request is submitted without unjustified delay. The sender shall send the original signed paper version without unjustified delay.

Formal notifications shall be made by registered mail with return receipt or equivalent, or by electronic mail, which provides the sender with compelling evidence that the message was delivered to the specified recipient.

II.2.2 Date of communications

Any communication is deemed to have been made when it is received by the receiving party, unless the agreement refers to the date when the communication was sent.

Electronic communication is deemed to have been received by the receiving party on the day of successful dispatch of that communication, provided that it is sent to the addressees listed in Article 6. Dispatch shall be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party shall immediately send again such communication to any of the other addresses listed in Article 6. In case of unsuccessful dispatch, the sending party shall not be held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Agency using the postal services is considered to have been received by the Agency on the date on which it is registered by the department identified in Article 6.2.

Formal notifications made by registered mail with return receipt or equivalent, or by equivalent electronic means, shall be considered to have been received by the receiving party on the date of receipt indicated on the return receipt or equivalent.

ARTICLE II.3 – LIABILITY FOR DAMAGES

II.3.1 The Agency shall not be held liable for any damage caused or sustained by any of the beneficiaries, including any damage caused to third parties as a consequence of or during the implementation of the action.

II.3.2 Except in cases of force majeure, the beneficiaries shall compensate the Agency for any damage sustained by it as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

ARTICLE II.4 - CONFLICT OF INTERESTS

II.4.1 The beneficiaries shall take all necessary measures to prevent any situation where the impartial and objective implementation of the Agreement is compromised for reasons involving economic interest, political or national affinity, family or emotional life or any other shared interest with the Agency, or any third party related to the subject matter of the Agreement (“conflict of interests”).

II.4.2 Any situation constituting or likely to lead to a conflict of interests during the implementation of the Agreement shall be notified to the Agency, in writing, without delay. The beneficiaries shall immediately take all the necessary steps to rectify this situation. The Agency reserves the right to verify that the measures taken are appropriate and may require additional measures to be taken within a specified deadline.

ARTICLE II.5 – CONFIDENTIALITY

II.5.1 The Agency and the beneficiaries shall preserve the confidentiality of any information

and documents, in any form, which are disclosed in writing or orally in relation to the implementation of the Agreement and which are explicitly indicated in writing as confidential. It does not include information that is publicly available.

II.5.2 The Agency and the beneficiaries shall not use confidential information and documents for any reason other than fulfilling their obligations under the Agreement, unless otherwise agreed with the other party in writing.

II.5.3 The Agency and the beneficiaries shall be bound by the obligations referred to in Articles II.5.1 and II.5.2 during the implementation of the Agreement and for a period of five years starting from the payment of the balance, unless:

- (a) the party concerned agrees to release the other party from the confidentiality obligations earlier;
- (b) the confidential information or documents become public through other means than a breach of the confidentiality obligations;
- (c) the disclosure of the confidential information or documents is required by law.

ARTICLE II.6 – PROCESSING OF PERSONAL DATA

II.6.1 Processing of personal data by the Agency

Any personal data included in the Agreement shall be processed by the Agency pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Such data shall be processed by the data controller identified in Article 6.1 solely for the purposes of the implementation, management and monitoring of the Agreement or to protect the financial interests of the EU, including checks, audits and investigations in accordance with Article II.27.

The beneficiaries shall have the right of access to their personal data and the right to rectify any such data. Should the beneficiaries have any queries concerning the processing of their personal data, they shall address them to the data controller, identified in Article 6.1.

The beneficiaries shall have the right of recourse at any time to the European Data Protection Supervisor.

II.6.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The access to data that the beneficiaries grant to their personnel shall be limited to the extent strictly necessary for the implementation, management and monitoring of the Agreement.

The beneficiaries undertake to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned, in order to:

- (a) prevent any unauthorised person from gaining access to computer systems processing personal data, and especially:
 - (i) unauthorised reading, copying, alteration or removal of storage media;
 - (ii) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
 - (iii) unauthorised use of data-processing systems by means of data transmission facilities;
- (b) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
- (c) record which personal data have been communicated, when and to whom;
- (d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the Agency;
- (e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;
- (f) design their organisational structure in such a way that it meets data protection requirements.

ARTICLE II.7 – VISIBILITY OF UNION FUNDING

II.7.1 Information on Union funding and use of European Union emblem

Unless the Agency requests or agrees otherwise, any communication or publication related to the action, made by the beneficiaries jointly or individually, including at conferences, seminars or in any information or promotional materials (such as brochures, leaflets, posters, presentations, etc.), shall indicate that the action has received funding from the Union and shall display the European Union emblem.

When displayed in association with another logo, the European Union emblem must have appropriate prominence.

The obligation to display the European Union emblem does not confer to the beneficiaries a right of exclusive use. The beneficiaries shall not appropriate the European Union emblem or any similar trademark or logo, either by registration or by any other means.

For the purposes of the first, second and third subparagraphs and under the conditions specified therein, the beneficiaries are exempted from the obligation to obtain prior

permission from the Agency to use the European Union emblem.

II.7.2 Disclaimers excluding Agency responsibility

Any communication or publication related to the action, made by the beneficiaries jointly or individually in any form and using any means, shall indicate that it reflects only the author's view and that the Agency is not responsible for any use that may be made of the information it contains.

ARTICLE II.8 – PRE-EXISTING RIGHTS AND OWNERSHIP AND USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

II.8.1 Ownership of the results by the beneficiaries

Unless stipulated otherwise in the Agreement, ownership of the results of the action, including industrial and intellectual property rights, and of the reports and other documents relating to it, shall be vested in the beneficiaries.

II.8.2 Pre-existing rights

Pre-existing material is any materials, document, technology or know-how which exists prior to the beneficiary using it for the production of a result in the implementation of the action. Pre-existing right is any industrial and intellectual property right on pre-existing material; it may consist in a right of ownership, a licence right and/or a right of use belonging to the beneficiary or any other third parties.

If the Agency sends the beneficiaries a written request specifying which of the results it intends to use, the beneficiaries must:

- (a) establish a list specifying all pre-existing rights included in those results; and
- (b) provide this list to the Agency at the latest with the request for payment of the balance.

The beneficiaries shall ensure that they or their affiliated entities have all the rights to use any pre-existing rights during the implementation of the Agreement.

II.8.3 Rights of use of the results and of pre-existing rights by the Agency

The beneficiaries grant the Agency the following rights to use the results of the action:

- (a) for its own purposes, and in particular, to make available to persons working for the Agency, Union institutions, other Union agencies and bodies and to Member States' institutions, as well as to copy and reproduce in whole or in part and in an unlimited number of copies;
- (b) reproduction: the right to authorise direct or indirect, temporary or permanent reproduction of the results by any means (mechanical, digital or other) and in any form, in whole or in part;

- (c) communication to the public: the right to authorise any display performance or communication to the public, by wire or wireless means, including making the results available to the public in such a way that members of the public may access them from a place and at a time individually chosen by them; this right also includes communication and broadcasting by cable or by satellite;
- (d) distribution: the right to authorise any form of distribution of results or copies of the results to the public;
- (e) adaptation: the right to modify the results;
- (f) translation;
- (g) the right to store and archive the results in line with the document management rules applicable to the Agency, including digitalisation or converting the format for preservation or new use purposes;
- (h) where the results are documents, the right to authorise the reuse of the documents in conformity with Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents if that Decision is applicable and if the documents fall within its scope and are not excluded by any of its provisions. For the sake of this provision, the terms 'reuse' and 'document' have the meanings given to them by Decision 2011/833/EU.

Additional rights of use for the Agency may be provided for in the Special Conditions.

The beneficiaries shall warrant that the Agency has the right to use any pre-existing rights, which have been included in the results of the action. Unless specified otherwise in the Special Conditions, those pre-existing rights shall be used for the same purposes and under the same conditions applicable to the rights of use of the results of the action.

Information about the copyright owner shall be inserted when the result is divulged by the Agency. The copyright information shall read: "© – [year] – [name of the copyright owner]. All rights reserved. Licenced to the Innovation and Networks Executive Agency under conditions."

If the beneficiaries grant rights of use to the Agency, this does not affect their confidentiality obligations under Article II.5 or the beneficiaries' obligations under Article II.1.

ARTICLE II.9 – AWARD OF CONTRACTS NECESSARY FOR THE IMPLEMENTATION OF THE ACTION

II.9.1 Where the implementation of the action requires the procurement of goods, works or services, the beneficiaries shall award the contract to the tender offering best value for money or, as appropriate, to the tender offering the lowest price. In doing so, they shall avoid any conflict of interests.

The beneficiaries shall ensure that the Agency, the Commission, the European Anti-

Fraud Office (OLAF) and the European Court of Auditors may exercise their rights under Article II.27 also towards the contractor.

II.9.2 Beneficiaries acting in their capacity of 'contracting authorities' within the meaning of Directive 2004/18/EC¹ or Directive 2014/24/EU² or any previous applicable Union legislation or 'contracting entities' within the meaning of Directive 2004/17/EC³ or Directive 2014/25/EU⁴ or any previous applicable Union legislation must comply with the applicable national public procurement rules.

II.9.3 The beneficiaries shall retain sole responsibility for carrying out the action and for compliance with the provisions of the Agreement. The beneficiaries shall ensure that any procurement contract contains provisions stipulating that the contractor has no rights vis-à-vis the Agency under the Agreement.

II.9.4 The beneficiaries shall ensure that the conditions applicable to them under Articles II.3, II.4, II.5 and II.8 are also applicable to the contractor.

II.9.5 Where, in accordance with Article 3(a), the grant takes the form of the reimbursement of eligible costs:

- If a beneficiary breaches any of its obligations under Article II.9.1, the costs related to the contract concerned shall be ineligible;
- If a beneficiary breaches any of its obligations under Article II.9.2, II.9.3 or II.9.4, the grant may be reduced in proportion to the seriousness of the breach of obligations.

Where, in accordance with Article 3(b), (c) or (d) the grant takes the form of a unit, lump sum or flat-rate contribution, if a beneficiary breaches any of its obligations under Article II.9.1, II.9.2, II.9.3 or II.9.4, the grant may be reduced in proportion to the seriousness of the breach of obligations.

ARTICLE II.10 – SUBCONTRACTING OF TASKS FORMING PART OF THE ACTION

II.10.1 A "subcontract" is a procurement contract within the meaning of Article II.9, which covers the implementation by a third party of tasks forming part of the action as described in Annex I.

II.10.2 Beneficiaries may subcontract tasks forming part of the action, provided that, in addition to the conditions specified in Article II.9.1, the following conditions are complied with:

¹ Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts

² Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC

³ Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors

⁴ Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC

- (a) subcontracting does not cover core tasks of the action;
- (b) recourse to subcontracting is justified having regard to the nature of the action and what is necessary for its implementation;
- (c) the estimated costs of the subcontracting are clearly identifiable in the estimated budget set out in Annex III;
- (d) any recourse to subcontracting, if not provided for in Annex I, is communicated by the coordinator and approved by the Agency. The Agency may grant approval:
 - (i) before any recourse to subcontracting, if the beneficiaries request an amendment as provided for in Article II.12; or
 - (ii) after recourse to subcontracting if the subcontracting:
 - is specifically justified in the interim or final technical report referred to in Article II.23.2; and
 - does not entail changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants.

II.10.3 Beneficiaries acting in their capacity of 'contracting authorities' within the meaning of Directive 2004/18/EC and Directive 2014/24/EU⁵ or any previous applicable Union legislation or contracting entities within the meaning of Directive 2004/17/EC and Directive 2014/25/EU⁶ or any previous applicable Union legislation must comply with the applicable national public procurement rules.

II.10.4 The beneficiaries shall retain sole responsibility for carrying out the action and for compliance with the provisions of the Agreement. The beneficiaries shall ensure that any subcontract contains provisions stipulating that the subcontractor has no rights vis-à-vis the Agency under the Agreement.

II.10.5 The beneficiaries shall ensure that the conditions applicable to them under Articles II.3, II.4, II.5, II.7 and II.8 are also applicable to the subcontractor.

II.10.6 Where, in accordance with Article 3(a), the grant takes the form of the reimbursement of eligible costs:

- If a beneficiary breaches any of its obligations under Article II.10.2, the costs related to the subcontract concerned shall be ineligible;
- If a beneficiary breaches any of its obligations under Article II.10.3, II.10.4 or II.10.5, the grant may be reduced in proportion to the seriousness of the breach of

⁵ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC

⁶ Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC

obligations.

Where, in accordance with Article 3(b), (c) or (d) the grant takes the form of a unit, lump sum or flat-rate contribution if a beneficiary breaches any of its obligations under Article II.10.2, II.10.3, II.10.4 or II.10.5, the grant may be reduced in proportion to the seriousness of the breach of obligations.

ARTICLE II.11 - FINANCIAL SUPPORT TO THIRD PARTIES

II.11.1 Where the implementation of the action requires giving financial support to third parties, the beneficiaries shall give such financial support in accordance with the conditions specified in Annex I, which shall at least contain:

- (a) the maximum amount of financial support, which shall not exceed EUR 60 000 for each third party except where the financial support is the primary aim of the action as specified in Annex I;
- (b) the criteria for determining the exact amount of the financial support;
- (c) the different types of activity that may receive financial support, on the basis of a fixed list;
- (d) the definition of the persons or categories of persons which may receive financial support;
- (e) the criteria for giving the financial support.

The beneficiaries shall ensure that the Agency, the Commission, the European Anti-Fraud Office (OLAF) and the European Court of Auditors may exercise their rights under Article II.27 also towards the third parties receiving financial support.

II.11.2 By way of derogation from Article II.11.1, in case the financial support takes the form of a prize, the beneficiaries shall give such financial support in accordance with the conditions specified in Annex I, which shall at least contain:

- (a) the conditions for participation;
- (b) the award criteria;
- (c) the amount of the prize;
- (d) the payment arrangements.

The beneficiaries shall ensure that the Agency, the Commission, the European Anti-Fraud Office (OLAF) and the European Court of Auditors may exercise their rights under Article II.27 also towards the third parties receiving a prize.

II.11.3 The beneficiaries shall ensure that the conditions applicable to them under Articles II.3, II.4, II.5, II.7 and II.8 are also applicable to the third parties receiving financial

support.

II.11.4 Where, in accordance with Article 3(a), the grant takes the form of the reimbursement of eligible costs:

- If a beneficiary breaches any of its obligations under Article II.11.1 or II.11.2, the costs related to the financial support shall be ineligible;
- If a beneficiary breaches any of its obligations under Article II.11.3, the grant may be reduced in proportion to the seriousness of the breach of obligations.

Where, in accordance with Article 3(b), (c) or (d) the grant takes the form of a unit, lump sum or flat-rate contribution if a beneficiary breaches any of its obligations under Article II.11.1 II.11.2 or II.11.3, the grant may be reduced in proportion to the seriousness of the breach of obligations.

ARTICLE II.12 – AMENDMENTS TO THE AGREEMENT

II.12.1 Any amendment to the Agreement shall be made in writing.

II.12.2 An amendment may not have the purpose or the effect of making changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants.

II.12.3 Any request for amendment shall be duly justified, be accompanied by appropriate supporting documents and shall be sent to the other party in due time before it is due to take effect, and in any case three months before the end of the period set out in Article 2.2, except in cases duly substantiated by the party requesting the amendment and accepted by the other party.

II.12.4 A request for amendment on behalf of the beneficiaries shall be submitted by the coordinator. If a change of coordinator is requested without its agreement, the request shall be jointly submitted by all other beneficiaries or shall be submitted by a beneficiary acting on behalf of all beneficiaries, and shall be accompanied by the opinion of the coordinator or proof that this opinion has been requested in writing.

II.12.5 Amendments shall enter into force on the date on which the last party signs or on the date of approval of the request for amendment.

Amendments shall take effect on a date agreed by the parties or, in the absence of such an agreed date, on the date on which the amendment enters into force.

ARTICLE II.13 – ASSIGNMENT OF CLAIMS FOR PAYMENTS TO THIRD PARTIES

II.13.1 Claims for payments of the beneficiaries against the Agency may not be assigned to third parties, except in duly justified cases where the situation warrants it.

The assignment shall only be enforceable against the Agency if it has accepted the

assignment on the basis of a written and reasoned request to that effect made by the coordinator on behalf of the beneficiaries.

In the absence of such an acceptance, or in the event of failure to observe the terms thereof, the assignment shall have no effect on the Agency.

II.13.2 In no circumstances shall such an assignment release the beneficiaries from their obligations towards the Agency.

ARTICLE II.14 – FORCE MAJEURE

II.14.1 "*Force majeure*" shall mean any unforeseeable, exceptional situation or event beyond the parties' control, which prevents either of them from fulfilling any of their obligations under the Agreement, which was not attributable to error or negligence on their part or on the part of subcontractors, affiliated entities, implementing bodies or third parties in receipt of financial support and which proves to be inevitable in spite of exercising due diligence. Any default of a service, defect in equipment or material or delays in making them available, as well as labour disputes, strikes or financial difficulties cannot be invoked as *force majeure*, unless they stem directly from a relevant case of *force majeure*.

II.14.2 A party faced with *force majeure* shall formally notify the other party without delay, stating the nature of the situation or of the event, its likely duration and foreseeable effects.

II.14.3 The parties shall take the necessary measures to limit any damage due to *force majeure*. They shall do their best to resume the implementation of the action as soon as possible.

II.14.4 The party faced with *force majeure* shall not be held to be in breach of its obligations under the Agreement if it has been prevented from fulfilling them by *force majeure*.

ARTICLE II.15 – SUSPENSION OF THE IMPLEMENTATION OF THE ACTION

II.15.1 Suspension of the implementation by the beneficiaries

The coordinator, on behalf of the beneficiaries, may suspend the implementation of the action or any part thereof, if exceptional circumstances make such implementation impossible or excessively difficult, in particular in the event of *force majeure*. The coordinator shall inform the Agency without delay, giving the reasons for suspension, including details about the date or period when the exceptional circumstances occurred and the expected date of resumption.

Unless the Agreement or the participation of a beneficiary is terminated in accordance with Articles II.16.1, II.16.2 or points (c) or (d) of Article II.16.3.1, the coordinator shall, once the circumstances allow resuming the implementation of the action, inform the Agency immediately and present a request for amendment of the Agreement as provided for in Article II.15.3.

II.15.2 Suspension of the implementation by the Agency

II.15.2.1 The Agency may suspend the implementation of the action or any part thereof:

- (a) if the Agency has evidence that a beneficiary has committed substantial errors, irregularities or fraud in the award procedure or in the implementation of the Agreement or if a beneficiary fails to comply with its obligations under the Agreement;
- (b) if the Agency has evidence that a beneficiary has committed systemic or recurrent errors, irregularities, fraud or serious breach of obligations under other grants funded by the Union or the European Atomic Energy Community which were awarded to that beneficiary under similar conditions, provided that those errors, irregularities, fraud or breach of obligations have a material impact on this grant;
- (c) if the Agency suspects substantial errors, irregularities, fraud or breach of obligations committed by a beneficiary in the award procedure or in the implementation of the Agreement and needs to verify whether they have actually occurred; or
- (d) following an evaluation of the progress of the project, in particular in the event of major delays in the implementation of the action.

II.15.2.2 Before suspending the implementation the Agency shall formally notify the coordinator of its intention to suspend, specifying the reasons thereof, and, in the cases referred to in points (a), (b) and (d) of Article II.15.2.1, the necessary conditions for resuming the implementation. The coordinator shall be invited to submit observations on behalf of all beneficiaries within 30 calendar days from receipt of this notification.

If, after examination of the observations submitted by the coordinator, the Agency decides to stop the suspension procedure, it shall formally notify the coordinator thereof.

If no observations have been submitted or if, despite the observations submitted by the coordinator, the Agency decides to pursue the suspension procedure, it may suspend the implementation by formally notifying the coordinator thereof, specifying the reasons for the suspension and, in the cases referred to in points (a), (b) and (d) of Article II.15.2.1, the definitive conditions for resuming the implementation or, in the case referred to in point (c) of Article II.15.2.1, the indicative date of completion of the necessary verification.

The coordinator shall inform the other beneficiaries immediately. The suspension shall take effect five calendar days after the receipt of the notification by the coordinator or on a later date, where the notification so provides.

In order to resume the implementation, the beneficiaries shall endeavour to meet the notified conditions as soon as possible and shall inform the Agency of any

progress made in this respect.

Unless the Agreement or the participation of a beneficiary is terminated in accordance with Articles II.16.1, II.16.2 or points (c), (i), (j), (k) or (o) of Article II.16.3.1, the Agency shall, as soon as it considers that the conditions for resuming the implementation have been met or the necessary verification, including on-the-spot checks, has been carried out, formally notify the coordinator thereof and invite the coordinator to present a request for amendment of the Agreement as provided for in Article II.15.3.

II.15.3 Effects of the suspension

If the implementation of the action can be resumed and the Agreement is not terminated, an amendment to the Agreement shall be made in accordance with Article II.12 in order to establish the date on which the action shall be resumed, to extend the duration of the action and to make any other modifications that may be necessary to adapt the action to the new implementing conditions.

The suspension is deemed lifted with effect as from the date of resumption of the action agreed by the parties in accordance with the first subparagraph and set out in the amendment. Such a date may be before the date on which the amendment enters into force.

Any costs incurred by the beneficiaries, during the period of suspension, for the implementation of the suspended action or the suspended part thereof, shall not be reimbursed or covered by the grant.

The right of the Agency to suspend the implementation is without prejudice to its right to terminate the Agreement or the participation of a beneficiary in accordance with Article II.16.3 and its right to reduce the grant or recover amounts unduly paid in accordance with Articles II.25.4 and II.26.

Neither party shall be entitled to claim damages due to a suspension by the other party.

ARTICLE II.16 – TERMINATION OF THE AGREEMENT

II.16.1 Termination of the Agreement by the coordinator

In duly justified cases, the coordinator, on behalf of all beneficiaries, may terminate the Agreement by formally notifying the Agency thereof, stating clearly the reasons and specifying the date on which the termination shall take effect. The notification shall be sent before the termination is due to take effect.

If no reasons are given or if the Agency considers that the reasons exposed cannot justify the termination, it shall formally notify the coordinator, specifying the grounds thereof, and the Agreement shall be deemed to have been terminated improperly, with the consequences set out in the fourth subparagraph of Article II.16.4.1. The termination takes effect on the day specified in the formal notification.

II.16.2 Termination of the participation of one or more beneficiaries by the coordinator

In duly justified cases, the participation of any one or several beneficiaries in the Agreement may be terminated by the coordinator, acting on request of that beneficiary or those beneficiaries, or on behalf of all the other beneficiaries. When notifying such termination to the Agency, the coordinator shall include the reasons for the termination of the participation, the opinion of the beneficiary or beneficiaries the participation of which is terminated (or proof that this opinion has been requested in writing), the date on which the termination shall take effect and the proposal of the remaining beneficiaries relating to the reallocation of the tasks of that beneficiary or those beneficiaries or, where relevant, to the nomination of one or more replacements which shall succeed that beneficiary or those beneficiaries in all their rights and obligations under the Agreement, and a request for amendment as provided for in Article II.16.4.1. The notification shall be sent before the termination is due to take effect.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

If no reasons are given or if the Agency considers that the reasons exposed cannot justify the termination, it shall formally notify the coordinator, specifying the grounds thereof, and the participation shall be deemed to have been terminated improperly, with the consequences set out in the fourth subparagraph of Article II.16.4.1. The termination takes effect on the day specified in the formal notification.

II.16.3 Termination of the Agreement or the participation of one or more beneficiaries by the Agency

II.16.3.1 The Agency may decide to terminate the Agreement or the participation of any one or several beneficiaries participating in the action, in the following circumstances:

- (a) if a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to affect the implementation of the Agreement substantially or calls into question the decision to award the grant;
- (b) if, following the termination of the participation of any one or several beneficiaries, the necessary modifications to the Agreement would call into question the decision awarding the grant or would result in unequal treatment of applicants;
- (c) if the beneficiaries do not implement the action as specified in Annex I or if a beneficiary fails to comply with another substantial obligation incumbent on it under the terms of the Agreement;
- (d) in the event of *force majeure*, notified in accordance with Article II.14, or in the event of suspension by the coordinator as a result of exceptional circumstances, notified in accordance with Article II.15, where resuming the implementation is impossible or where the necessary modifications to the Agreement would call into question the decision awarding the grant or would result in unequal treatment of applicants;

- (e) if a beneficiary or any person that assumes unlimited liability for the debts of that beneficiary comes under any of the situations provided for in points (a) or (b) of Article 106 (1) of the Financial Regulation⁷;
- (f) if a beneficiary or any related person, as defined in the second subparagraph, comes under any of the situations provided for in points (c), (d), (e) or (f) of Article 106 (1) or comes under Article 106 (2) of the Financial Regulation;
- (g) not applicable;
- (h) not applicable;
- (i) if the Agency has evidence that a beneficiary or any related person, as defined in the second subparagraph, have committed substantial errors, irregularities or fraud in the award procedure or in the implementation of the Agreement, including in the event of submission of false information or failure to submit required information;
- (j) if the Agency has evidence that a beneficiary has committed systemic or recurrent errors, irregularities, fraud or serious breach of obligations under other grants funded by the Union or the European Atomic Energy Community which were awarded to that beneficiary under similar conditions, provided that those errors, irregularities, fraud or breach of obligations have a material impact on this grant;
- (k) following an evaluation of the progress of the project, in particular in the event of major delays in the implementation of the action;
- (l) if the action has not started within two years of the starting date set out in Article 2.2 or, for grants for studies, if the action has not started within one year of the starting date set out in Article 2.2;
- (m) not applicable;
- (n) not applicable;
- (o) if the Agency has sent a beneficiary, through the coordinator, a formal notification asking it to end the participation of its affiliated entity because that entity is in a situation provided for in points (f), (i) or (j) and that beneficiary has failed to request an amendment ending the participation of the entity and reallocating its tasks.

For the purposes of points (f) and (i), "any related person" shall mean any person who has the power to represent the beneficiary or to take decisions on its behalf.

For the purposes of points (i) and (j), "fraud" shall mean any intentional act or

⁷ Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union.

omission affecting the Union's financial interests relating to the use or presentation of false, incorrect or incomplete statements or documents, to non-disclosure of information in violation of a specific obligation.

For the purposes of point (i), "substantial error" shall mean any infringement of a provision of an agreement resulting from an act or omission, which causes or might cause a loss to the Union's budget.

For the purposes of points (i) and (j), "irregularity" shall mean any infringement of a provision of Union law resulting from an act or omission by a beneficiary, which has or would have the effect of prejudicing the Union's budget.

II.16.3.2 Before terminating the Agreement or the participation of any one or several beneficiaries, the Agency shall formally notify the coordinator of its intention to terminate, specifying the reasons thereof and inviting the coordinator, within 45 calendar days from receipt of the notification, to submit observations on behalf of all beneficiaries and, in the case of point (c) of Article II.16.3.1, to inform the Agency about the measures taken to ensure that the beneficiaries continue to fulfil their obligations under the Agreement.

If, after examination of the observations submitted by the coordinator, the Agency decides to stop the termination procedure, it shall formally notify the coordinator thereof.

If no observations have been submitted or if, despite the observations submitted by the coordinator, the Agency decides to pursue the termination procedure, it may terminate the Agreement or the participation of any one or several beneficiaries by formally notifying the coordinator thereof, specifying the reasons for the termination. The coordinator must immediately inform the other beneficiaries of the termination.

In the cases referred to in points (a), (b), (c), (e) and (k) of Article II.16.3.1, the formal notification shall specify the date on which the termination takes effect. In the cases referred to in points (d), (f), (i), (j), (l) and (o) of Article II.16.3.1, the termination shall take effect on the day following the date on which the formal notification was received by the coordinator.

II.16.4 Effects of termination

II.16.4.1 Where the Agreement is terminated, payments by the Agency shall be limited to the amount determined in accordance with Article II.25 on the basis of the eligible costs incurred by the beneficiaries and the actual level of implementation of the action on the date when the termination takes effect. Costs relating to current commitments, which are not due for execution until after the termination, shall not be taken into account. The coordinator shall have 60 days from the date when the termination of the Agreement takes effect, as provided for in Articles II.16.1 and II.16.3.2, to produce a request for payment of the balance in accordance with Article II.23.2. If no request for payment of the balance is received within this time limit, the Agency shall not reimburse or cover any costs which are not

included in a financial statement approved by it or which are not justified in a technical report approved by it. In accordance with Article II.26, the Agency shall recover any amount already paid, if its use is not substantiated by the technical reports and, where applicable, by the financial statements approved by the Agency.

Where the participation of a beneficiary is terminated, the coordinator must submit a request for amendment including:

- (i) a proposal to reallocate the tasks of the beneficiary or beneficiaries concerned by the termination; and
- (ii) if necessary, the addition of one or more new beneficiaries to succeed the beneficiary or beneficiaries concerned in all their rights and obligations under the Agreement.

If the Agency terminates the participation of a beneficiary, the coordinator must submit the request for amendment within 60 calendar days from the day on which the termination takes effect. If the coordinator terminates the participation of a beneficiary, the request for amendment must be included in the formal notification of termination referred to in Article II.16.2.

If termination takes effect after the end of the implementation period, no request for amendment must be provided unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If the request for amendment is rejected by the Agency, the Agreement may be terminated in accordance with Article II.16.3.1 (b). The request for amendment may be rejected if it calls into question the decision awarding the grant or is contrary to the equal treatment of applicants.

The beneficiary concerned shall submit to the coordinator a technical report and, where applicable, a financial statement covering the period from the end of the last reporting period according to Article 4.1.1 for which a report has been submitted to the Agency to the date on which the termination takes effect. The technical report and the financial statement shall be submitted in due time to allow the coordinator to draw up the corresponding payment request. Only those costs incurred by the beneficiary concerned up to the date when termination of its participation takes effect shall be reimbursed or covered by the grant. Costs relating to current commitments, which were not due for execution until after the termination, shall not be taken into account. The request for payment for the beneficiary concerned shall be included in the next payment request submitted by the coordinator in accordance with the schedule laid down in Article 4.

Where the Agency, in accordance with point (c) of Article II.16.3.1, is terminating the Agreement on the grounds that the coordinator has failed to produce the request for payment and, after a reminder, has still not complied with this obligation within the deadline set out in Article II.23.3, the first subparagraph shall apply, subject to the following:

- (a) there shall be no additional time period from the date when the termination of the Agreement takes effect for the coordinator to produce a request for payment of the balance in accordance with Article II.23.2; and

- (b) the Agency shall not reimburse or cover any costs incurred by the beneficiaries up to the date of termination or up to the end of the period set out in Article 2.2, whichever is the earlier, which are not included in a financial statement approved by it or which are not justified in a technical report approved by it.

In addition to the first, second and third subparagraphs, where the Agreement or the participation of a beneficiary is terminated improperly by the coordinator within the meaning of Articles II.16.1 and II.16.2, or where the Agreement or the participation of a beneficiary is terminated by the Agency on the grounds set out in points (c), (f), (i), (j), (k) and (o) of Article II.16.3.1, the Agency may also reduce the grant or recover amounts unduly paid in accordance with Articles II.25.4 and II.26, in proportion to the gravity of the failings in question and after allowing the coordinator, and, where relevant, the beneficiaries concerned, to submit their observations.

After termination, the concerned beneficiary's obligations continue to apply, in particular those under Articles 4, II.5, II.7, II.8, II.13, II.27 and any additional provisions on the use of the results, as set out in the Special Conditions.

II.16.4.2 Where the Agency, in accordance with point (l) of Article II.16.3.1, is terminating the Agreement on the ground that the action has not started by the set deadline, the following shall apply:

- (a) the coordinator shall not produce a request for payment of the balance; and
(b) the final amount of the grant shall be EUR 0 (zero euro). The Agency shall recover any amounts unduly paid in accordance with Article II.26.

II.16.4.3 Neither party shall be entitled to claim compensation on account of a termination by the other party.

ARTICLE II.17 – NOT APPLICABLE

ARTICLE II.18 – APPLICABLE LAW, SETTLEMENT OF DISPUTES AND ENFORCEABLE DECISION

II.18.1 The Agreement is governed by the applicable Union law complemented, where necessary, by the law of Belgium.

II.18.2 Pursuant to Article 272 TFEU, the General Court or, on appeal, the Court of Justice of the European Union, shall have sole jurisdiction to hear any dispute between the Union and any beneficiary concerning the interpretation, application or validity of this Agreement, if such dispute cannot be settled amicably.

II.18.3 By virtue of Article 299 TFEU, for the purposes of recoveries within the meaning of Article II.26, the Commission may adopt an enforceable decision to impose pecuniary obligations on persons other than States. An action may be brought

against such decision before the General Court of the European Union pursuant to Article 263 TFEU.



PART B – FINANCIAL PROVISIONS

ARTICLE II.19 – ELIGIBLE COSTS

II.19.1 Conditions for the eligibility of costs

"Eligible costs" of the action are costs actually incurred by the beneficiary which meet the following criteria:

- (a) they are incurred in the period set out in Article 2.2, with the exception of costs relating to the request for payment of the balance and the corresponding supporting documents referred to in Article II.23.2.

Costs of contracts for goods, works or services or of subcontracts are considered to be incurred when the contract or subcontract (or a part of it) is executed, i.e. when the goods, works or services (including studies) are supplied, delivered or provided;

- (b) they are indicated in the estimated budget of the action set out in Annex III;
- (c) they are incurred in connection with the action as described in Annex I and are necessary for its implementation; in particular, for the costs of contracts for goods, the goods are supplied in a Member State or in any other countries where the action is implemented as described in Annex I; for the costs of contracts for works, the works are delivered in a Member State or in any other countries where the action is implemented as described in Annex I; for the costs of contracts for services (including studies), the services provided concern a Member State or any other countries where the action is implemented as described in Annex I;
- (d) they are identifiable and verifiable, in particular being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and with the usual cost accounting practices of the beneficiary;
- (e) they comply with the requirements of applicable tax and social legislation; and
- (f) they are reasonable, justified, and comply with the principle of sound financial management, in particular regarding economy and efficiency.

II.19.2 Eligible direct costs

"Direct costs" of the action are those specific costs which are directly linked to the implementation of the action and can therefore be attributed directly to it. They may not include any indirect costs.

To be eligible, direct costs shall comply with the conditions of eligibility set out in Article II.19.1.

In particular, the following categories of costs are eligible direct costs, provided that they satisfy the conditions of eligibility set out in Article II.19.1 as well as the following

conditions:

- (a) the costs of personnel working under an employment contract with the beneficiary or an equivalent appointing act and assigned to the action, provided that these costs are in line with the beneficiary's usual policy on remuneration.

Those costs include actual salaries plus social security contributions and other statutory costs included in the remuneration. They may also comprise additional remunerations, including payments on the basis of supplementary contracts regardless of the nature of those contracts, provided that they are paid in a consistent manner whenever the same kind of work or expertise is required, independently from the source of funding used;

The costs of natural persons working under a contract with the beneficiary other than an employment contract or who are seconded to the beneficiary by a third party against payment may be included under such costs of personnel, provided that the following conditions are fulfilled:

- (i) the natural person works under the conditions similar to those of an employee (in particular regarding the way the work is organized, the tasks are performed and the premises where they are performed);
- (ii) the result of the work belongs to the beneficiary (unless exceptionally agreed otherwise); and
- (iii) the costs are not significantly different from the costs of staff performing similar tasks under an employment contract with the beneficiary;
- (b) costs of travel and related subsistence allowances, provided that these costs are in line with the beneficiary's usual practices on travel;
- (c) the full costs of purchase of equipment and other assets shall be eligible, provided that they are treated as capital expenditure in accordance with the tax and accounting rules applicable to the beneficiary and are recorded in the fixed assets account of its balance sheet and if the asset has been purchased in accordance with Article II.9.1.

The costs of rental or lease of equipment or other assets are also eligible, provided that these costs do not exceed the depreciation costs of similar equipment or assets and are exclusive of any finance fee;

- (d) costs of consumables and supplies, provided that they are purchased in accordance with the first subparagraph of Article II.9.1 and are directly assigned to the action;
- (e) costs arising directly from requirements imposed by the Agreement (dissemination of information, specific evaluation of the action, audits, translations, reproduction), including the costs of requested financial guarantees, provided that the corresponding services are purchased in accordance with the first subparagraph of Article II.9.1;
- (f) costs entailed by service contracts, including costs of environmental studies on the protection of the environment and on compliance with the relevant Union law, provided

that the corresponding services are purchased in accordance with the first subparagraph of Article II.9.1 and costs entailed by subcontracts within the meaning of Article II.10, provided that the conditions laid down in Article II.10.2 are met;

- (g) costs of financial support to third parties within the meaning of Article II.11, provided that the conditions laid down in Article II.11.1 or II.11.2 are met;
- (h) duties, taxes and charges paid by the beneficiary, notably non-deductible value added tax (VAT), provided that they are included in eligible direct costs, and unless specified otherwise in the Agreement.

II.19.3 Indirect costs

"Indirect costs" of the action are those costs which are not specific costs directly linked to the implementation of the action and can therefore not be attributed directly to it. They may not include any costs identifiable or declared as eligible direct costs.

Eligible indirect costs shall be declared on the basis of a flat rate of 7% of the total eligible direct costs minus subcontracting costs within the meaning of Article II.10 and costs of financial support to third parties within the meaning of Article II.11.

II.19.4 Ineligible costs

In addition to any other costs which do not fulfil the conditions set out in Article II.19.1, the following costs shall not be considered eligible:

- (a) return on capital and dividends paid by a beneficiary;
- (b) debt and debt service charges;
- (c) provisions for losses or debts;
- (d) interest owed;
- (e) doubtful debts;
- (f) exchange losses;
- (g) costs of transfers from the Agency charged by the bank of a beneficiary;
- (h) costs declared by the beneficiary in the framework of another action receiving a grant financed from the Union budget (including grants awarded by a Member State and financed from the Union budget and grants awarded by other bodies than the Commission for the purpose of implementing the Union budget); In particular, beneficiaries receiving an operating grant financed by the EU or Euratom budget cannot declare indirect costs for the period(s) covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action.
- (i) contributions in kind from third parties;

- (j) excessive or reckless expenditure;
- (k) deductible VAT.

ARTICLE II.20 – IDENTIFIABILITY AND VERIFIABILITY OF THE AMOUNTS DECLARED

II.20.1 Reimbursement of actual costs

Where, in accordance with Article 3(a)(i), the grant takes the form of the reimbursement of actual costs, the beneficiary must declare as eligible costs the costs it actually incurred for the action.

If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the costs declared, such as contracts, invoices and accounting records. In addition, the beneficiary's usual accounting and internal control procedures must permit direct reconciliation of the amounts declared with the amounts recorded in its accounting statements as well as with the amounts indicated in the supporting documents.

II.20.2 Reimbursement of pre-determined unit costs or pre-determined unit contribution

Where, in accordance with Article 3(a)(ii) or (b), the grant takes the form of the reimbursement of unit costs or of a unit contribution, the beneficiary must declare as eligible costs or as requested contribution the amount obtained by multiplying the amount per unit specified in Article 3(a)(ii) or (b) by the actual number of units used or produced.

If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the number of units declared. However, the beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, notably accounting statements, to prove the amount declared per unit.

II.20.3 Reimbursement of pre-determined lump sum costs or pre-determined lump sum contribution

Where, in accordance with Article 3(a)(iii) or (c), the grant takes the form of the reimbursement of lump sum costs or of a lump sum contribution, the beneficiary must declare as eligible costs or as requested contribution the global amount specified in Article 3(a)(iii) or (c), subject to the proper implementation of the corresponding tasks or part of the action as described in Annex I.

If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the proper implementation. However, the beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, notably accounting

statements, to prove the amount declared as lump sum.

II.20.4 Reimbursement of pre-determined flat-rate costs or pre-determined flat-rate contribution

Where, in accordance with Article 3(a)(iv) or (d), the grant takes the form of the reimbursement of flat-rate costs or of a flat-rate contribution, the beneficiary must declare as eligible costs or as requested contribution the amount obtained by applying the flat rate specified in Article 3(a)(iv) or (d).

If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the eligible costs or requested contribution to which the flat rate applies. However, the beneficiary does not need to identify the actual eligible costs covered or to provide supporting documents, notably accounting statements, for the flat rate applied.

II.20.5 Reimbursement of costs declared on the basis of the beneficiary's usual cost accounting practices

Where, in accordance with Article 3(a)(v), the grant takes the form of the reimbursement of unit costs declared on the basis of the beneficiary's usual cost accounting practices, the beneficiary must declare as eligible costs the amount obtained by multiplying the amount per unit calculated in accordance with its usual cost accounting practices by the actual number of units used or produced. If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the number of units declared.

Where, in accordance with Article 3(a)(v), the grant takes the form of the reimbursement of lump sum costs declared on the basis of the beneficiary's usual cost accounting practices, the beneficiary must declare as eligible costs the global amount calculated in accordance with its usual cost accounting practices, subject to the proper implementation of the corresponding tasks or part of the action. If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the proper implementation.

Where, in accordance with Article 3(a)(v), the grant takes the form of the reimbursement of flat-rate costs declared on the basis of the beneficiary's usual cost accounting practices, the beneficiary must declare as eligible costs the amount obtained by applying the flat rate calculated in accordance with its usual cost accounting practices. If requested to do so in the context of the checks or audits described in Article II.27, the beneficiary must be able to provide adequate supporting documents to prove the eligible costs to which the flat rate applies.

In all three cases provided for in the first, second and third subparagraphs, the beneficiary does not need to identify the actual eligible costs covered, but it must ensure that the cost accounting practices used for the purpose of declaring eligible costs are in compliance with the following conditions:

- (a) the cost accounting practices used constitute its usual cost accounting practices and are applied in a consistent manner, based on objective criteria independent from the source of funding;
- (b) the costs declared can be directly reconciled with the amounts recorded in its general accounts; and
- (c) the categories of costs used for the purpose of determining the costs declared are exclusive of any ineligible cost or costs covered by other forms of grant in accordance with Article 3.

ARTICLE II.21 – ELIGIBILITY OF COSTS OF ENTITIES AFFILIATED TO THE BENEFICIARIES AND OF IMPLEMENTING BODIES DESIGNATED BY THE BENEFICIARIES

II.21.1 Where the Special Conditions contain a provision on entities affiliated to the beneficiaries or a provision on implementing bodies, costs incurred by such an entity or body are eligible, provided that they satisfy the same conditions under Articles II.19 and II.20 as apply to the beneficiary, and that the beneficiary to which the entity is affiliated or by which the implementing body is designated ensures that the Agency, the Commission, the European Anti-Fraud Office (OLAF) and the European Court of Auditors may exercise their rights under Article II.27 also towards the entity or body.

II.21.2 The beneficiary to which the entity is affiliated or by which the implementing body is designated shall ensure that the conditions applicable to it under Articles II.3, II.4, II.5, II.7, II.9 and II.10 are also applicable to the entity or body.

II.21.3 The beneficiaries shall retain sole responsibility for carrying out the action and for compliance with the provisions of the Agreement. The beneficiaries shall ensure that any agreement or contract with an affiliated entity or implementing body contains provisions stipulating that the affiliated entity or implementing body has no right vis-à-vis the Agency under the Agreement.

ARTICLE II.22 – BUDGET TRANSFERS

The estimated budget set out in Annex III may be adjusted by transfers of amounts between beneficiaries and between budget categories, without this adjustment being considered as an amendment of the Agreement within the meaning of Article II.12, provided that the action is implemented as described in Annex I.

The beneficiaries may not however:

- adjust amounts which, in accordance with Article 3(a)(iii) or (c), take the form of lump sums;
- add costs relating to subcontracts not provided for in Annex I, unless such additional subcontracts are approved in accordance with Article II.10.

By way of derogation from the first subparagraph, should beneficiaries want to modify the value of the estimated CEF contribution that each of them is entitled to as referred to in point (b) of Article II.17.1 and point (c) of II.26.3, the coordinator shall request an amendment in accordance to Article II.12.

ARTICLE II.23 – TECHNICAL AND FINANCIAL REPORTING – REQUESTS FOR PAYMENT AND SUPPORTING DOCUMENTS

II.23.1 Action Status Reports - Requests for further pre-financing payments and supporting documents

Not applicable.

II.23.2 Interim and final reports - Requests for interim payments or for payment of the balance and supporting documents

The coordinator shall submit a request for an interim payment or for payment of the balance within 60 days following the end of each reporting period for which, in accordance with Article 4.1, an interim payment or the payment of the balance is due.

This request shall be accompanied by the following documents:

- (a) an interim report (“interim technical report”) or, for the payment of the balance, a final report on implementation of the action (“final technical report”), drawn up in accordance with Annex V; the interim or final technical report must contain the information needed to justify the eligible costs declared or the contribution requested on the basis of unit costs and lump sums where the grant takes the form of the reimbursement of unit or lump sum costs or of a unit or lump sum contribution in accordance with Article 3(a)(ii), (iii), (b) or (c), as well as information on subcontracting as referred to in Article II.10.2(d);
- (b) an interim financial statement (“interim financial statement”) or, for the payment of the balance, a final financial statement (“final financial statement”); the interim or final financial statements must include a consolidated statement as well as a breakdown of the amounts claimed by each beneficiary, its affiliated entities and implementing bodies; they must be drawn up in accordance with the structure of the estimated budget set out in Annex III and with Annex VI and detail the amounts for each of the forms of grant set out in Article 3 for the reporting period concerned;
- (c) only for the payment of the balance, a summary financial statement (“summary financial statement”); this statement must include a consolidated financial statement and a breakdown of the amounts declared or requested by each beneficiary, its affiliated entities and its implementing bodies, aggregating the financial statements already submitted previously and indicating the receipts referred to in Article II.25.3.2 for each beneficiary, its affiliated entities and its implementing bodies; it must be drawn up in accordance with Annex VI;
- (d) only for the payment of the balance and for beneficiaries established in the European

Union, the certification by the Member State in which the beneficiary is established that (i) the information provided is full, reliable and true and (ii) the costs declared in the final financial statement are real and eligible in accordance with this Agreement; in exceptional cases, at the request of the beneficiary, the certification may be provided by the Member State in which the action is implemented;

- (e) unless the Special Conditions provide otherwise, a certificate on the financial statements and underlying accounts ('certificate on the financial statements') for each beneficiary, each affiliated entity and each implementing body, if:
- (i) the cumulative amount of payments the beneficiary requests as reimbursement of actual costs as referred to in Article 3(a)(i) (and for which no certificate has yet been submitted) is EUR 325 000 or more;
 - (ii) the maximum grant amount indicated for that beneficiary, its affiliated entities and implementing bodies in the estimated budget as reimbursement of actual costs is EUR 750 000 or more.

This certificate shall be produced by an approved auditor or, in case of public bodies, by a competent and independent public officer and drawn up in accordance with Annex VII. It shall certify that the costs declared in the interim or final financial statement by the beneficiary concerned, its affiliated entities or and its implementing bodies for the categories of costs reimbursed in accordance with Article 3(a)(i) are real, accurately recorded and eligible in accordance with the Agreement. In addition, for the payment of the balance, it shall certify that all the receipts referred to in Article II.25.3.2 have been declared.

The coordinator shall certify that the information provided in the request for interim payment or for payment of the balance is full, reliable and true. It shall also certify that the costs incurred can be considered eligible in accordance with the Agreement and that the request for payment is substantiated by adequate supporting documents that can be produced in the context of the checks or audits described in Article II.27. In addition, for the payment of the balance, it shall certify that all the receipts referred to in Article II.25.3.2 have been declared.

II.23.3 Non-submission of documents

Where the coordinator has failed to submit a request for interim payment or payment of the balance accompanied by the documents referred to above by the deadline set out in Article II.23.2 and where the coordinator still fails to submit such a request within 60 days following a written reminder sent by the Agency, the Agency reserves the right to terminate the Agreement in accordance with Article II.16.3.1(c), with the effects described in the third and the fourth subparagraphs of Article II.16.4.1.

II.23.4 Currency for requests for payment and financial statements and conversion into euro

Requests for payment and financial statements shall be drafted in euro.

Beneficiaries with general accounts in a currency other than the euro shall convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of *Official Journal of the European Union*, determined over the corresponding

reporting period, available at:

<http://www.ecb.europa.eu/stats/exchange/eurofxref/html/index.en.html>.

Where no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, conversion shall be made at the average of the monthly accounting rates established by the Commission and published on its website (http://ec.europa.eu/budget/contracts_grants/info_contracts/infoeuro/infoeuro_en.cfm), determined over the corresponding reporting period.

Beneficiaries with general accounts in euro shall convert costs incurred in another currency into euro according to their usual accounting practices.

ARTICLE II.24 – PAYMENTS AND PAYMENT ARRANGEMENTS

II.24.1 Pre-financing

II.24.1.1 The pre-financing is intended to provide the beneficiaries with a float. It remains the property of the Union until it is cleared against the payment of the balance to the coordinator.

Where payment of pre-financing is conditional on receipt of a financial guarantee, the financial guarantee shall fulfill the following conditions:

- (a) it is provided by an approved bank or an approved financial institution. The guarantee shall be denominated in euros. Where a beneficiary is established in a third country, the Agency may agree that a bank or a financial institution established in that third country may provide the guarantee if it considered that the bank or financial institution offers equivalent security and characteristics as those offered by a bank or financial institution established in a Member State. At the request of the coordinator and acceptance by the Agency, the financial guarantee may be replaced by a joint and several guarantee by a third party;
- (b) the guarantor stands as first-call guarantor and does not require the Agency to have recourse against the principal debtor (i.e. the beneficiary concerned); and
- (c) it provides that it remains in force until the pre-financing is cleared against the payment of the balance by the Agency and, in case the payment of the balance is made in the form of a debit note, three months after the debit note is notified to the coordinator. The Agency shall release the guarantee within the following month.

II.24.1.2 Without prejudice to Article II.24.5, where Article 4.1 provides for a pre-financing payment upon entry into force of the Agreement or following a later date, the Agency shall pay to the coordinator within 30 days following that date or, where required by Article 4.1, following receipt of the financial guarantee.

II.24.2 Interim payments

Interim payments are intended to reimburse or cover the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

Without prejudice to Articles II.24.4 and II.24.5, on receipt of the documents referred to in Article II.23.2, the Agency shall pay to the coordinator the amount due as interim payment within the time limit specified in Article 4.2.

This amount shall be determined following approval of the request for interim payment and of the accompanying documents and in accordance with the fourth subparagraph. Approval of the request for interim payment and of the accompanying documents shall not imply recognition of the compliance, authenticity, completeness or correctness of the declarations and information they contain.

The amount due as interim payment shall be determined as follows:

- (a) the following amounts, which depend on the form of the grant, shall be added:
 - (i) where, in accordance with Article 3(a), the grant takes the form of the reimbursement of eligible costs, the amount obtained by application of the reimbursement rate specified in that Article to the eligible costs of the action approved by the Agency for the concerned reporting period and the corresponding categories of costs, beneficiaries, affiliated entities and implementing bodies;
 - (ii) where, in accordance with Article 3(b), the grant takes the form of a unit contribution, the amount obtained by multiplying the unit contribution specified in that Article by the actual number of units approved by the Agency for the concerned reporting period and for the corresponding beneficiaries, affiliated entities and implementing bodies;
 - (iii) where, in accordance with Article 3(c), the grant takes the form of a lump sum contribution, the lump sum specified in that Article for the corresponding beneficiaries, affiliated entities and implementing bodies, subject to approval by the Agency of the proper implementation during the concerned reporting period of the corresponding tasks or part of the action in accordance with Annex I;
 - (iv) where, in accordance with Article 3(d), the grant takes the form of a flat-rate contribution, the amount obtained by applying the flat rate referred to in that Article to the eligible costs or to the contribution accepted by the Agency for the concerned reporting period and the corresponding beneficiaries, affiliated entities and implementing bodies.
- (b) the amount obtained in accordance with point (a) shall be limited to the difference between the ceiling for pre-financing and interim payments set out in Article 4.1.3 and the total amount of the pre-financing and interim payments already made.

II.24.3 Payment of the balance

The payment of the balance, which may not be repeated, is intended to reimburse or cover after the end of the period set out in Article 2.2 the remaining part of the eligible costs

incurred by the beneficiaries for its implementation. Where the total amount of earlier payments is greater than the final amount of the grant determined in accordance with Article II.25, the payment of the balance may take the form of a recovery as provided for by Article II.26.

Without prejudice to Articles II.24.4 and II.24.5, on receipt of the documents referred to in Article II.23.2, the Agency shall pay the amount due as the balance within the time limit specified in Article 4.2.

This amount shall be determined following approval of the request for payment of the balance and of the accompanying documents and in accordance with the fourth subparagraph. Approval of the request for payment of the balance and of the accompanying documents shall not imply recognition of the compliance, authenticity, completeness or correctness of the declarations and information they contain.

The amount due as the balance shall be determined by deducting, from the final amount of the grant determined in accordance with Article II.25, the total amount of pre-financing and interim payments already made.

II.24.4 Suspension of the time limit for payment

The Agency may suspend the time limit for payment specified in Article 4.2, at any time by formally notifying the coordinator that its request for payment cannot be met, either because it does not comply with the provisions of the Agreement, or because the appropriate supporting documents have not been produced, or because there is doubt about the eligibility of the costs declared in the financial statement.

The coordinator shall be notified as soon as possible of any such suspension, together with the reasons thereof.

Suspension shall take effect on the date when notification is sent by the Agency. The remaining payment period shall start to run again from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension exceeds two months, the coordinator may request a decision by the Agency on whether the suspension is to be continued.

Where the time limit for payment has been suspended following the rejection of one of the technical reports or financial statements provided for by Article II.23 and the new report or statement submitted is also rejected, the Agency reserves the right to terminate the Agreement in accordance with Article II.16.3.1(c), with the effects described in Article II.16.4.

II.24.5 Suspension of payments

II.24.5.1 The Agency may, at any time during the implementation of the Agreement, suspend the pre-financing payments, interim payments or payment of the balance for all beneficiaries, or suspend the pre-financing payments or interim payments for any one or several beneficiaries:

- (a) if the Agency has evidence that a beneficiary has committed substantial errors, irregularities or fraud in the award procedure or in the implementation of the grant, or if a beneficiary fails to comply with its obligations under the Agreement;
- (b) if the Agency has evidence that a beneficiary has committed systemic or recurrent errors, irregularities, fraud or serious breach of obligations under other grants funded by the Union or by the European Atomic Energy Community which were awarded to that beneficiary under similar conditions, provided that those errors, irregularities, fraud or breach of obligations have a material impact on this grant;
- (c) if the Agency suspects substantial errors, irregularities, fraud or breach of obligations committed by a beneficiary in the award procedure or in the implementation of the Agreement and needs to verify whether they have actually occurred; or
- (d) following an evaluation of the progress of the project, in particular in the event of major delays in the implementation of the action.

II.24.5.2 Before suspending payments, the Agency shall formally notify the coordinator of its intention to suspend payments, specifying the reasons thereof and, in the cases referred to in points (a), (b) and (d) of Article II.24.5.1, the necessary conditions for resuming payments. The coordinator shall be invited to make any observations on behalf of all beneficiaries within 30 calendar days from receipt of this notification.

If, after examination of the observations submitted by the coordinator, the Agency decides to stop the procedure of payment suspension, the Agency shall formally notify the coordinator thereof.

If no observations have been submitted or if, despite the observations submitted by the coordinator, the Agency decides to pursue the procedure of payment suspension, it may suspend payments by formally notifying the coordinator, specifying the reasons for the suspension and, in the cases referred to in points (a), (b) and (d) of Article II.24.5.1, the definitive conditions for resuming payments or, in the case referred to in point (c) of Article II.24.5.1, the indicative date of completion of the necessary verification.

The coordinator shall inform the other beneficiaries immediately. The suspension of payments shall take effect on the date when the notification is sent by the Agency.

In order to resume payments, the beneficiaries shall endeavour to meet the notified conditions as soon as possible and shall inform the Agency of any progress made in this respect.

The Agency shall, as soon as it considers that the conditions for resuming payments

have been met or the necessary verification, including on-the-spot checks, has been carried out, formally notify the coordinator thereof.

During the period of suspension of payments and without prejudice to the right to suspend the implementation of the action in accordance with Article II.15.1 or to terminate the Agreement or the participation of a beneficiary in accordance with Article II.16.1 and Article II.16.2, the coordinator is not entitled to submit any requests for payments or, where the suspension concerns the pre-financing payments or interim payments for one or several beneficiaries only, any requests for payments and supporting documents relating to the participation of the concerned beneficiary or beneficiaries in the action.

The corresponding requests for payments and supporting documents may be submitted as soon as possible after resumption of payments or may be included in the first request for payment due following resumption of payments in accordance with the schedule laid down in Article 4.1.

II.24.6 Notification of amounts due

The Agency shall formally notify the amounts due, specifying whether it is a further pre-financing payment, an interim payment or the payment of the balance. In the case of payment of the balance, it shall also specify the final amount of the grant determined in accordance with Article II.25.

II.24.7 Interest on late payment

On expiry of the time limits for payment specified in Articles 4.2 and II.24.1, and without prejudice to Articles II.24.4 and II.24.5, the beneficiaries are entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros ("the reference rate"), plus three and a half points. The reference rate shall be the rate in force on the first day of the month in which the time limit for payment expires, as published in the C series of the *Official Journal of the European Union*.

The first subparagraph shall not apply where all beneficiaries are Member States of the Union, including regional and local government authorities and other public bodies acting in the name and on behalf of the Member State for the purpose of this Agreement.

The suspension of the time limit for payment in accordance with Article II.24.4 or of payment by the Agency in accordance with Article II.24.5 may not be considered as late payment.

Interest on late payment shall cover the period running from the day following the due date for payment, up to and including the date of actual payment as established in Article II.24.9. The interest payable shall not be considered for the purposes of determining the final amount of grant within the meaning of Article II.25.3.

By way of derogation from the first subparagraph, when the calculated interest is lower than or equal to EUR 200, it shall be paid only upon request submitted by the coordinator within two months of the late payment.

II.24.8 Currency for payments

Payments by the Agency shall be made in euro.

II.24.9 Date of payment

Payments by the Agency shall be deemed to be effected on the date when they are debited to the Agency's account.

II.24.10 Costs of payment transfers

Costs of the payment transfers shall be borne in the following way:

- (a) costs of transfer charged by the bank of the Agency shall be borne by the Agency;
- (b) costs of transfer charged by the bank of a beneficiary shall be borne by the beneficiary;
- (c) all costs of repeated transfers caused by one of the parties shall be borne by the party which caused the repetition of the transfer.

II.24.11 Payments to the coordinator

The Agency shall make all payments to the coordinator. Payments to the coordinator shall discharge the Agency from its payment obligation.

ARTICLE II.25 – DETERMINING THE FINAL AMOUNT OF THE GRANT

II.25.1 Calculation of the final amount

The final amount of the grant depends on the extent to which the action has been implemented in accordance with the terms of the Agreement. Without prejudice to Articles II.25.2, II.25.3 and II.25.4, the final amount of the grant shall be determined as follows:

- (a) where, in accordance with Article 3(a), the grant takes the form of the reimbursement of eligible costs, the amount obtained by application of the reimbursement rate(s) specified in that Article to the eligible costs of the action approved by the Agency for the corresponding categories of costs, beneficiaries, affiliated entities and implementing bodies;
- (b) where, in accordance with Article 3(b), the grant takes the form of a unit contribution, the amount obtained by multiplying the unit contribution specified in that Article by the actual number of units approved by the Agency for the corresponding beneficiaries, affiliated entities and implementing bodies;
- (c) where, in accordance with Article 3(c), the grant takes the form of a lump sum contribution, the lump sum specified in that Article for the corresponding beneficiaries, affiliated entities and implementing bodies, subject to approval by the Agency of the proper implementation of the corresponding tasks or part of the action in accordance

with Annex I;

- (d) where, in accordance with Article 3(d), the grant takes the form of a flat-rate contribution, the amount obtained by applying the flat rate referred to in that Article to the eligible costs or to the contribution accepted by the Agency for the corresponding beneficiaries, affiliated entities and implementing bodies.

Where Article 3 provides for a combination of different forms of grant, these amounts shall be added.

II.25.2 Maximum amount

The total amount paid by the Agency for the action may in no circumstances exceed the maximum amount of the grant specified in Article 3.

Where the amount determined in accordance with Article II.25.1 exceeds this maximum amount, the final amount of the grant shall be limited to the maximum amount specified in Article 3.

II.25.3 No-profit rule and taking into account of receipts

II.25.3.1 The grant may not produce a profit for the beneficiaries, unless specified otherwise in the Special Conditions. "Profit" shall mean a surplus of the amount determined in accordance with Articles II.25.1 and II.25.2 plus the total receipts of the action over the total eligible costs of the action.

II.25.3.2 The total receipts of the action are the consolidated total receipts established, generated or confirmed on the date on which the request for payment of the balance is drawn up by the coordinator, which fall within one of the following two categories:

- (a) income generated by the action; or
- (b) financial contributions given by third parties to a beneficiary, an affiliated entity or implementing body, if they are specifically assigned by the third parties to the financing of the eligible costs of the action reimbursed by the Agency in accordance with Article 3(a)(i).

II.25.3.3 The following shall not be considered as receipts to be taken into account for the purpose of verifying whether the grant produces a profit for the beneficiaries:

- (a) financial contributions by third parties referred to in point (b) of Article II.25.3.2, if they may be used to cover costs other than the eligible costs under the Agreement;
- (b) financial contributions by third parties referred to in point (b) of Article II.25.3.2, with no obligation to repay any amount unused at the end of the period set out in Article 2.2.

II.25.3.4 The total eligible costs of the action to be taken into account are the consolidated total eligible costs approved by the Agency for the categories of costs reimbursed in accordance with Article 3(a).

II.25.3.5 Where the final amount of the grant determined in accordance with Articles II.25.1 and II.25.2 would result in a profit for the beneficiaries, the profit shall be deducted in proportion to the final rate of reimbursement of the actual eligible costs of the action approved by the Agency for the categories of costs referred to in Article 3(a)(i). This final rate shall be calculated on the basis of the final amount of the grant in the form referred to in Article 3(a)(i), as determined in accordance with Articles II.25.1 and II.25.2.

II.25.4 Reduction for poor, partial or late implementation, or breach of contractual obligations

The Agency may reduce the maximum grant amount set out in Article 3 if the action has not been implemented properly in accordance with Annex I (i.e. if it has not been implemented or has been implemented poorly, partially or late), or if any beneficiary fails to comply with any other obligations under this Agreement.

The amount of the reduction will be proportionate to the degree to which the action has been implemented improperly or to the seriousness of the breach.

Before the Agency reduces the grant, it must send a formal notification to the coordinator:

(a) informing it of:

- (i) its intention to reduce the maximum amount of the grant;
- (ii) the amount by which it intends to reduce the grant;
- (iii) the reasons for reduction;

(b) inviting it to submit observations within 30 calendar days of receiving the formal notification.

If the Agency does not receive any observations or decides to pursue reduction despite the observations it has received, it will send a formal notification informing the coordinator of its decision.

If the grant is reduced, the Agency must calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations) from the maximum amount of the grant.

The final amount of the grant will be the lower of the following two:

- (a) the amount determined in accordance with Article II.25.1, II.25.2 and II.25.3; or
- (b) the reduced grant amount determined in accordance with Article II.25.4.

ARTICLE II.26 – RECOVERY

II.26.1 Recovery at the time of payment of the balance

Where the payment of the balance takes the form of a recovery, the Agency shall formally notify the coordinator of its intention to recover the amount unduly paid:

- (a) specifying the amount due and the reasons for recovery;
- (b) inviting the coordinator to make any observations within a specified period ; and
- (c) requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within a specified period.

If no observations have been submitted or if, despite the observations submitted by the coordinator, the Agency decides to pursue the recovery procedure, the Agency may confirm recovery by formally notifying to the coordinator a debit note (“debit note”), specifying the terms and the date for payment.

If the coordinator does not repay the Agency by the date specified in the debit note and has not submitted the report on the distribution of payments, the Agency or the Commission shall recover the amount due from the coordinator in accordance with Article II.26.3, even if it has not been the final recipient of the amount due.

If the coordinator does not repay the Agency by the date specified in the debit note but has submitted the report on the distribution of payments made to the beneficiaries, the Agency shall recover the amount due from the beneficiary which has been the final recipient of the amount due.

For that purpose, the Agency shall:

- (a) where, in accordance with Article 3(a), the grant takes the form of the reimbursement of eligible costs:
 - (i) identify the beneficiaries for which the amount calculated as follows is negative:
$$\left\{ \left\{ \left\{ \begin{array}{l} \text{Beneficiary's costs (including the costs of its affiliated entities and} \\ \text{implementing bodies if applicable) declared in the final financial} \\ \text{statement and approved by the Agency multiplied by the} \\ \text{reimbursement rate(s) set out in Article 3(a) for the beneficiary} \\ \text{concerned} \end{array} \right. \right\} \right\}$$
divided by
the amount calculated according to Article II.25.1 }
multiplied by
the final grant amount calculated according to Article II.25 } ,
minus
the pre-financing and interim payments received by the beneficiary }

- (ii) formally notify to each beneficiary identified according to point (i) a debit note specifying the terms and date for payment. The amount of the debit note shall be calculated as follows:
- $$\left\{ \begin{array}{l} \text{\{ amount calculated according to point (i) for the beneficiary} \\ \text{concerned} \\ \text{divided by} \\ \text{the sum of the amounts calculated according to point (i) for all the} \\ \text{beneficiaries identified according to point (i) } \\ \text{multiplied by} \\ \text{the amount set out in the debit note formally notified to the} \\ \text{coordinator } \end{array} \right\}$$
- (b) where, in accordance with Article 3(b), (c) or (d) the grant takes the form of a unit, lump sum or flat-rate contribution, formally notify to each beneficiary a debit note specifying the terms and date for payment. The amount of the debit note shall be calculated as follows:
- $$\left\{ \begin{array}{l} \text{\{ the pre-financing and interim payments received by the beneficiary} \\ \text{divided by} \\ \text{the total amount of pre-financing and interim payments paid by the Agency} \\ \text{multiplied by} \\ \text{the amount set out in the debit note formally notified to the coordinator } \end{array} \right\};$$
- (c) where Article 3 provides for a combination of different forms of grant, these amounts shall be added.

If the beneficiary concerned does not repay the Agency by the date specified in the debit note, the Agency or the Commission shall recover the amount due from the beneficiary in accordance with Article II.26.3.

II.26.2 Recovery after payment of the balance

Where an amount is to be recovered in accordance with Articles II.27.6, II.27.7 and II.27.8, the beneficiary concerned by the audit or OLAF findings shall repay the Agency the amount in question.

Where the audit findings do not concern a specific beneficiary, the coordinator shall repay the Agency the amount in question, even if it has not been the final recipient of the amount due.

Before recovery, the Agency shall formally notify the beneficiary concerned or the coordinator of its intention to recover the amount unduly paid:

- (a) specifying the amount due (including any amount unduly paid by the Agency as a

contribution towards the costs incurred by its affiliated entities or its implementing bodies) and the reasons for recovery;

- (b) inviting the beneficiary concerned or the coordinator to make any observations within a specified period.

If no observations have been submitted or if, despite the observations submitted by the beneficiary concerned or the coordinator, the Agency decides to pursue the recovery procedure, the Agency may confirm recovery by formally notifying to the beneficiary concerned or the coordinator a debit note (“debit note”), specifying the terms and the date for payment.

If the beneficiary concerned or the coordinator does not repay the Agency by the date specified in the debit note, the Agency shall recover the amount due from the beneficiary concerned or the coordinator in accordance with Article II.26.3.

II.26.3 Recovery procedure failing repayment by the date specified in the debit note

If payment has not been made by the date specified in the debit note, the Agency or the Commission shall recover the amount due:

- (a) by offsetting it against any amounts owed to the beneficiary concerned by the Commission or an executive agency (from the Union or the European Atomic Energy Community (Euratom) budget) (“offsetting”); in exceptional circumstances, justified by the necessity to safeguard the financial interests of the Union, the Agency may recover by offsetting before the due date; the beneficiary’s prior consent shall not be required; an action may be brought against such offsetting before the General Court of the European Union pursuant to Article 263 TFEU;
- (b) by drawing on the financial guarantee where provided for in accordance with Article 4.1 (“drawing on the financial guarantee”);
- (c) where provided for in the Special Conditions, by holding the beneficiaries jointly and severally liable;
- (d) by taking legal action in accordance with Article II.18.2 or with the Special Conditions or by adopting an enforceable decision in accordance with Article II.18.3.

II.26.4 Interest on late payment

If payment has not been made by the date set out in the debit note, the amount due shall bear interest at the rate established in Article II.24.7. Interest on late payment shall cover the period running from the day following the due date for payment, up to and including the date when the Agency or the Commission actually receives payment in full of the outstanding amount.

Any partial payment shall first be appropriated against charges and interest on late payment and then against the principal.

II.26.5 Bank charges

Bank charges incurred in connection with the recovery of the sums owed to the Agency shall be borne by the beneficiary concerned except where Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC applies.

ARTICLE II.27 – CHECKS, AUDITS AND EVALUATION

II.27.1 Technical and financial checks, audits, interim and final evaluations

The Commission or the Agency may carry out technical and financial checks and audits to determine that the beneficiaries are implementing the action properly and are complying with the obligations under the Agreement. It may also check the statutory records of the beneficiaries for the purpose of periodic assessments of lump sum, unit cost or flat-rate amounts.

Information and documents provided in the framework of checks or audits shall be treated on a confidential basis.

In addition, the Commission or the Agency may carry out interim or final evaluation of the impact of the action measured against the objective of the Union programme concerned, in order to assess whether the objectives, including those relating to environmental protection, have been attained.

Checks, audits or evaluations made by the Commission or the Agency may be carried out either directly by its own staff or by any other outside body authorised to do so on its behalf.

Such checks, audits or evaluations may be initiated during the implementation of the Agreement and for a period of five years starting from the date of payment of the balance. This period shall be limited to three years if the maximum amount specified in Article 3 is not more than EUR 60 000.

The check, audit or evaluation procedure shall be deemed to be initiated on the date of receipt of the letter of the Commission or the Agency announcing it.

If the audit is carried out on an affiliated entity or implementing body, the beneficiary concerned must inform that affiliated entity or implementing body.

II.27.2 Duty to keep documents

The beneficiaries shall keep all original documents, especially accounting and tax records, stored on any appropriate medium, including digitalised originals when they are authorised by their respective national law and under the conditions laid down therein, for a period of five years starting from the date of payment of the balance.

This period shall be limited to three years if the maximum amount specified in Article 3 is not more than EUR 60 000.

The periods set out in the first and second subparagraphs shall be longer if there are on-going audits, appeals, litigation or pursuit of claims concerning the grant, including in the case referred to in Article II.27.7. In such cases, the beneficiaries shall keep the documents until such audits, appeals, litigation or pursuit of claims are closed.

II.27.3 Obligation to provide information

Where a check or audit is initiated before the payment of the balance, the coordinator shall provide any information, including information in electronic format, requested by the Commission or the Agency, or by any other outside body authorised by it. Where appropriate, the Commission or the Agency may request such information to be provided directly by a beneficiary. Where a check or audit is initiated after payment of the balance, such information shall be provided by the beneficiary concerned.

For an evaluation, the coordinator shall provide any information, including information in electronic format, requested by the Commission or the Agency, or by any other outside body authorised by it. Where appropriate, the Commission or the Agency may request such information to be provided directly by a beneficiary.

In case the beneficiary concerned does not comply with the obligations set out in the first and second subparagraphs, the Commission or the Agency may consider:

- (a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible;
- (b) any unit, lump sum or flat-rate contribution insufficiently substantiated by information provided by the beneficiary as undue.

II.27.4 On-the-spot visits

During an on-the-spot visit, the beneficiaries shall allow Commission or Agency staff and outside personnel authorised by the Commission or the Agency to have access to the sites and premises where the action is or was carried out, and to all the necessary information, including information in electronic format.

They shall ensure that the information is readily available at the moment of the on-the-spot visit and that information requested is handed over in an appropriate form.

In case a beneficiary refuses to provide access to the sites, premises and information in accordance with the first and second subparagraphs, the Commission or the Agency may consider:

- (a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible;
- (b) any unit, lump sum or flat-rate contribution insufficiently substantiated by information provided by the beneficiary as undue.

II.27.5 Contradictory audit procedure

On the basis of the findings made during the audit, a provisional report (“draft audit report”) shall be drawn up. It shall be sent by the Commission or the Agency or its authorised representative to the beneficiary concerned, which shall have 30 days from the date of receipt to submit observations. The final report (“final audit report”) shall be sent to the beneficiary concerned within 60 days of expiry of the time limit for submission of observations.

II.27.6 Effects of audit findings

On the basis of the final audit findings, the Commission or the Agency may take the measures which it considers necessary, including recovery at the time of payment of the balance or after payment of the balance of all or part of the payments made by it, in accordance with Article II.26.

In the case of final audit findings made after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant, determined in accordance with Article II.25, and the total amount paid to the beneficiaries under the Agreement for the implementation of the action.

II.27.7 Correction of systemic or recurrent errors, irregularities, fraud or breach of obligations

II.27.7.1 The Commission or the Agency may extend audit findings from other grants to this grant if:

- (a) the beneficiary is found, on the basis of an audit of other EU or Euratom grants awarded to it under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant; and
- (b) the final audit report containing the findings of the systemic or recurrent errors, irregularities, fraud or breach of obligations is formally received by the beneficiary, together with the list of grants affected by the findings, within the period referred to in Article II.27.1.

The extension of findings may lead to:

- (a) the rejection of costs as ineligible;
- (b) reduction of the grant as provided for in Article II.25.4;
- (c) recovery of undue amounts as provided for in Article II.26;
- (d) suspension of payments as provided for in Article II.24.5;
- (e) suspension of the action implementation as provided for in Article II.15.2;
- (f) termination as provided for in Article II.16.3.

II.27.7.2 The Commission or the Agency must send a formal notification to the beneficiary concerned informing it of the systemic or recurrent errors and of its intention to extend the audit findings, together with the list of grants affected.

(a) If the findings concern eligibility of costs, the procedure is as follows:

The formal notification must include:

- (i) an invitation to submit observations on the list of grants affected by the findings;
- (ii) a request to submit revised financial statements for all grants affected;
- (iii) where possible, the correction rate for extrapolation established by the Commission or the Agency to calculate the amounts to be rejected on the basis of the systemic or recurrent errors, irregularities, fraud or breach of obligations, if the beneficiary concerned:
 - considers that the submission of revised financial statements is not possible or practicable; or
 - will not submit revised financial statements.

The beneficiary concerned has 60 calendar days from when it receives the formal notification to submit observations and revised financial statements or to propose a duly substantiated alternative correction method. This period may be extended by the Commission or the Agency in justified cases.

If the beneficiary concerned submits revised financial statements that take account of the findings, the Commission or the Agency will determine the amount to be corrected on the basis of those revised statements.

If the beneficiary proposes an alternative correction method and the Commission or the Agency accepts it, the Commission or the Agency must send a formal notification to the beneficiary concerned informing it:

- (i) that it accepts the alternative method;
- (ii) of the revised eligible costs determined by applying this method.

Otherwise the Commission or the Agency must send a formal notification to the beneficiary concerned informing it:

- (i) that it does not accept the observations or the alternative method proposed;
- (ii) of the revised eligible costs determined by applying the extrapolation method initially notified to the beneficiary.

In the case of systemic or recurrent errors, irregularities, fraud or breach of obligations found after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant, determined in accordance with Article II.25 on the basis of the revised eligible costs declared by the beneficiary and approved by the Commission or the Agency or on the basis of the revised eligible costs after extrapolation, and the total amount paid to the beneficiaries under the Agreement for the implementation of the action;

- (b) If the findings concern improper implementation or a breach of another obligation (i.e. where ineligible costs cannot serve as a basis for determining the amount to be corrected), the procedure is as follows:

The Commission or the Agency shall formally notify the beneficiary concerned of the correction flat rate to be applied to the maximum amount of the grant specified in Article 3 or to part of it, according to the principle of proportionality, and invite the beneficiary to submit observations on the list of grants affected by the findings.

The beneficiary concerned shall have 60 days from the date of receipt of the notification to submit observations and to propose a duly substantiated alternative flat rate.

If the Commission or the Agency accepts the alternative flat rate proposed by the beneficiary, it shall formally notify the beneficiary concerned thereof and correct the grant amount by applying the accepted alternative flat rate.

If no observations have been submitted or if the Commission or the Agency does not accept the observations or the alternative flat rate proposed by the beneficiary, the Commission or the Agency shall formally notify the beneficiary concerned thereof and correct the grant amount by applying the flat rate initially notified to the beneficiary.

In the case of systemic or recurrent errors, irregularities, fraud or breach of obligations found after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant after flat-rate correction and the total amount paid to the beneficiaries under the Agreement for the implementation of the action.

II.27.8 Checks and inspections by OLAF

The European Anti-Fraud Office (OLAF) shall have the same rights as the Commission and the Agency, notably right of access, for the purpose of checks and investigations.

By virtue of Council Regulation (Euratom, EC) No 2185/96⁸ of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to

⁸ OJ L 292, 15.11.1996, p.2

protect the European Communities' financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013⁹ of the European Parliament and the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF), OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the Union against fraud and other irregularities.

Where appropriate, OLAF findings may lead to recovery by the Agency. They may also lead to criminal prosecution under national law.

II.27.9 Checks and audits by the European Court of Auditors

The European Court of Auditors shall have the same rights as the Agency and the Commission, notably right of access, for the purpose of checks and audits.

⁹ OJ L 248, 18.09.2013, p.1

ANNEX III
ESTIMATED BUDGET OF THE ACTION

Table 1: Planned sources of financing of the eligible costs of the action

Financing sources	Amount of financial contribution to the action eligible costs (EUR)	Amount of financial contribution to the action eligible costs (EUR)
	Kraj Vysočina	SUKL
1. CEF-Telecom financing	257,650	274,977
2. Beneficiary's own resources	85,883	91,659
3. State budget(s)	0	0
4. Regional/ local budget(s)	0	0
5. Income generated by the action	0	0
6. Other sources	0	0
TOTAL	343,533	366,636

Table 2: Indicative breakdown per activity and per beneficiary of estimated eligible costs of the action (EUR)

	Direct eligible costs				Indirect eligible costs	Total eligible costs	Estimated CEF contribution
	Personnel costs	Subcontracting costs	Other costs	Total			
Activity 1	196,000	0	23,800	219,800	15,386	235,186	176,389.5
Kraj Vysočina	80,500	0	12,250	92,750	6,492.5	99,242.5	74,431.88
SUKL	115,500	0	11,550	127,050	8,893.5	135,943.5	101,957.62
Activity 2	143,500	30,000	17,920	191,420	11,299.4	202,719.4	152,039.55
Kraj Vysočina	59,500	30,000	9,520	99,020	4,831.4	103,851.4	77,888.55
SUKL	84,000	0	8,400	92,400	6,468	98,868	74,151
Activity 3	84,000	0	10,920	94,920	6,644.4	101,564.4	76,173.3
Kraj Vysočina	42,000	0	6,720	48,720	3,410.4	52,130.4	39,097.8
SUKL	42,000	0	4,200	46,200	3,234	49,434	37,075.5
Activity 4	101,500	0	10,150	111,650	7,815.5	119,465.5	89,599.12
Kraj Vysočina	45,500	0	4,550	50,050	3,503.5	53,553.5	40,165.12
SUKL	56,000	0	5,600	61,600	4,312	65,912	49,434
Activity 5	42,002	0	5,880	47,882	3,351.74	51,233.74	38,425.3
Kraj Vysočina	28,002	0	4,480	32,482	2,273.74	34,755.74	26,066.8
SUKL	14,000	0	1,400	15,400	1,078	16,478	12,358.5
TOTAL	567,002	30,000	68,670	665,672	44,497.04	710,169.04	532,626.78
Kraj Vysočina	255,502	30,000	37,520	323,022	20,511.54	343,533.54	257,650.16
SUKL	311,500	0	31,150	342,650	23,985.5	366,635.5	274,976.62

ANNEX IV
MANDATE 1

I, the undersigned,

Irena Storova, Director of State Institute for Drug Control,

representing,

State Institute for Drug Control (SUKL)

-

Registration No 00023817

Šrobárova 48

10041 Prague

Czech Republic

VAT No CZ00023817,

hereinafter referred to as "the beneficiary",

for the purposes of the signature and the implementation of the grant agreement No INEA/CEF/ICT/A2017/1529838 for the Action No 2017-CZ-IA-0110 entitled "Deployment of Cross Border Services in the Czech Republic - NIX-ZD.CZ II. (ePrescription/eDispensation)" with the Innovation and Networks Executive Agency (hereinafter referred to as "the grant agreement")

hereby mandate:

Vysočina Region (Kraj Vysočina)

-

Registration No N/A

Žižkova 57

58733 Jihlava

Czech Republic

VAT No N/A,

represented by Jiri Behounek, President of Vysočina Region (hereinafter referred to as "the coordinator")

1. to sign in my name and on my behalf the grant agreement and its possible subsequent amendments with the Innovation and Networks Executive Agency,

and

2. to act on behalf of the beneficiary in compliance with the grant agreement.

I hereby confirm that the beneficiary accepts all terms and conditions of the grant agreement and, in particular, all provisions affecting the coordinator and the other beneficiaries. In particular, I acknowledge that, by virtue of this mandate, the coordinator alone is entitled to receive funds from the Innovation and Networks Executive Agency and distribute the

amounts corresponding to the beneficiary's participation in the action.

I hereby accept that the beneficiary will do everything in its power to help the coordinator fulfil its obligations under the grant agreement, and in particular, to provide to the coordinator, on its request, whatever documents or information may be required.

I hereby declare that the beneficiary agrees that the provisions of the grant agreement, including this mandate, shall take precedence over any other agreement between the beneficiary and the coordinator which may have an effect on the implementation of the grant agreement.

This mandate shall be annexed to the grant agreement and shall form an integral part thereof.

SIGNATURE

Irena Storova, Director of State Institute for Drug Control

Done at Prague, on

In duplicate in English

ANNEX V

MODEL TECHNICAL REPORT(S)

The templates for technical report(s) as referred to in Article II.23 are those provided by the Agency, and are available on the Agency website at the following link:

<http://ec.europa.eu/inea/en/connecting-europe-facility/cef-telecom/beneficiaries-info-point>

ANNEX VI

MODEL FINANCIAL STATEMENT(S)

The templates for financial statements as referred to in Article II.23 are those provided by the Agency, and are available on the Agency website at the following link:

<http://ec.europa.eu/inea/en/connecting-europe-facility/cef-telecom/beneficiaries-info-point>

ANNEX VII

MODEL TERMS OF REFERENCE FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

The model terms of reference for the certificate on the financial statements as referred to in Article II.23 are those provided by the Agency, and are available on the Agency website at the following link:

<http://ec.europa.eu/inea/en/connecting-europe-facility/cef-telecom/beneficiaries-info-point>

The model terms of reference for the certificate on the financial statements include templates for:

- the Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Connecting Europe Facility (CEF), and
- the independent report of factual findings on costs declared under a grant agreement financed under the Connecting Europe Facility (CEF), including its annex.