

Work Package 1 - Project Management and Coordination

Milestone 2 – Consortium Agreement

Document Information

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Project Information

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Coordinator:	Istituto Superiore di Sanità (Italy)

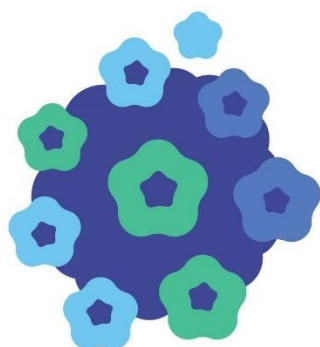


PERCH
PartnERship to
Contrast HPV



Co-funded by
the European Union

Consortium Agreement



PERCH
PartnERship to
Contrast HPV

PERCH



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CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (Text with EEA relevance) (hereinafter referred to as the "Regulation") and on the European Commission's General Model Grant Agreement and its Annexes, and is made on November 1st, 2022 hereinafter referred to as the Effective Date.

BETWEEN:

ISTITUTO SUPERIORE DI SANITA (ISS), PIC 999978821, established in VIALE REGINA ELENA, 299, 00161 ROMA, ITALY, the Coordinator,

SCIENSANO (SCI), PIC 906160809, established in JULIETTE WYTSMANSTRAAT 14, ELSENE 1050, BELGIUM,

HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH), PIC 998128255, established in ROCKEFELLEROVA 7, ZAGREB 10000, CROATIA,

USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY (UZIS), PIC 920415929, established in PALACKEHO NAMESTI 4, PRAHA 12801, CZECHIA,

TERVISE ARENGU INSTITUUT (TAI), PIC 997543539, established in Hiiu 42, TALLINN 11619, ESTONIA,

INSTITUT NATIONAL DU CANCER GIP (INCA), PIC 999953892, established in AVENUE ANDRE MORIZET 52, BOULOGNE BILLANCOURT 92513, FRANCE,

BUNDESZENTRALE FÜR GESUNDHEITLICHE AUFKLÄRUNG (BZgA), PIC 998190723, established in MAARWEG 149-161, KÖLN 50825, GERMANY,

1ST YGEIONOMIKI PERIFEREIA DYPE ATTIKIS (1ST YPE), PIC 998963910, established in ODOSS ZACHAROF 3, ATHINA 11521, GREECE,

NEMZETI NEPEGESZSEGUGYI KOZPONT (NNK), PIC 998706957, established in ALBERT FLORIAN UT 2-6, BUDAPEST 1097, HUNGARY,

NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS (NVSC), PIC 918030796, established in KALVARIJU 153, VILNIUS LT-08221, LITHUANIA,

FOLKEHELSEINSTITUTTET (NIPH), PIC 999478883, established in LOVISENBERGGATA 8, OSLO 0456, NORWAY,



NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PZH – PANSTWOWY INSTYTUT BADAWCZY (NIZP-PZH), PIC 998403735, established in CHOCIMSKA 24, WARSZAWA 00791, POLAND,

INSTITUTUL NATIONAL DE SANATATE PUBLICA (INSP), PIC 985926237, established in STR DR LEONTE 1-3 SECTOR 5, BUCURESTI 050463, ROMANIA,

MINISTERSTVO ZDRAVOTNICTVA SLOVENSKEJ REPUBLIKY (SK MoH), PIC 999825173, established in LIMBOVA 2, BRATISLAVA 83752, SLOVAKIA,

ONKOLOSKI INSTITUT LJUBLJANA (IOL), PIC 986222475, established in ZALOSKA CESTA 2, LJUBLJANA 1000, SLOVENIA,

INSTITUT CATALA D'ONCOLOGIA (ICO), PIC 998420031, established in AV GRAN VIA DE L'HOSPITALET 199-203, L'HOSPITALET DEL LLOBREGAT 08908, SPAIN,

FOLKHALSOMYNDIGHETEN (FOHM), PIC 949789954, established in NOBELS VAG 18, SOLNA 171 82, SWEDEN,

hereinafter, jointly or individually, referred to as "Beneficiaries " or "Beneficiary" having signed the Grant Agreement N. 101075314

HEALTH SERVICE EXECUTIVE HSE (HSE), PIC 993521919, LIMETREE AVENUE 2ND FLO OAK HOUSE, NAAS, IRELAND

ANDREAS SYGGROS HOSPITAL FOR SKIN AND VENEREAL DISEASES (ASH), PIC 885049632, 5, I. DRAGOUMI KESARIANI, ATHENS, GREECE

ALEXANDRA GENERAL HOSPITAL (AH), PIC 885014227, VASIL. SOFIAS 80, PC 11528, ATHENS, GREECE.

hereinafter, jointly or individually, referred to as "Associated Partners" or "Associated Partner",

hereinafter Beneficiaries and Associated Partners, jointly or individually, referred to as "Parties" or "Party"

relating to the action entitled "PartnERship to Contrast HPV" in short PERCH hereinafter referred to as the "Action"

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WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Action to the European Health and Digital Executive Agency (HaDEA), as part of EU4Health.

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement to be signed by the Beneficiaries and the European Health and Digital Executive Agency (hereinafter “Grant Agreement”).

The Parties are aware that this Consortium Agreement is based upon the DESCA model consortium agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Grant Agreement including its Annexes.

1.2 Additional Definitions

“Consortium Agreement” or “CA”

Consortium Agreement or CA means this body text, its exhibit and its possible further amendments.

“Coordinator”

Coordinator means the Istituto Superiore di Sanità (“ISS”).

“Executive Agency” or “HaDEA”

Executive Agency or HaDEA means the European Health and Digital Executive Agency, acting under powers delegated by the European Commission (the “EC”) and is the body that awards the grant for the action.

“Consortium Body”

Consortium Body means any management body described in Section 6 (Governance Structure) of this Consortium Agreement.

“Consortium Plan”

Consortium Plan means the description of the Action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the General Assembly (GA).



“Competent authority”

Competent authority means the central authority nominated by the Member State which has signed the Grant Agreement as Beneficiary of EU Funding

“Affiliated entities”

Affiliated entities means Entities that have a distinct legal personality, that are indicated in the Grant Agreement or its Annexes

“Third Parties”

Third Parties can be defined as any entity/person who is not in a PERCH Consortium Body, i.e. that is not a Beneficiary, Affiliated Entity or Associated Partner, and is not bound by rules of confidentiality under United4Surveillance. These rules are e.g., stipulated in the Grant Agreement, Consortium Agreement, collaboration agreements and confidentiality agreements. Subcontractors are included in this definition.

“Defaulting Party”

Defaulting Party means a Party which the General Assembly has declared to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.3 of this Consortium Agreement.

“Data”

Data means the data which is either owned/stored by a Party before the commencement of the Action or collected/generated by a Party during the Action which may be transferred between the Parties for the performance of the Action.

“Background”

Background means any and all, data, information, know-how IPRs that is/are:

1. owned or controlled by a Party prior to the Effective Date; or
2. developed or acquired by a Party independently from the work in the Action even if in parallel with the performance of the Action, but solely to the extent that such data, information, know-how and/or IPRs are introduced into the Action by the owning Party.

Background used within the scope of the Action is defined in Attachment 1.

“Results”

Results means the results, including information, material, knowledge, generated within the Action, whether or not they can be protected. It includes IPRs, similar forms of protections and unprotected know-how. Results generated outside the Action (i.e. before, after or in parallel with the Action) do not constitute Results.

“Intellectual Property Rights” or “IPR(s)”

Intellectual Property Rights or IPR(s) means patents, patent applications and other statutory rights in inventions; copyrights (including without limitation copyrights in Software); registered design rights, applications for registered design rights, unregistered design rights and other statutory rights in designs; and other similar or equivalent forms of statutory protection, wherever in the world arising or available, but excluding rights in Confidential Information and/or trade secrets.



“Access Rights”

Access Rights means rights to use Results or Background under the terms and conditions laid down in this Consortium Agreement and as completed by any separate agreement signed between the concerned Parties.

“Exploitation”

Exploitation jointly refers to the use of the Results and/or Background (either directly or indirectly, in particular through transfer or licensing) by:

- (a) using them in further internal research and academic and educational activities (outside the Action);
- (b) developing, creating or marketing a product or process;
- (c) creating and providing a service; or
- (d) using them in standardization activities.

“Needed”

means:

For the implementation of the Action:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

For Exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

“Software”

Software means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

2 Purpose

The purpose of this Consortium Agreement is to specify with respect to the Action the relationship among the Parties, in particular concerning the organization of the work between the Parties, the management of the Action and the rights and obligations of the Parties concerning inter alia liability, Access Rights and dispute resolution.

3 Entry into force, duration and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative.



This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

A new entity becomes a Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and the Coordinator in accordance with the decision of the Steering Committee (SC). Such accession shall have effect from the date identified in the accession document.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.

If

- the Grant Agreement is not signed by the Executive Agency or a Beneficiary, or
- the Grant Agreement is terminated, or
- a Beneficiary's participation in the Grant Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

If an Associated Partner's participation in the Project is terminated, its participation in this Consortium Agreement may be terminated subject to the provisions surviving the expiration or termination under this Consortium Agreement (Section 4.2 and Section 3.3).

3.3 Survival of rights and obligations

The provisions relating to Access Rights, Dissemination and Non-disclosure of information, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Action incurred prior to the date of termination, unless otherwise agreed between the General Assembly and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.



4 Responsibilities of Parties

4.1 General principles

Each Party undertakes to take part in the efficient implementation of the Action, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

Each Party shall forward to the Coordinator all data and information for the technical and financial reports within the deadlines set by the Coordinator by continuous email.

Each Party undertakes to notify promptly, in accordance with the governance structure of the Action, any significant information, fact, problem or delay likely to affect the Action.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks and shall responsibly manage the access of its employees to the EU Funding & Tenders Portal.

Each Party shall take reasonable measures to ensure the accuracy of any information it supplies to the other Parties.

4.2 Specific responsibilities for Associated Partner(s)

For the avoidance of doubt, the Associated Partner(s) do(es) not sign the Grant Agreement and do(es) not receive funding from the Executive Agency and therefore do(es) not have a right to charge costs or claim contributions from the Executive Agency. Associated Partner(s) must ensure its/their own funding for the implementation of the Action. However, certain terms and conditions of the Grant Agreement and its Annexes are applicable to the Associated Partner(s). The Coordinator will share a copy of the signed Grant Agreement and information on any amendments with the Associated Partner(s).

The Associated Partner(s) hereby commit(s) to implement the Action tasks attributed to it/them in Annex 1 of the Grant Agreement.

In addition, the Associated Partner(s) hereby commit(s) especially to the following articles of the Grant Agreement and related regulations of Annex 5:

- Proper implementation of the action (Article 11)
- Conflicts of interest (Article 12)
- Confidentiality and security (Article 13)
- Ethics and values (Article 14)
- Visibility (Article 17.2)
- Specific rules for carrying out the action (Article 18)
- Information obligations (Article 19)



- Record-keeping (Article 20)

The Associated Partner(s) support(s) the Beneficiaries regarding their exploitation, dissemination and Open Science obligations and commit(s) to contribute to the technical and continuous reporting during and after the implementation of the Action.

Furthermore, the Associated Partner(s) hereby explicitly agree to cooperate with and grant access to bodies according to Article 25 of the Grant Agreement (the Executive Agency, the European Anti-Fraud Office (OLAF), the European Public Prosecutor's Office (EPPO), the European Court of Auditors (ECA)), so that these bodies can carry out checks, reviews, audits and investigations also towards the Associated Partner(s).

Any Associated Partner from a non EU-country undertakes to comply additionally with any other obligation arising from Art. 10.1 of the Grant Agreement.

In case of termination or being declared a Defaulting Party, an Associated Partner shall, within the limits specified in section 5.2 of this Consortium Agreement, bear any reasonable and justifiable costs occurring to the other Parties for performing this Associated Partners tasks and the costs for additional efforts necessary to implement the Action.

Moreover, an Associated Partner is obliged to indemnify the other Parties for any claim of the Executive Agency against them, caused by this Associated Partner's actions or omissions during Grant Agreement preparation, Action implementation or after Action end.

Should the Associated Partner(s) be obliged to sign a separate agreement concerning its funding for the Action, it is the responsibility of the Associated Partner to ensure such agreement is not in conflict with this Consortium Agreement.

4.3 Breach

In the event that the General Assembly identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g.: improper implementation of the Action), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the General Assembly, will give formal notice to such Party requiring that such breach will be remedied within 30 calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the General Assembly may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof, which may include termination of its participation.

In addition to contractual measures, the Executive Agency or the EC may also adopt administrative sanctions under Articles 106 and 131(4) of the Financial Regulation No 2018/1046 (i.e. exclusion from future procurement contracts, grants and expert contracts and/or financial penalties).

4.4 Involvement of Third Parties

A Party that enters into a subcontract or otherwise involves Third Parties in the Action remains responsible for carrying out its relevant part of the Action and for such Third Party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement.



Each Party has to ensure that the involvement of Third Parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

A Party that involves Third Parties (included Affiliated Entities) shall conclude a written contract with that Third Party that ensures the obligations set out in this Consortium Agreement and in the Grant Agreement or have in place a framework collaboration agreement.

4.5 Specific responsibilities regarding data protection

Where necessary, the Parties shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* and relevant national data protection law applicable to said Party) within the scope of the performance and administration of the Action and of this Consortium Agreement.

In particular, the Parties shall, where necessary:

- conclude a separate data processing, data sharing and/or joint controller agreement before any data processing or data sharing takes place.
- conclude a separate data transfer agreement before any data is transferred from one Party to another.

4.6 Compliance

Each Party shall ensure that its work on the Action complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Grant Agreement, including those governing health and safety and data protection.

5 Liability towards each other

5.1 No warranties

In respect of any information (incl. Results and Background) supplied by one Party to another under the Action, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of Third Parties.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information, and
- no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a Third Party resulting from any other Party exercising its Access Rights.



5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act or by a breach of confidentiality.

A Party's general aggregate liability towards the other Parties collectively shall be limited to once the Beneficiary's share of the total costs of the Project as identified in Annex 2 of the Grant Agreement and in case of Associated Partner to once of its total budget as indicated in Annex 1 of the Grant Agreement.

A Party's liability shall not be limited under either of the two foregoing paragraphs to the extent such damage was caused by a wilful act or gross negligence or to the extent that such limitation is not permitted by law.

5.3 Damage caused to Third Parties

Each Party shall be solely liable for any loss, damage or injury to Third Parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

5.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by force majeure.

Each Party will notify the competent Consortium Bodies of any force majeure without undue delay. If the consequences of force majeure for the Action are not overcome within six (6) weeks after such notification, the transfer of tasks - if any - shall be decided by the competent Consortium Bodies.

6 Governance structure

6.1 General structure

The organizational structure of the Consortium shall comprise the following Consortium Bodies:

- The General Assembly GA is responsible for laying out the strategic planning of the Joint Action (JA) in adherence to the Grant Agreement and Consortium Agreement.
- The Steering Committee SC is the delegate body of the GA for day-to-day scientific and technical coordination.
- The Scientific Advisory Board (SAB) is an advisory body responsible for strengthening the scientific quality of the work and optimal policy relevance.



- Governmental Advisory Board (GAB) is an advisory body responsible for providing feedback on key findings and policy guidance on the progress and achievements of the JA by contributing to the development of an integration and sustainability plan.

The Coordinator is the legal entity acting as the intermediary between the Parties and the Executive Agency. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.

6.2 General operational procedures for all Consortium Bodies

6.2.1 Preparation and organization of meetings

6.2.1.1 Convening meetings

The Coordinator shall convene meetings of that Consortium Body.

	Ordinary meeting	Extraordinary meeting
General Assembly	Annually unless a need for an additional face-to-face meeting arises.	At any time upon written request of the SC.
Steering Committee	Monthly virtual meeting (last Wednesday of each month); face-to-face meeting (twice a year).	At any time upon written request of the SC.
Scientific Advisory Board	SAB members will meet (face-to-face) SC members during the General Assemblies and possibly in specific meetings both virtual or face to face.	At any time upon written request of the SC or the SAB.
Governmental Advisory Board	GAB members will meet (virtually or face-to-face) with SC members approximately three times during the JA period.	At any time upon written request of the SC or GAB.

6.2.1.2 Notice of a meeting:

The Coordinator shall give notice in writing of a meeting to each Member of that Consortium Body as soon as possible and no later than the minimum number of days preceding the meeting as indicated below.



	Ordinary meeting	Extraordinary meeting
General Assembly	30 calendar days	15 calendar days
Steering Committee	30 calendar days	15 calendar days
Scientific Advisory Board	30 calendar days	15 calendar days
Governmental Advisory Board	30 calendar days	15 calendar days

6.2.1.3 Sending the agenda:

The Coordinator shall prepare and send each Member of that Consortium Body a written (original) agenda no later than the minimum number of days preceding the meeting as indicated below.

General Assembly	The Coordinator will prepare in writing the agenda of the meetings and send it to each GA member at least fifteen (15) days before meetings, with all relevant background information and supporting documents to any decision proposed to be taken (15 calendar days for an extraordinary meeting).
Steering Committee	The Coordinator will prepare in writing the agenda of the meetings and send it to each SC member at least (7) days before meetings, with all relevant background information and supporting documents to any decision proposed to be taken (15 calendar days for an extraordinary meeting).
Scientific Advisory Board	The Coordinator will prepare in writing the agenda of the meetings and send it to each SAB member at least fifteen (15) days before meetings, with all relevant background information and supporting documents to any decision proposed to be taken (15 calendar days for an extraordinary meeting).
Governmental Advisory Board	The Coordinator together with the SC will prepare in writing the agenda of the meetings and send it to each GAB member at least fifteen (15) days before meetings, with all relevant background information and supporting documents to any decision proposed to be taken (15 calendar days for an extraordinary meeting).



6.2.1.4 Adding agenda items:

Any agenda item requiring a decision by the Members of a Consortium Body must be identified as such on the agenda.

Any Member of a Consortium Body may add an item to the original agenda by written notification to all of the other Members of that Consortium Body up to the minimum number of days preceding the meeting as indicated below.

General Assembly	10 calendar days, 10 calendar days for an extraordinary meeting
Steering Committee	Any time before the SC both for ordinary and extraordinary
Scientific Advisory Board	10 calendar days, 10 calendar days for an extraordinary meeting
Governmental Advisory Board	10 calendar days, 10 calendar days for an extraordinary meeting

6.2.1.5 During a meeting the Members of a Consortium Body present or represented can unanimously agree to add a new item to the original agenda.

6.2.1.6 Meetings of each Consortium Body may also be held by teleconference or other telecommunication means.

6.2.1.7 Decisions will only be binding once the relevant part of the Minutes has been accepted according to Section 6.2.4.

6.2.1.8 Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Consortium Body a written document, which is then agreed by the defined majority (see Section 6.2.3.) of all Members of the Consortium Body. Such document shall include the deadline for responses.

Decisions taken without a meeting shall be considered as accepted if, within the period set out in article 6.2.3.4, no Member has sent an objection in writing to the chairperson.

The decisions will be binding after the chairperson sends to all Members of the Consortium Body and to the Coordinator a written notification of this acceptance.

6.2.2 Voting rules and quorum

6.2.2.1 Each Beneficiary shall not deliberate and decide validly unless the majority of its are present or represented (quorum).

If the quorum is not reached, the coordinator shall convene another ordinary meeting within fifteen (15) calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented.

6.2.2.2 Each Beneficiary present or represented in the meeting shall have one vote.

6.2.2.3 A Party which the GA has declared according to Section 4.2 to be a Defaulting Parties may not vote.



6.2.2.4 Decisions shall be taken by a majority of the votes cast, with the exception of the following decisions, which shall require a unanimous vote:

- entry of a new Party and approval of the settlement on the conditions of the accession of such a new Party;
- declaration of a Party to be a Defaulting Part;
- termination of a Defaulting Party's participation in the consortium and measures relating thereto;
- proposal to the Executive Agency for a change of the Coordinator;
- proposal to the Executive Agency for suspension of all or part of the Action;
- proposal to the Executive Agency for termination of the Action and the Consortium Agreement.

6.2.3 Veto rights

6.2.3.1 A Member which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of a Consortium Body may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.2.3.2 When the decision is foreseen on the original agenda, a Member may veto such a decision during the meeting only.

6.2.3.3 When a decision has been taken on a new item added to the agenda before or during the meeting, a Member may veto such decision during the meeting and within fifteen (15) calendar days after the draft minutes of the meeting are sent. A party that is not a Member of a particular Consortium Body may veto a decision within the same number of calendar days after the draft minutes of the meeting are sent.

6.2.3.4 When a decision has been taken without a meeting, a Member may veto such decision within fifteen (15) calendar days after written notification by the chairperson of the outcome of the vote.

6.2.3.5 In case of exercise of veto, the Members of the related Consortium Body shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all its Members.

6.2.3.6 A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the Action or the consequences of them.

6.2.3.7 A Party requesting to leave the Action may not veto decisions relating thereto.



6.2.4 Minutes of meetings

6.2.4.1 The Coordinator shall produce minutes of each SC which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within thirty (30) calendar days of the meeting.

The WP2-leader (Dissemination) along with Coordinator shall produce written minutes of each GA, SAB and GAB meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within thirty (30) calendar days of the meeting.

6.2.4.2 The minutes shall be considered as accepted if, within ten (10) calendar days from sending, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.

6.2.4.3 The Coordinator shall send the accepted minutes of each GA, SAB meeting, GAB meeting to all the Members of the Consortium Body, who shall safeguard them. If requested, the Coordinator shall provide authenticated duplicates to Parties.

6.3 Specific operational procedures for the Consortium Bodies

6.3.1 General Assembly

In addition to the rules described in Section 6.2, the following rules apply:

6.3.1.1 Members

6.3.1.1.1 The GA shall consist at least of one representative per each Party (hereinafter GA) and it is chaired by the Coordinator.

6.3.1.1.2 Each GA member shall be deemed to be duly authorized to deliberate, negotiate and decide on all matters listed in Section 6.3.1.2. of this Consortium Agreement.

6.3.1.1.3 The Coordinator shall chair all meetings of the GA, unless decided otherwise in a meeting of the GA.

6.3.1.1.4 The Parties agree to abide by all decisions of the GA. This does not prevent the Parties to submit a dispute to resolution in accordance with the provisions of Settlement of disputes in Section 11.8.

6.3.1.2 Decisions

The GA shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein. In addition, all proposals made by the SC shall also be considered and decided upon by the GA.



The following decisions shall be taken by the GA:

- Take decisions as to the implementation of the Action and its deliverables, as proposed by the SC;
- Decide on the overall development of the project based on input from the Coordinator and the SC;
- Monitor and review the progress of the Action;
- Take the necessary actions and corrective measures in case of default of a partner.
- Proposals for changes to Annex 1 and 2 of the Grant Agreement to be agreed by the SC.
- Changes to the Consortium Plan.
- Modifications to Attachment 1 (Background Included).

Evolution of the Consortium Agreement

- Entry of a new Party to the Consortium Agreement and approval of the settlement on the conditions of the accession of such a new Party.
- Withdrawal of a Party from the Consortium Agreement and the approval of the settlement on the conditions of the withdrawal.
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement.
- Proposal to the Executive Agency for a change of the Coordinator.
- Proposal to the Executive Agency for suspension of all or part of the Action.
- Proposal to the Executive Agency for termination of the Action and the Consortium Agreement.

In the event of a tie, the decision by the Coordinator will prevail.

6.3.2 Steering Committee

In addition to the rules in Section 6.2, the following rules shall apply:

6.3.2.1 Members

The SC shall consist of the Coordinator and the Work-Package Leaders. It is chaired by the Coordinator.

Delegates of the EC DG SANTE and the Executive Agency may participate in GA meetings but will have no voting right.

The Coordinator shall chair all meetings of the SC, unless decided otherwise by a majority of two-thirds.

6.3.2.2 Minutes of meetings

Minutes of SC, will be done by the Coordinator and included in the Microsoft Team platform.

6.3.2.3 Tasks

The SC is the main executive body of the Action. It is the delegate body of the GA for day-to-day scientific and technical coordination.



6.3.2.3.1 The SC shall be responsible for the proper execution and implementation of the decisions of the GA.

6.3.2.3.2 In addition, the SC shall check the progress of the Action (Deliverables and Milestones), at least each month.

6.3.2.3.3 The SC shall:

- monitor and review the Action's progress;
- prioritize the projects objectives and outcomes;
- prepare draft decisions to be considered by the GA;
- formulate risk management strategies and ensure that risks are regularly reassessed;
- propose re-allocation of budget whenever changes need to be done;
- help the Coordinator resolve potential conflicts and disputes;
- prepare the content and timing of press releases and joint publications by the Action or proposed by the Executive Agency.

6.4 Scientific Advisory Board

The SAB consists of at least five international and multidisciplinary experts in the field of HPV prevention of HPV related disease in general and HPV vaccination in general. It is an advisory body responsible for strengthening the scientific quality of the work and optimal policy relevance.

6.5 Governmental Advisory Board

The GAB consists of representative from each participating country; It is an advisory body responsible for providing feedback on key findings and policy guidance on the progress and achievements of the JA by contributing to the development of an integration and sustainability plan.

6.6 Coordinator

6.6.1

The Coordinator shall be the intermediary between the Parties and the Executive Agency and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

6.6.2

In particular, the Coordinator shall be responsible for:

- the management and the achievement of the objectives of the Action (ensures timely delivery of the project deliverables);
- monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement;



- keeping the address list of Members and other contact persons updated and available;
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Executive Agency in accordance to the Grant Agreement and this Consortium Agreement;
- transmitting documents and information connected with the Action to any other Parties concerned (informs of the requirements from the EC; informs of any events that may delay WP implementation);
- administering the financial contribution of the Executive Agency and fulfilling the financial tasks described in Section 7.3;
- requesting and reviewing any documents or information required by the Executive Agency and verify their completeness and correctness before passing them on to the Executive Agency;
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.
- The Coordinator also acts as a mediator in case of conflicts or disagreement between partners.

If one or more of the Parties is late in submission of any Action deliverable, the Coordinator may nevertheless submit the other Parties' Action deliverables and all other documents required by the Grant Agreement to the Executive Agency in time.

6.6.3

If the Coordinator fails in its coordination tasks, the GA may propose to the Funding Authority to change the Coordinator.

Upon decision of the GA in accordance with Article 6.3.1, the Coordinator may be entitled to negotiate and sign in the names and on behalf of the Parties any confidentiality agreement necessary to disclose information of the Parties related to the Action to a Third Party for the purposes of assessing the potential involvement of such Third Party in the Action. The terms and conditions of such confidentiality agreement shall not be less stringent than the provisions of article 10 of the Consortium Agreement. It is understood between the Parties that the effective decision of the entry of a new Party in the consortium remain to the GA.

6.6.4

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the Action, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

6.6.5

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.



7 Financial provisions

7.1 General Principles

7.1.1 Distribution of financial contribution

The financial contribution of the Executive Agency to the Action shall be distributed by the Coordinator according to:

- the Grant Agreement;
- the approval of reports by the Executive Agency;
- the provision of payments in Point 4.1, 4.2 (Data Sheet) and Article 21,22 of the Grant Agreement.

A Beneficiary shall be funded only for its tasks carried out in accordance with the Annex 1 of the Grant Agreement.

7.1.2 Justifying Costs and Reporting

In accordance with its own usual accounting and management principles and practices, each Beneficiary shall be solely responsible for justifying its costs (including the costs of Affiliated Entity, if any) with respect to the action towards the Executive Agency. Neither the Coordinator nor any of the other Beneficiaries shall be in any way liable or responsible for such justification of costs towards the Executive Agency.

Beneficiaries and their identified Affiliated Entities will prepare and submit to the Coordinator individual financial statements for each reporting period. The Coordinator will then submit these individual financial statements to the Executive Agency within periodic report(s) set out on Article 21 of the Grant Agreement.

Each Beneficiary is responsible for its (and its Affiliated Entities if any) financial reporting via the Participant Portal for the reporting periods. Beneficiaries herein agree that the information provided in their financial reports is full, reliable and true.

Each Beneficiary shall keep all original documents relating to expenditure on the action for up to five years after the payment of the balance in the event of audits and evaluation checks in accordance to the Article 20 of the Grant Agreement.

7.1.3 Funding Principles

A Beneficiary that spends less than its allocated share of the budget as set out in the Annex 2 will be funded in accordance with its actual duly justified eligible costs only.

A Beneficiary that spends more than its allocated share of the budget as set out in the Annex 2 will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.



Beneficiaries hereby agree with financial rules and principles in accordance to the Grant Agreement to determine the justified eligible costs.

7.1.4 Return of excess payments; receipts

A Beneficiary has received excess payment

- a) if the payment received from the Coordinator exceeds the amount declared or
- b) if a Beneficiary has received payments but, within the last year of the Action, its real Action costs fall significantly behind the costs it would be entitled to according to the Annex 1 of the Grant Agreement

7.1.4.1 In case a Beneficiary has received excess payment, the Beneficiary has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within 30 days upon request for return of excess payment from the Coordinator, the Beneficiary is in substantial breach of the Consortium Agreement.

7.1.5 Revenue

In case a Beneficiary earns any revenue that is deductible from the total funding as set out in the Annex 2, the deduction is only directed toward the Beneficiary earning such income. The other beneficiaries' financial share of the budget shall not be affected by one Beneficiaries' receipt. In case the relevant receipt is more than the allocated share of the Beneficiary as set out in the Annex 2, the Beneficiary shall reimburse the funding reduction suffered by other Beneficiaries.

7.1.6 Financial Consequences of the termination of the participation of a Beneficiary

A Beneficiary leaving the Consortium shall refund to the Coordinator any payments it has received except the amount of contribution accepted by the Executive Agency or another contributor. Furthermore, a Defaulting party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Beneficiaries in order to perform its and their tasks.

7.2 Payments

7.2.1 Payments to Beneficiaries are the exclusive task of the Coordinator

Payments to Beneficiaries are the exclusive task of the Coordinator. Payments from the Beneficiary to the Affiliated Entities are the sole responsibility of the Beneficiaries.

In particular, the Coordinator shall:

- notify the Beneficiary concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references;



- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts;
- undertake to keep the Executive Agency's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Article 22 of the Grant Agreement, no Beneficiary shall before the end of the Project receive more than its allocated share of the maximum grant amount less the amounts retained by the Executive Agency for the Mutual Insurance Mechanism and for the final payment.

7.2.2

The transfer of the pre-financing, and interim payments to Beneficiaries will be handled in accordance with Article 22.1. and Article 7 of the Grant Agreement following this payment schedule.

Funding of costs included in the Grant Agreement will be paid by the Coordinator to the Beneficiaries after receipt of payments from the Executive Agency without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Executive Agency will be paid to the Beneficiary concerned.

The Coordinator is entitled to withhold any payments due to a Beneficiary identified by a responsible Consortium Body to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Beneficiary which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to Beneficiary declared as a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Executive Agency. The Coordinator is equally entitled to withhold payments to a Beneficiaries when this is suggested by or agreed with the Executive Agency.

8 Background and Results

8.1 Ownership of Results generated within PERCH

Results generated within PERCH are owned by the Party, including its Affiliated Entity that generates them.

8.2 Joint ownership

Joint ownership is governed by Grant Agreement Article 16.4 and its Annex 5, Section Ownership of results, with the following additions.

In case of joint ownership, the joint owners shall make their best efforts to establish a joint-ownership agreement regarding the allocation and terms of exercising such joint ownership as soon as possible and within a maximum of six (6) months as from the date on which the respective Results have been generated.

Unless otherwise agreed in the joint ownership agreement:



- each of the joint owners shall always be entitled to use their jointly owned Results for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s).
- each of the joint owners shall be entitled to otherwise Exploit the jointly owned Results and to grant non-exclusive licenses to third parties (without any right to sub-license), if the other joint owners are given: (a) at least 45 calendar days advance notice; and (b) fair and reasonable compensation.
- The joint owners shall agree on all protection measures and the division of related cost in advance.

The Parties, including their Affiliated Entities, must indicate the owner(s) of the Results (Results ownership list) in the final periodic report.

8.3 Exploitation of Results

As per Annex 5 of the Grant Agreement, all Parties, including their Affiliated Entities, which have received funding under the grant, must — up to four years after the end of the action — use their best efforts to exploit their Results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing.

If, despite a Party's best efforts, the Results are not exploited within one year after the end of the action, each Party must (unless otherwise agreed in writing with the Executive Agency) use the EU4 HEALTH Platform to find interested parties to exploit the Results.

If Results are incorporated in a standard, the Parties, including their Affiliated Entities, must (unless otherwise agreed with the Executive Agency or unless it is impossible) ask the standardization body to include the funding statement (see Article 17 of the Grant Agreement) in (information related to) the standard.

8.4 Transfer of Results

8.4.1 Transferring ownership

Each Party, including its Affiliated Entities, may transfer ownership of its own Results, including its share in jointly owned Results, following the procedures of the Grant Agreement Article 16.4 and its Annex 5, Section Transfer and licensing of results, sub-section "Transfer of ownership".

The Parties, including their Affiliated Entities, must ensure that obligations under the Consortium Agreement regarding their Results are passed on to the new owner and that this new owner has the obligation to pass them on in any subsequent transfer.

8.4.2 Informing of the transfer

The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties under the Consortium Agreement and the Grant Agreement will not be affected by such transfer.

The other Parties, including their Affiliated Entities, may object within 30 calendar days of receiving notification (or less if agreed in writing), if they can show that the transfer would



adversely affect their Access Rights. In this case, the transfer may not take place until agreement has been reached between the Parties concerned.

8.4.3 Granting licenses

The Parties, including their Affiliated Entities, may grant licenses to their own Results (or otherwise give the right to exploit them), including on an exclusive basis, provided this does not affect compliance with their obligations.

Exclusive licences for Results may be granted only if all the other Parties concerned have waived their Access Rights.

8.4.4 Specific cases of mergers or acquisitions

The Parties recognise that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give at least 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement.

8.4.5 Application of the obligations

The obligations above apply only for as long as other Parties, including their Affiliated Entities, still have - or still may request - Access Rights to the Results.

8.5 Dissemination

For the avoidance of doubt, the confidentiality obligations set out in Section 10 apply to all dissemination activities described in this Section 8.5 as far as Confidential Information is involved.

8.5.1 Dissemination of own (including jointly owned) Results

Dissemination

During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties, including their Affiliated Entities, referring but not restricted to publications and presentations, shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section Dissemination, subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties, including their Affiliated Entities, at least 21 calendar days before the publication, together with sufficient information on the Results it will disseminate.

Any objection to the planned publication shall be made in accordance with the Grant Agreement by written notice to the Coordinator and to the Party(ies), including its/their Affiliated Entities, proposing the dissemination within 15 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.



Objections to dissemination

An objection is justified if:

- a) the protection of the objecting Party's, including its Affiliated Entities, Results or Background would be adversely affected, or
- b) the objecting Party's, including its Affiliated Entities, legitimate interests in relation to its Results or Background would be significantly harmed, or
- c) the proposed publication includes Confidential Information of the objecting Party, including its Affiliated Entities.

The objection has to include a precise request for necessary modifications.

If an objection has been raised, the involved Parties, including their Affiliated Entities, shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party, including its Affiliated Entities, shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

Acknowledgment of EU support

Unless otherwise agreed with the executive agency, communication activities of the Parties, including their Affiliated Entities, related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded by the grant must acknowledge EU support and display the European flag (emblem) and funding statement. The emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands or text.

Any communication or dissemination activity related to the action must use factually accurate information. Moreover, it must indicate the following disclaimer (translated into local languages where appropriate): "Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the executive agency]. Neither the European Union nor the executive agency can be held responsible for them."

Acknowledgment of further support in the case of Associated Partners

Acknowledgment of further support e.g. by national funding agencies or ministries needs to be acknowledged as laid down in the respective agreements. This applies to any communication or dissemination related to the action involving Participants receiving such support.

Moreover, it must indicate the following disclaimer: "Also funded by the [name of the additional funding organisation]. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect the official views of the [respective funding agency]."



8.5.2 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published. Parties shall ensure that this obligation is extended to their Affiliated Entities.

8.5.3 Cooperation obligations

The Parties, including their Affiliated Entities, undertake to cooperate to allow the timely submission, examination, publication and, presentation of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

8.5.4 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties, including their Affiliated Entities, or any of their logos or trademarks without their prior written approval.

9 Access Rights

9.1 Background included

9.1.1

In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

9.1.2

Any Parties, including their Affiliated Entities, may add further own Background to Attachment 1 during PERCH by written notice to the Coordinator, who will inform the GA and update Attachment 1.

However, approval of the GA is needed should a Party, including its Affiliated Entities, wish to modify or withdraw its Background in Attachment 1. For the sake of clarity, should a Background be withdrawn, unless decided otherwise by the GA, after discussion of the reasons for the withdrawal, the Access Rights related to such Background already granted shall remain. Any possibility to further Access Rights to such withdrawn Background shall not be possible to request after the withdrawal.



9.1.3

The Parties, including their Affiliated Entities, must give each other access to the Background identified as needed for implementing the action, subject to any specific rules in Annex 5 of the Grant Agreement.

If Background is subject to rights of a Third Party, the Participant concerned must ensure that it is able to comply with its obligations under the Consortium Agreement.

Background held by a Party, including its Affiliated Entities, will remain the property of that Party, regardless of the property rights claimed with respect to Results developed in PERCH, and notwithstanding the use of such Background to develop Results in PERCH.

For the sake of clarity, each Party, including its Affiliated Entities, shall list its Background related to PERCH before the start of PERCH in Attachment 1 of this Consortium Agreement, and communicate additional Background during the execution of PERCH in writing to the Coordinator for subsequent inclusion in an update of Attachment 1.

9.2 General Principles

9.2.1

Each Party, including its Affiliated Entities, shall implement its tasks in accordance with the Description of Action and Annual Work Plan and shall bear sole responsibility for ensuring that its acts within PERCH do not knowingly infringe other Parties, including their Affiliated Entities, property rights.

9.2.2

Any Access Rights granted expressly exclude any rights to sublicense to Third Parties unless expressly stated otherwise.

9.2.3

Access Rights shall be free of any administrative transfer costs.

9.2.4

Access Rights are granted on a non-exclusive basis.

9.2.5

Results and Background shall be used only for the purposes for which Access Rights to it have been granted.



9.2.6

All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place. The requesting Party, including its Affiliated Entities, must show that the Access Rights are needed.

9.2.7

Parties shall ensure in their contracts with their Affiliated Entities and other Third Parties that the obligations of the present section are extended to such entities.

9.2.8

If a Party, including its Affiliated Entities, defaults on its obligations, the General Assembly may agree that this Participant no longer has Access Rights.

9.3 Access Rights for implementation

Without prejudice to Article 9.2.6, Access Rights to Results and Background Needed for the performance of the own work of a Party, including its Affiliated Entities, under PERCH shall be granted - on a royalty-free basis - unless otherwise agreed for Background in Attachment 1.

9.4 Access Rights for Exploitation

The Parties, including their Affiliated Entities, must grant each other access — under fair and reasonable conditions — to Background and Results needed for exploiting their Results, unless the Party that holds the Background has informed the other Parties, including their Affiliated Entities, in Attachment 1 that access to its Background is subject to restrictions and unless there are specific conditions regarding the Access Rights to Results.

Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the action

Access Rights to Results for non-commercial research activities and for teaching activities shall be granted on a royalty-free basis.

9.5 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Grant Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party, including its Affiliated Entities, and subject to such terms and conditions as may be agreed between the owning and receiving Parties, including their Affiliated Entities.



9.6 Access Rights for Parties entering or leaving the consortium

9.6.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the same conditions as when applying for Access Rights to Background. New Parties will have to give Access Rights to other Parties, based on the conditions of the Consortium Agreement, and complete Attachment 1.

9.6.2 Parties leaving the consortium

9.6.2.1. Defaulting Party

Access Rights granted to a Defaulting Party and such Participant's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the GA to terminate its participation in the consortium.

9.6.2.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation. It may request Access Rights within the period of time specified in Section 9.2.10.

9.6.2.3 Access Rights to be granted by any leaving Party

Any Party leaving PERCH shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of PERCH. However, following a hearing amongst the remaining Parties, the GA may decide that such Access Rights will not be necessary.

9.7 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

Parties' Access Rights to Software do not include any right to receive Source code or Object code ported to a certain hardware platform or any right to receive respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

10 Non-disclosure of information

10.1 Confidential information

Parties, including their Affiliated Entities, shall not divulge to Third Parties any confidential information that they have received for which confidential treatment has been requested and is justified, unless legally obliged.

For the avoidance of doubt, Associated Partners acknowledge and consent to be bound by obligations under Article 13 (confidentiality and security) of the Grant Agreement, the specific



rules on confidentiality and security set out in Annex 5 and all provisions included in this section, in the same way that they apply to Beneficiaries.

All information in whatever form or mode of communication, which is disclosed by a Party, including its Affiliated Entities, (the “disclosing Party”) to any other Party, including its Affiliated Entities, (the “recipient Party”) in connection with PERCH during its implementation and which has been explicitly marked as “confidential” at the time of disclosure, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the “disclosing Party, is “confidential information”.

10.2 Confidentiality obligations

Each “recipient Party” hereby undertakes in addition and without prejudice to any commitment on non-disclosure under the Grand Agreement, for a period of 5 years after the end of PERCH:

- not to use confidential information otherwise than for the purpose for which it was disclosed;
- not to disclose confidential Information without the prior written consent by the “disclosing Party”;
- to ensure that internal distribution of confidential information by a “recipient Party” shall take place on a strict need-to-know basis; and
- to return to the “disclosing Party”, or destroy, on request all confidential information that has been disclosed to a “recipient Party” including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. Each “recipient Party” may keep a copy to the extent it is required to keep, archive or store such confidential information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for the confidentiality period agreed above (5 years after the end of PERCH).

Each “recipient Party” shall be responsible for the fulfilment of the above obligations on the part of their employees or Third Parties involved in PERCH and shall ensure that they remain so obliged, as far as legally possible, during and after the end of PERCH and/or after the termination of the contractual relationship with the employee or Third Parties.

10.3 Exceptions

The above shall not apply for disclosure or use of confidential information, if and in so far as the “recipient Parties” can show that:

- the confidential information has become or becomes publicly available by means other than a breach of the “recipient Party’s” confidentiality obligations;
- the “disclosing Party” subsequently informs the “recipient Party” that the confidential information is no longer confidential;
- the confidential information is communicated to the “recipient Party” without any obligation of confidentiality by a Third Party who is to the best knowledge of the “recipient Party” in lawful possession thereof and under no obligation of confidentiality to the “disclosing Party”;



- the disclosure or communication of the confidential information is foreseen by provisions of the Grant Agreement;
- the confidential information, at any time, was developed by the Recipient completely independently of any such disclosure by the “disclosing Party”;
- the confidential information was already known to the “recipient Participant” prior to disclosure, or
- the “recipient Party” is required to disclose the confidential information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision of Sections 10.6 and 10.7 hereunder.

10.4 Reasonable care

The “recipient Party” shall apply the same degree of care with regard to the confidential information disclosed within the scope of PERCH as with its own confidential and/or proprietary information, but in no case less than reasonable care.

10.5 Unauthorized disclosure

Each Party, including its Affiliated Entities, shall promptly advise the other “disclosing Party” in writing of any unauthorized disclosure, misappropriation or misuse of confidential information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

10.6 Notifications

If any Party, including its Affiliated Entities, becomes aware that it will be required, or is likely to be required, to disclose confidential information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure:

- notify the Coordinator,
- notify the “disclosing Party” immediately, and
- comply with the “disclosing Party’s” reasonable instructions to protect the confidentiality of the information.

10.7 Extending obligations to Affiliated Entities and other Third Parties

Parties shall ensure in their contracts with their Affiliated Entities and other Third Parties that the obligations of the present section are extended to such entities.

10.8 Confidentiality agreements

If an entity/a person which is not a PERCH Consortium Body Participant requires and is given access to PERCH confidential information, a confidentiality agreement shall be signed by the Coordinator (who represents the PERCH Consortium), and the entity/the person. It shall be



concluded before any confidential information on PERCH will be exchanged, and its terms and conditions shall be no less strict than those of this Consortium Agreement.

The Parties will be notified of such a request no later than 5 working days after its receipt and will be given a 7 working days' notice to object to the request. The Parties will be notified immediately if such a Third Party is granted access and will at the same time be given access to the Confidentiality Agreement.

This does not apply if the information has to be compulsorily disclosed.

11 Miscellaneous

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and:

- Attachment 1: (Background included)
- Attachment 2: (Accession document)
- Attachment 3: (List of Affiliated Entities)
- Attachment 4: (Non-Disclosure Agreement)

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

11.2 No representation, partnership or agency

No Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Formal and written notices and other communication

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

Any change of persons or contact details shall be notified immediately by the respective Party, or Affiliated Entity, to the Coordinator. The address list shall be accessible to all Parties, including their Affiliated

**Formal notices:**

If it is required in this Consortium Agreement (Sections 4.3, 9.2.8 and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by postal mail with recorded with acknowledgement of receipt.

Written notice:

Where written notice is required by this Consortium Agreement, this is fulfilled also by other means of communication such as e-mail with acknowledgement of receipt.

Other communication:

Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

11.4 Assignment and amendments

Except as set out in Section 8.4.5, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any Third Party without the other Parties' prior formal approval.

11.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating. In particular, any transfer of Data shall comply with the applicable mandatory statutory law, notably the provisions relating to the protection of the personal data and to medical secrecy.

11.6 Language

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

11.8 Settlement of disputes

The Parties, including their Affiliated Entities, shall endeavor to settle their disputes amicably. The Parties agree that any dispute, controversy or claim arising under, out of or relating to this Consortium Agreement and any subsequent amendments of this Consortium Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination (a "Dispute") which cannot be solved amicably, shall first be submitted by

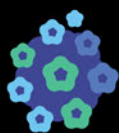


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the Parties to the Work Package Leader concerned. The Coordination Team may be involved in the conflict resolution if requested by the Work Package Leader. If the Coordinator is involved in the conflict, another Party selected jointly by the General Assembly should take over this role. All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably through the above mechanism, shall be finally settled by the courts of Brussels.



12 Signatures

The Parties have caused this Consortium Agreement to be duly signed by their authorized representatives in separate signature pages in accordance with the following signature process.

The Parties agree that facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.



PERCH

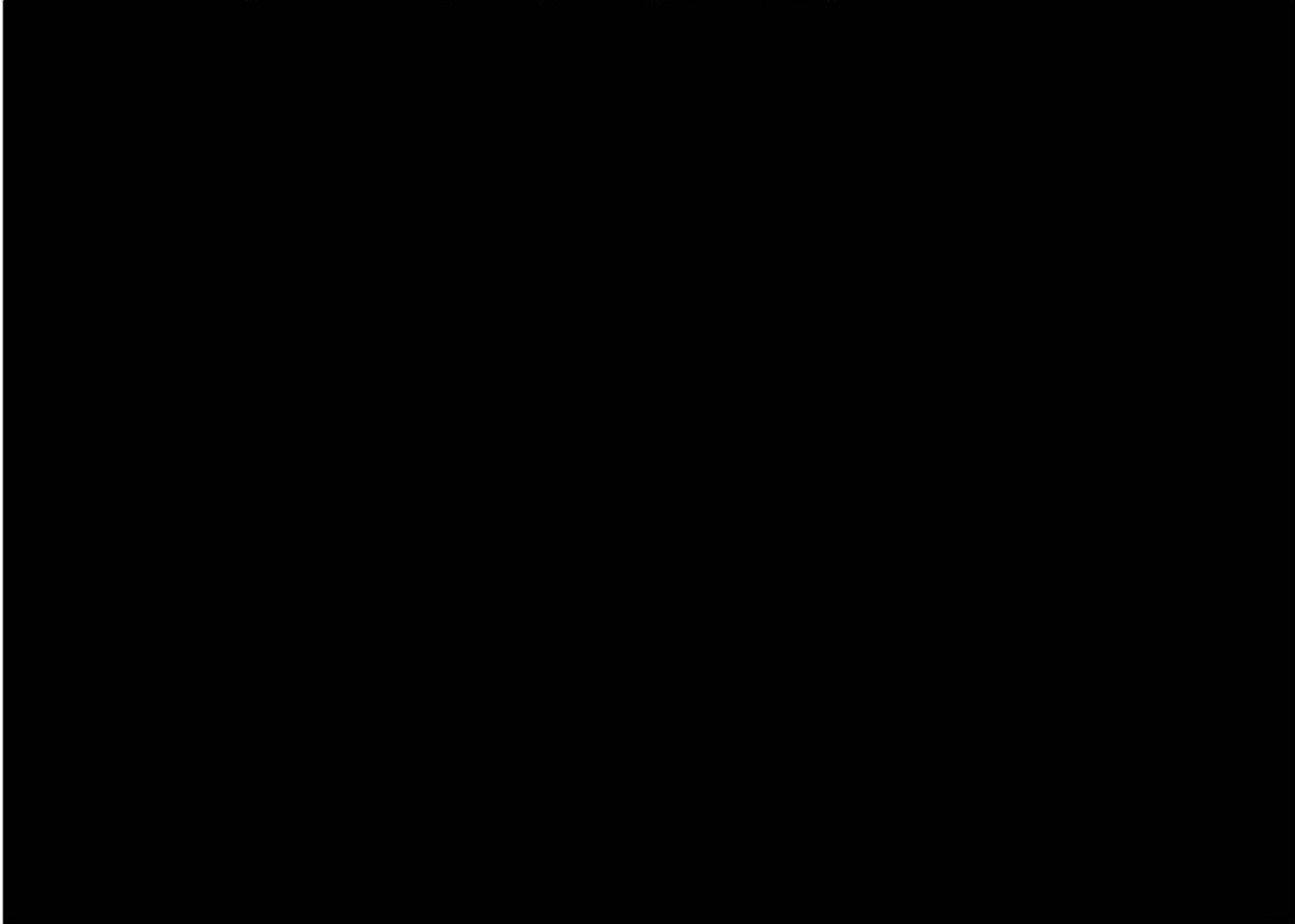
PartnERship to
Contrast HPV



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AS WITNESS:

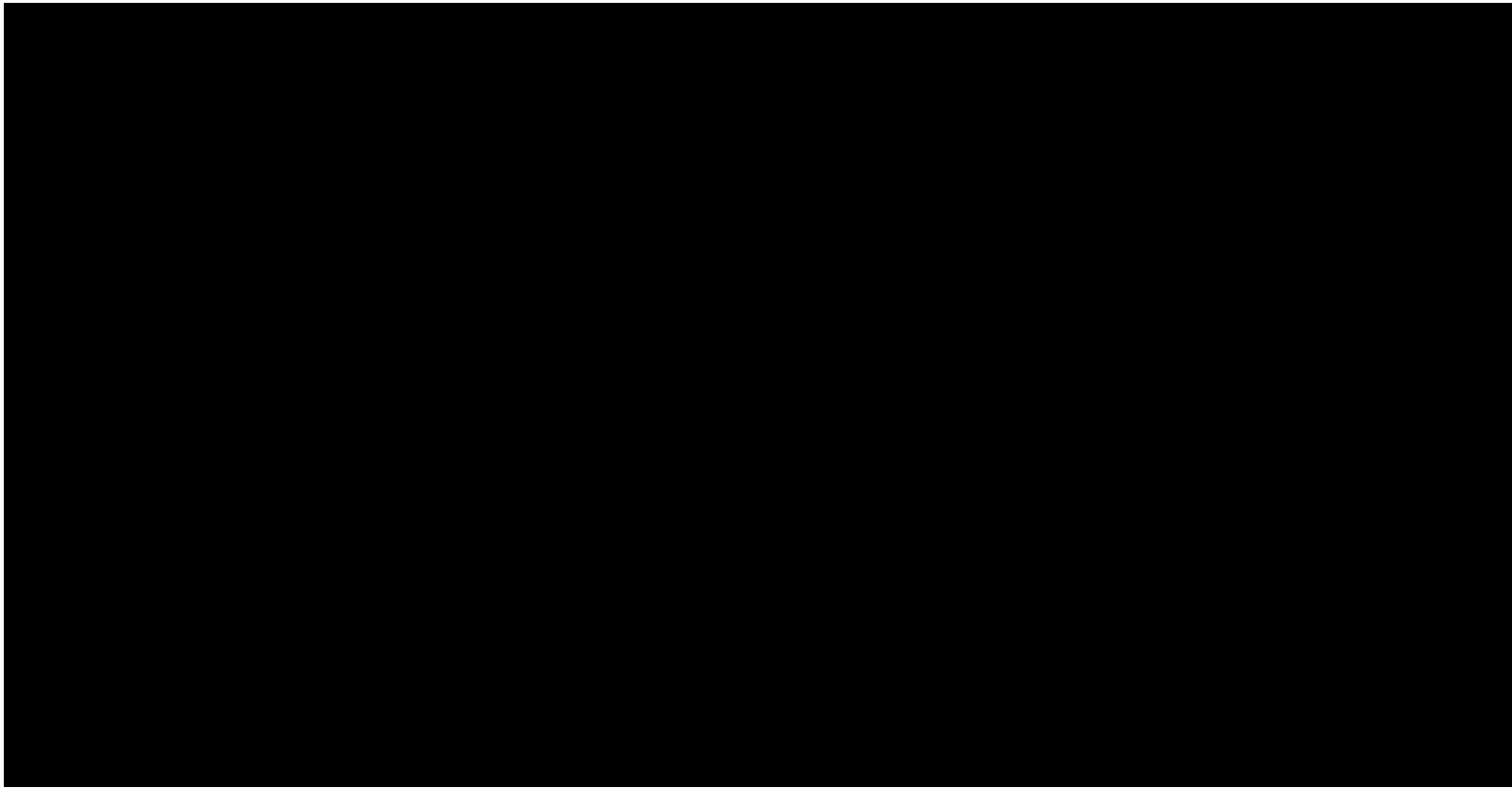
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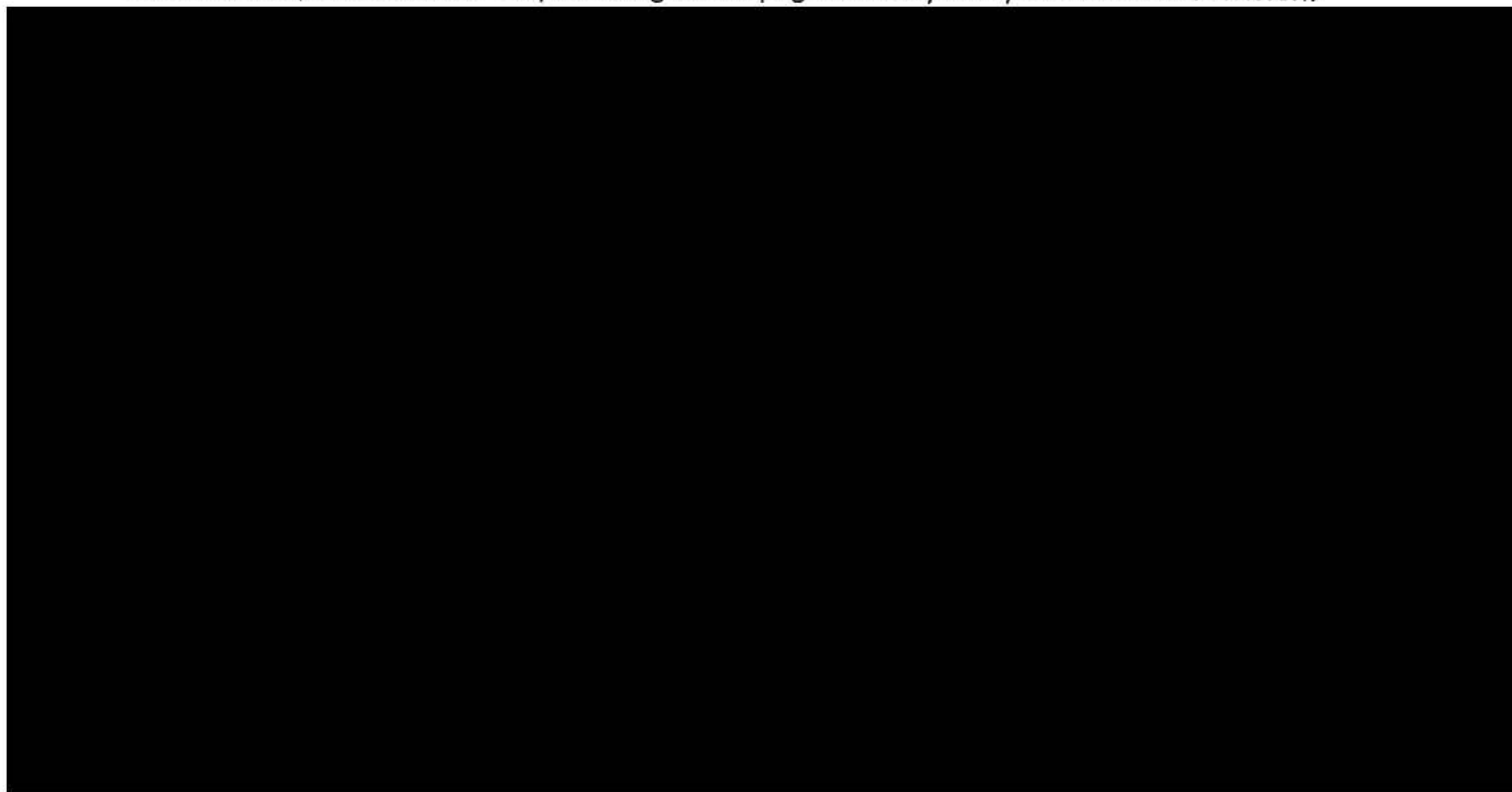
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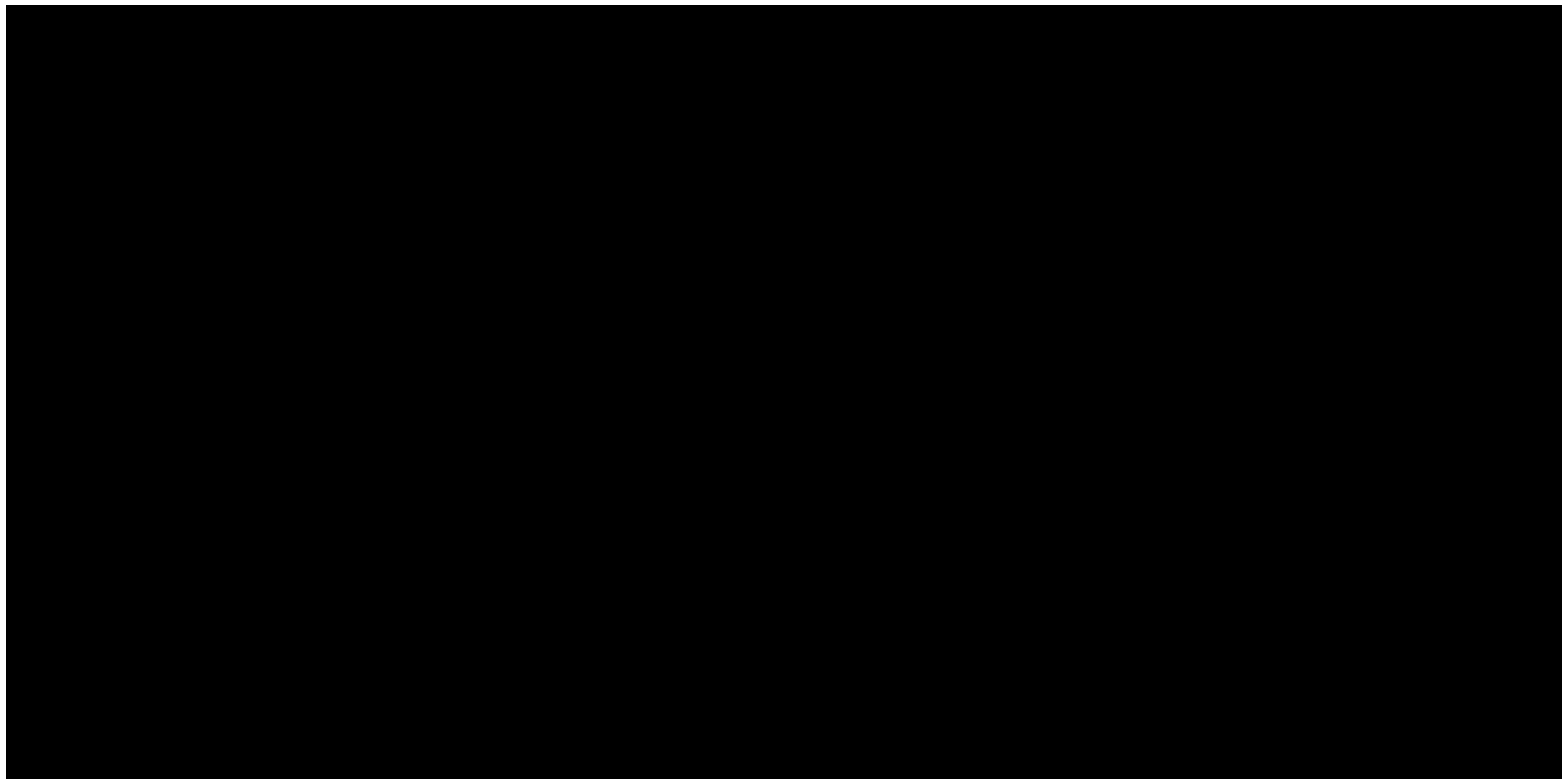
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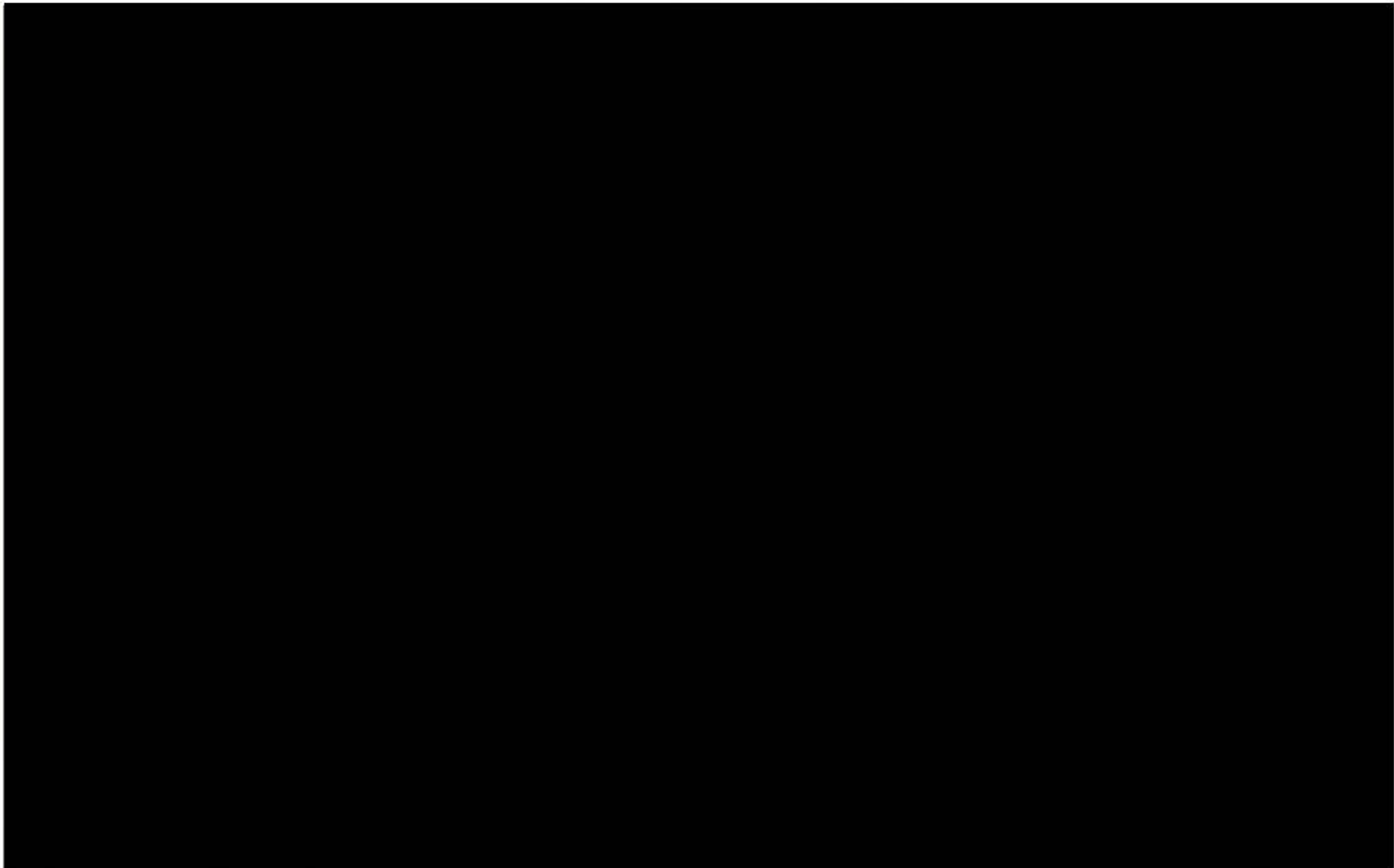
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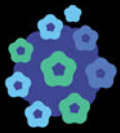




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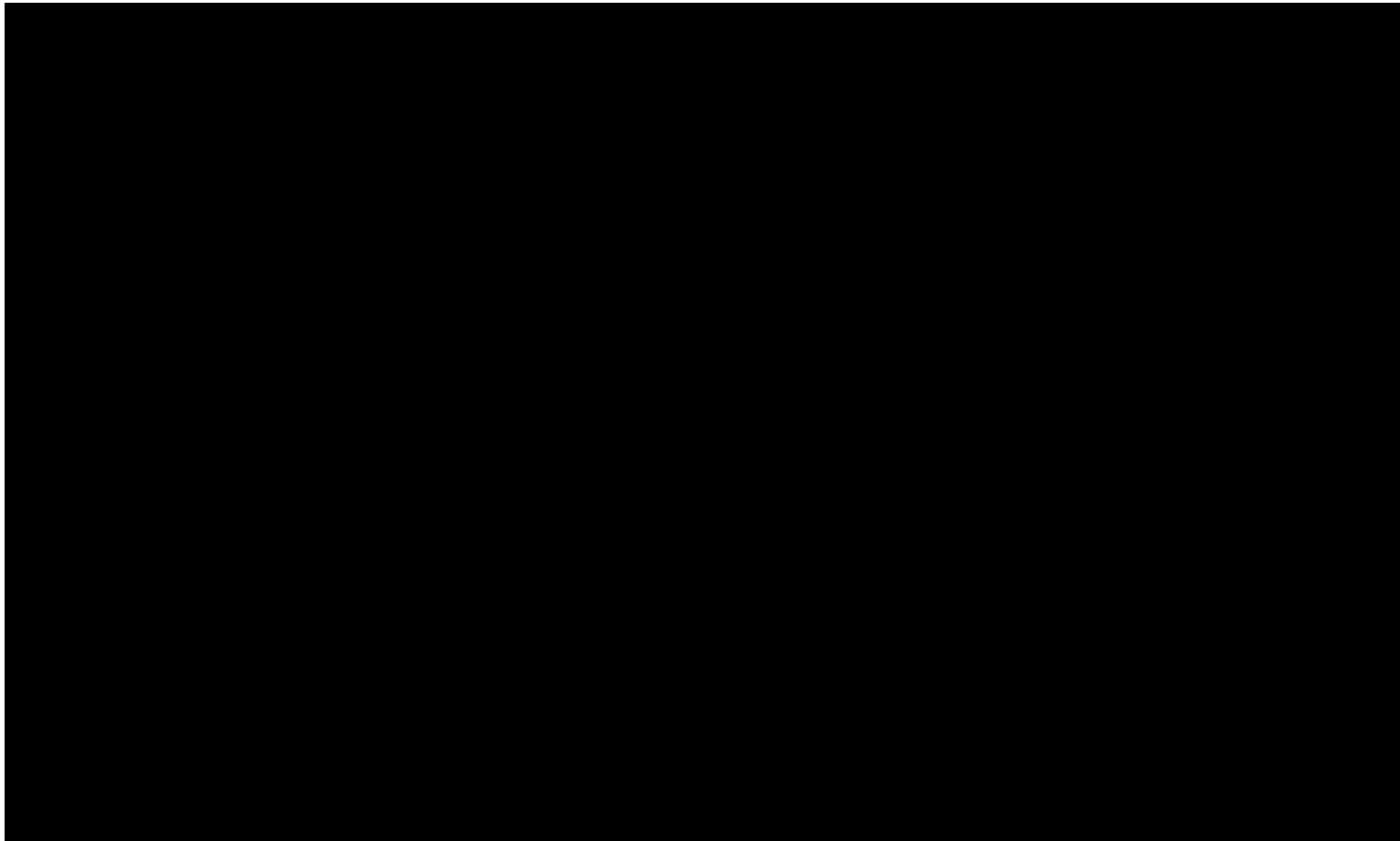
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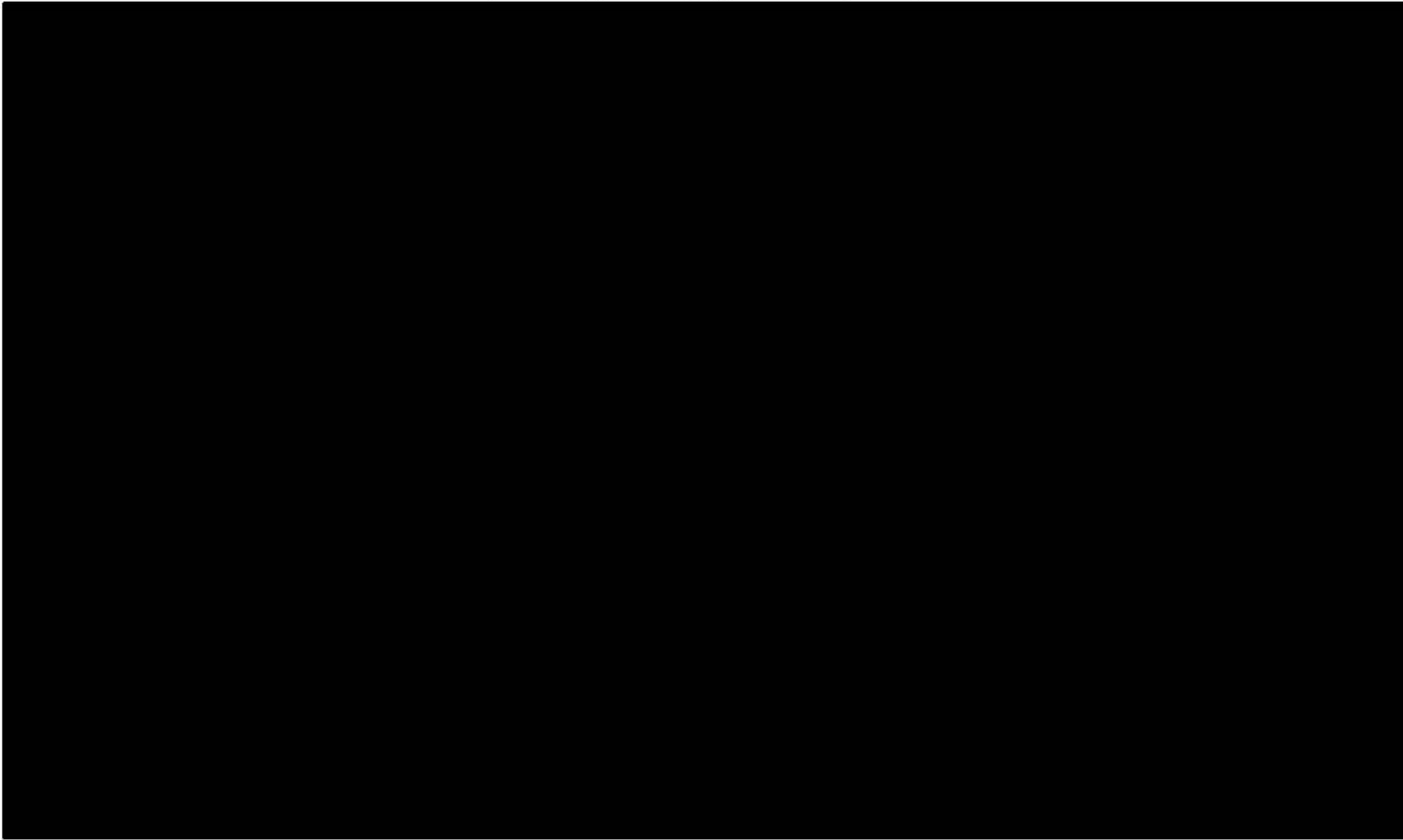


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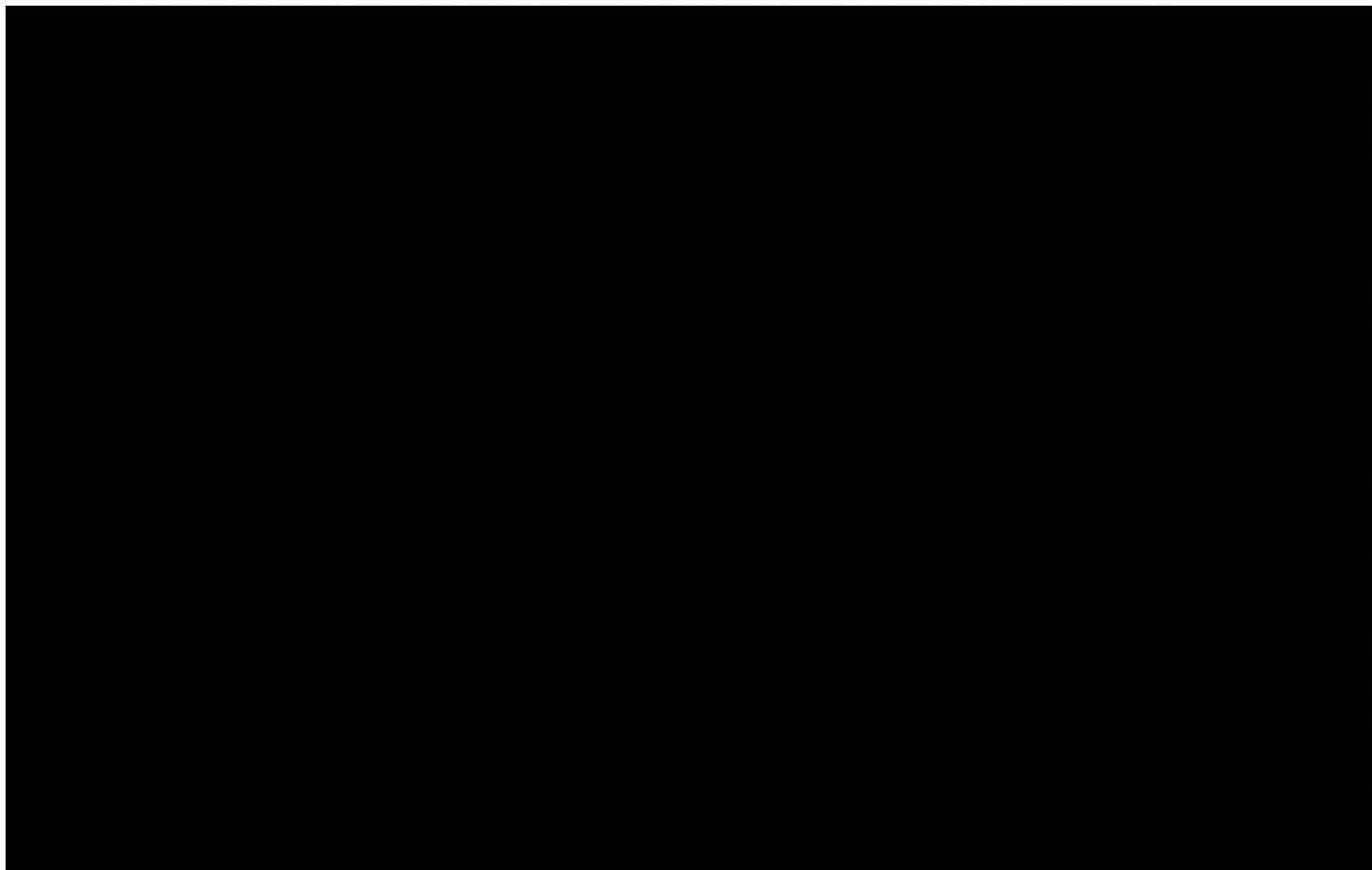
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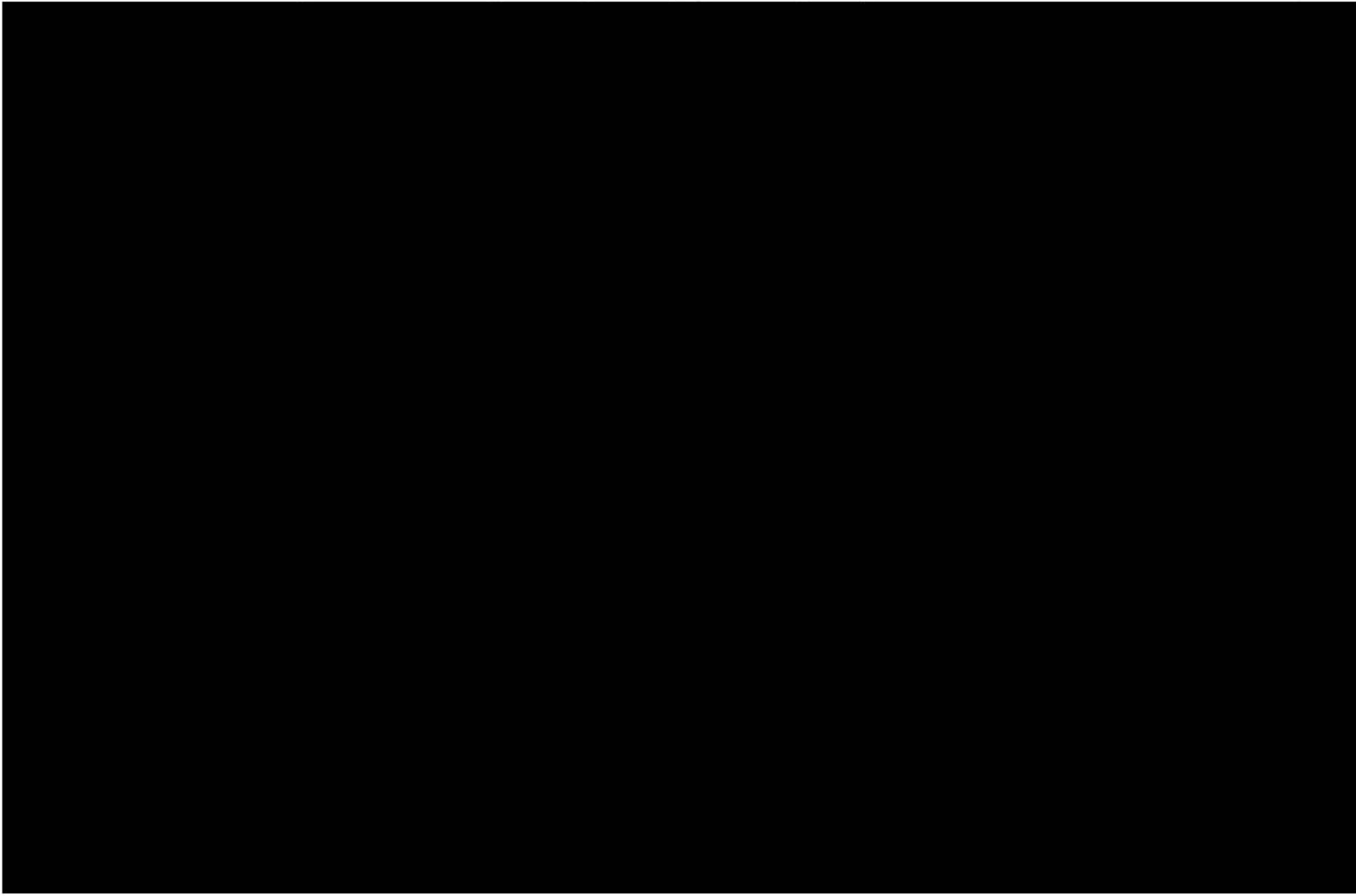
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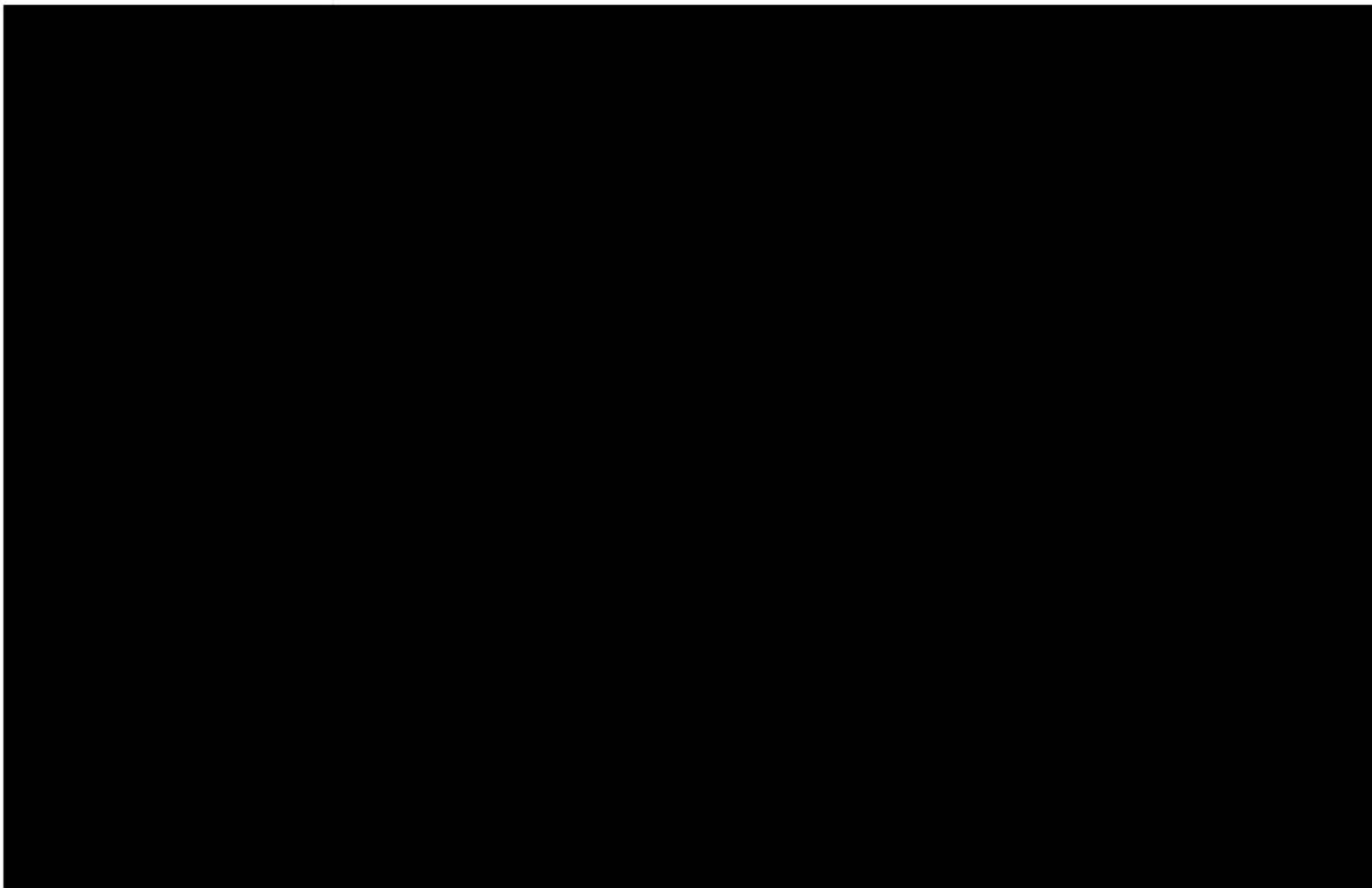
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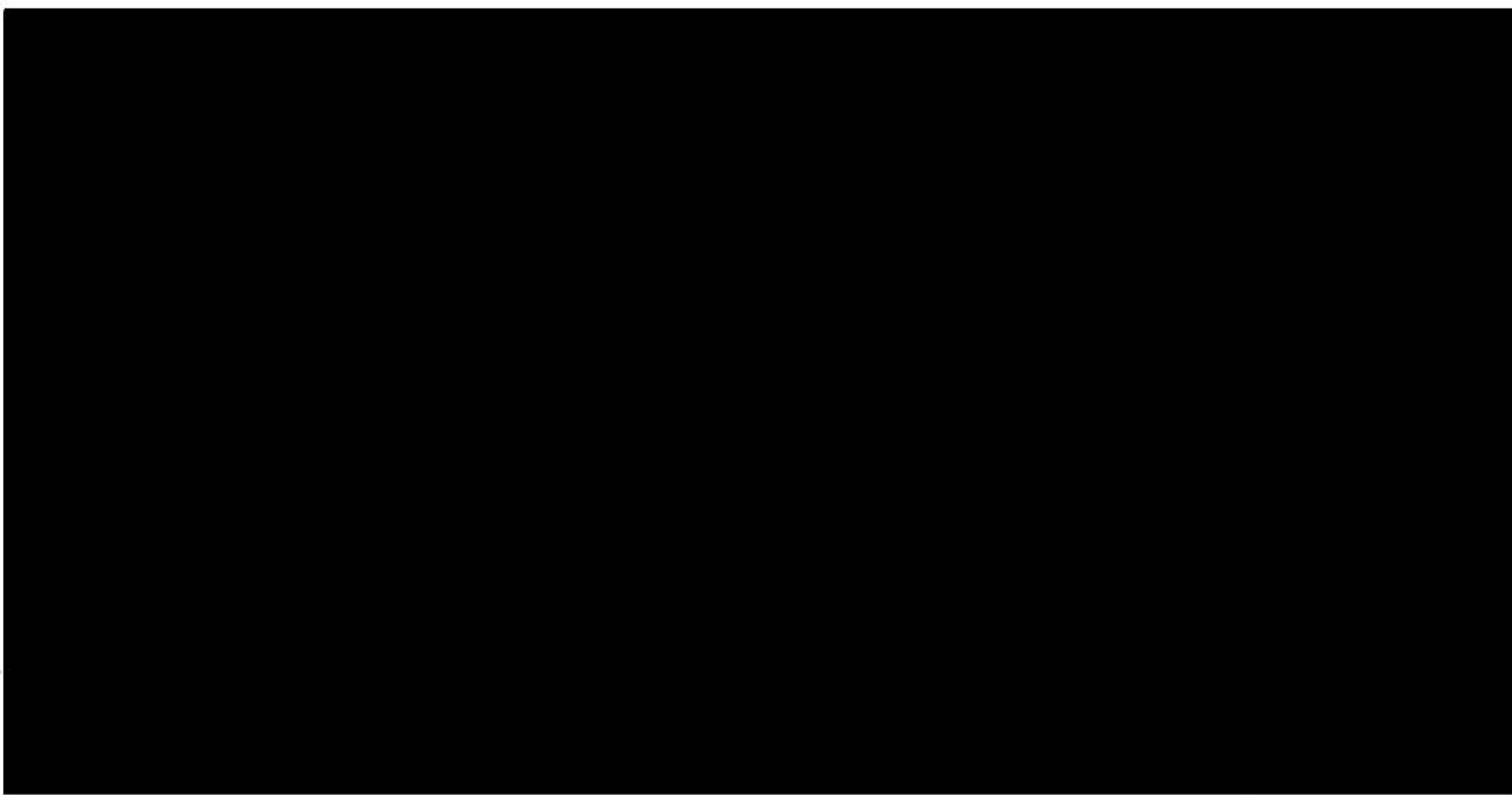
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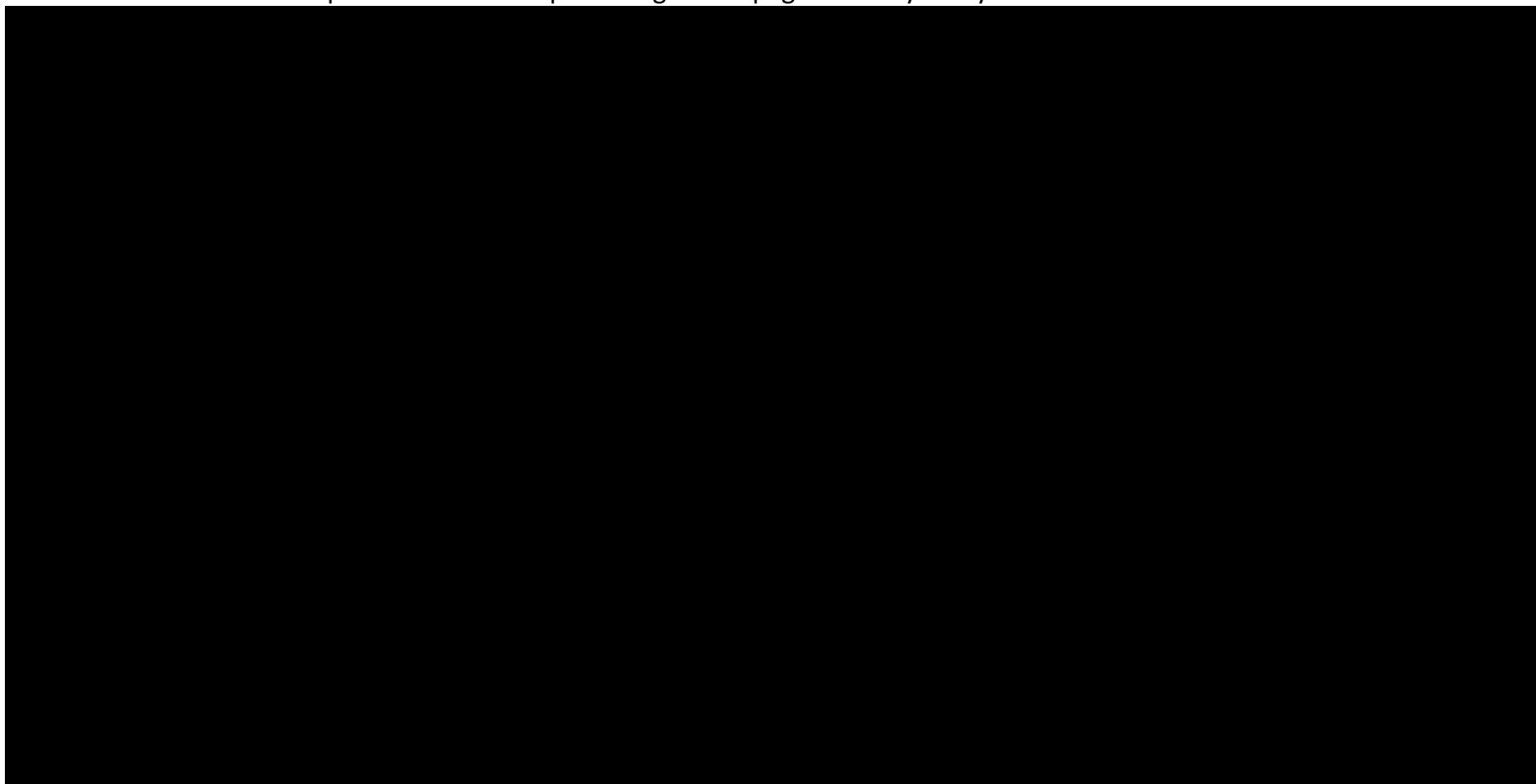
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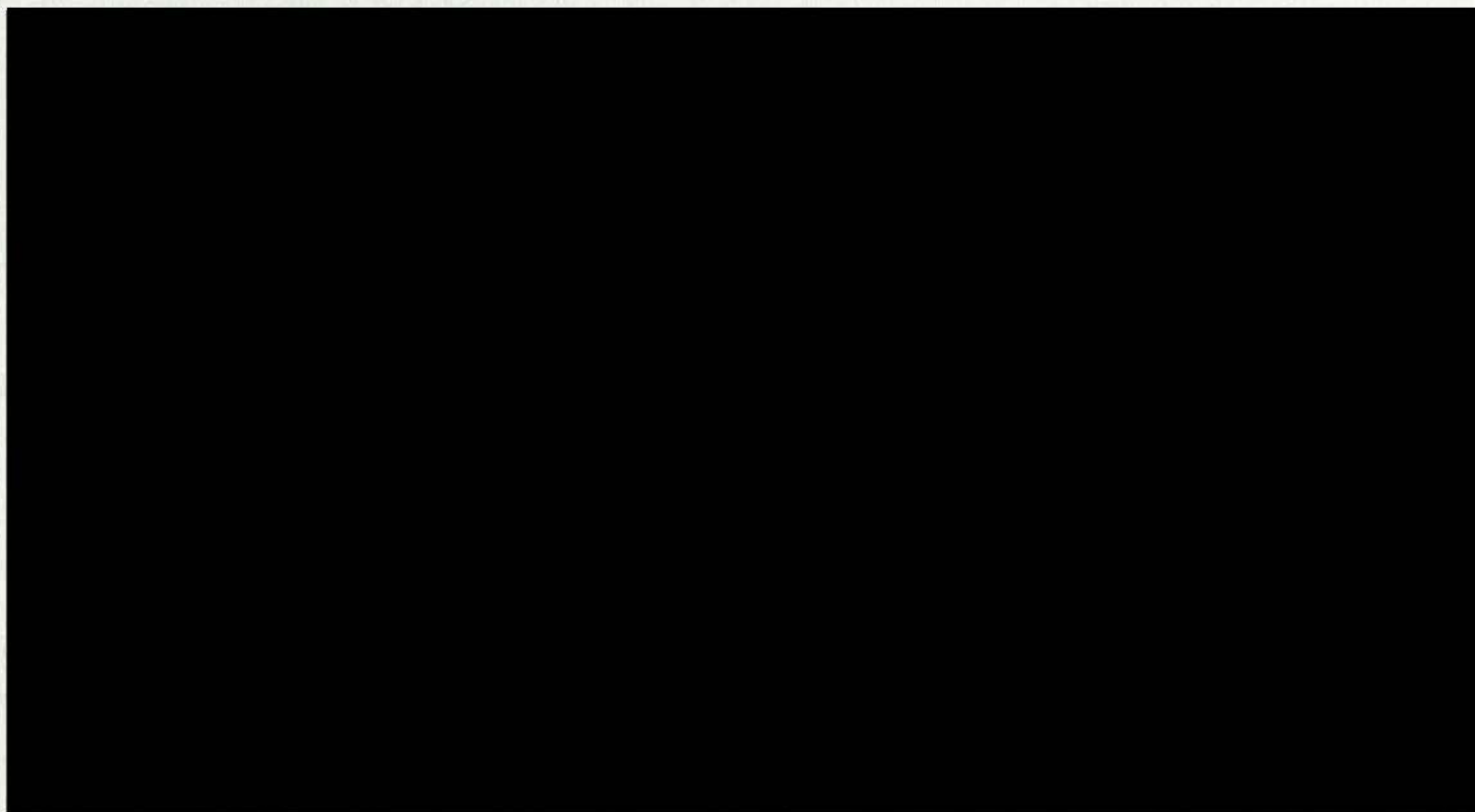
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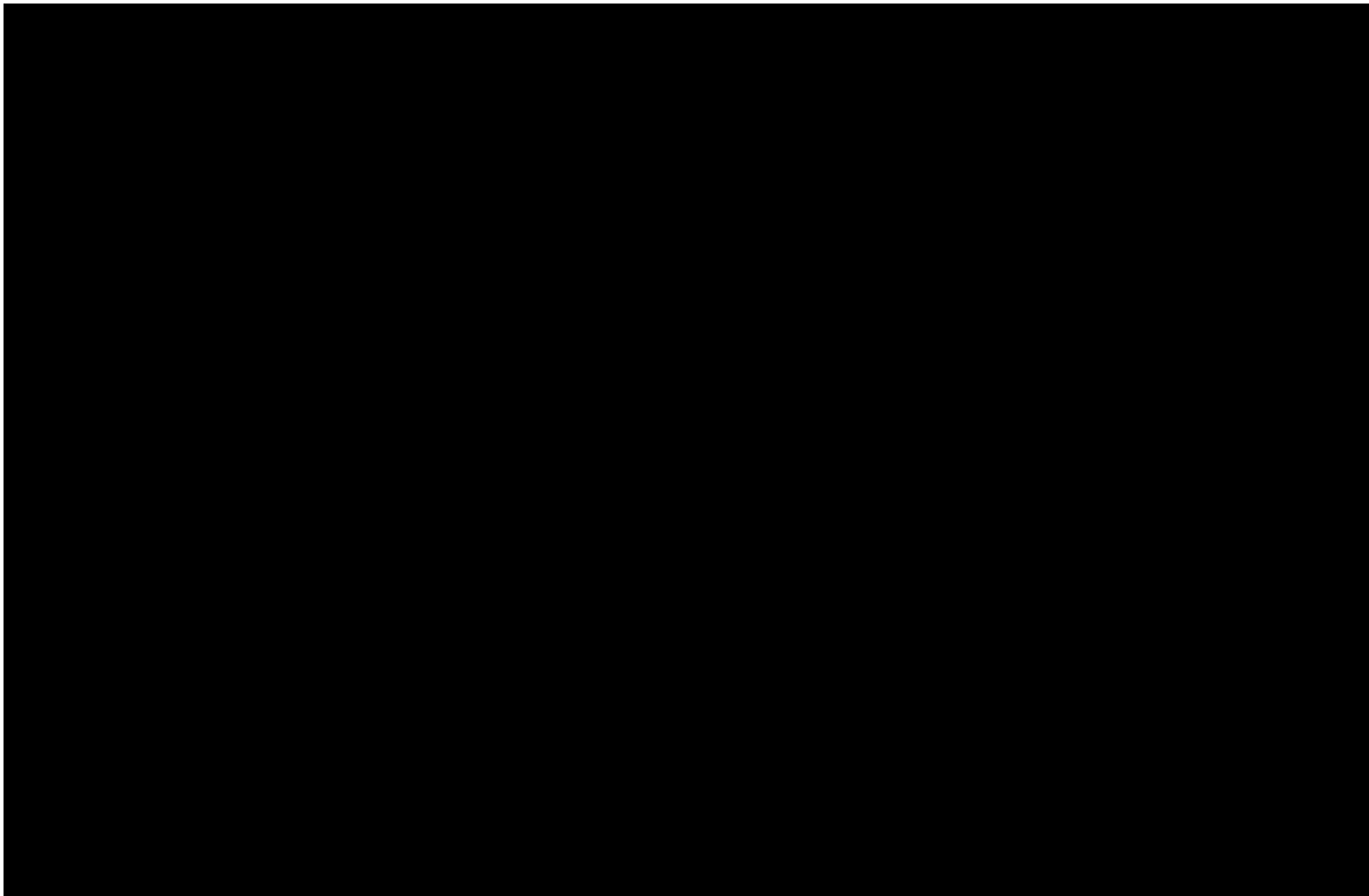
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AS WITNESS:

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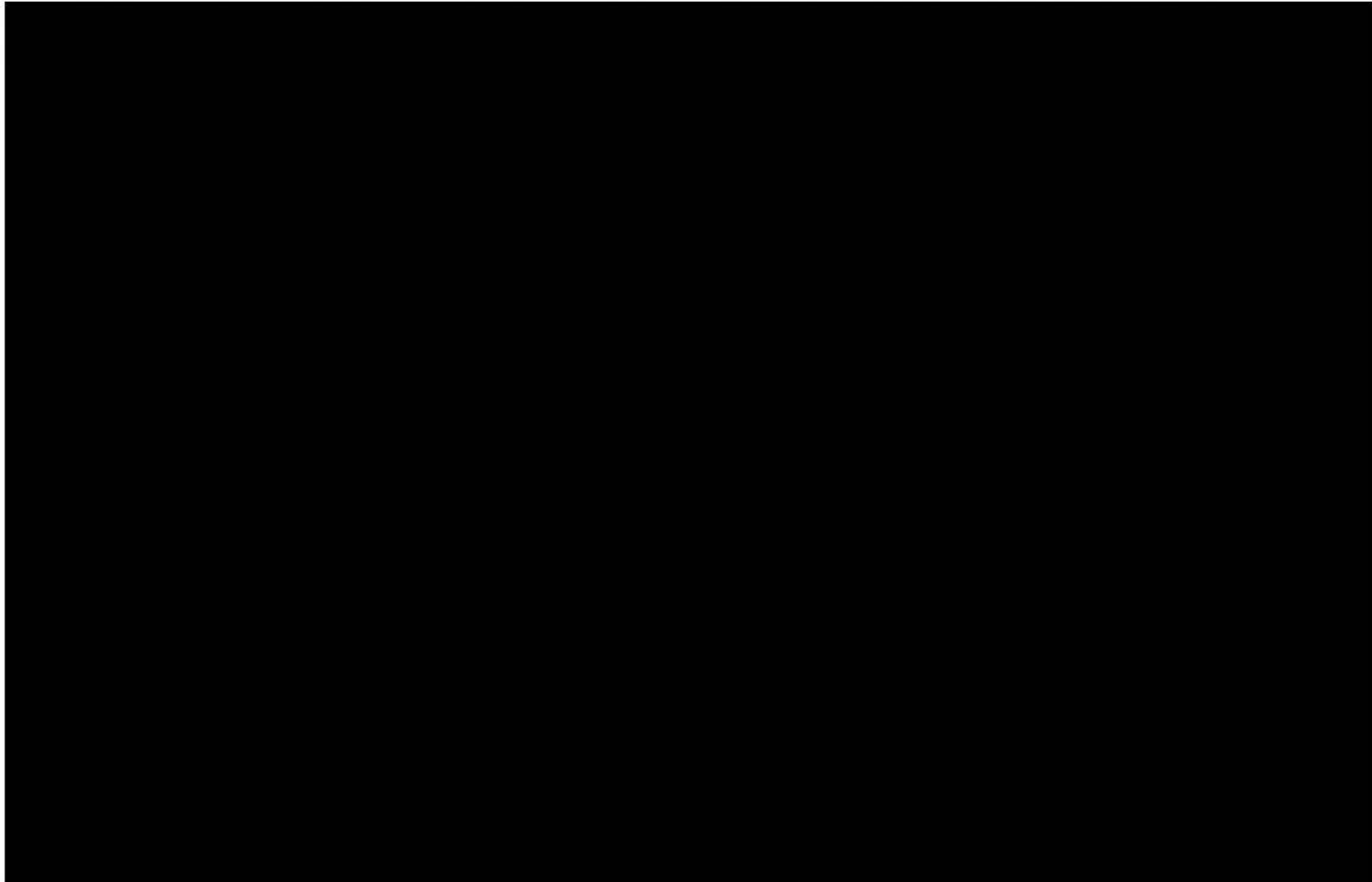
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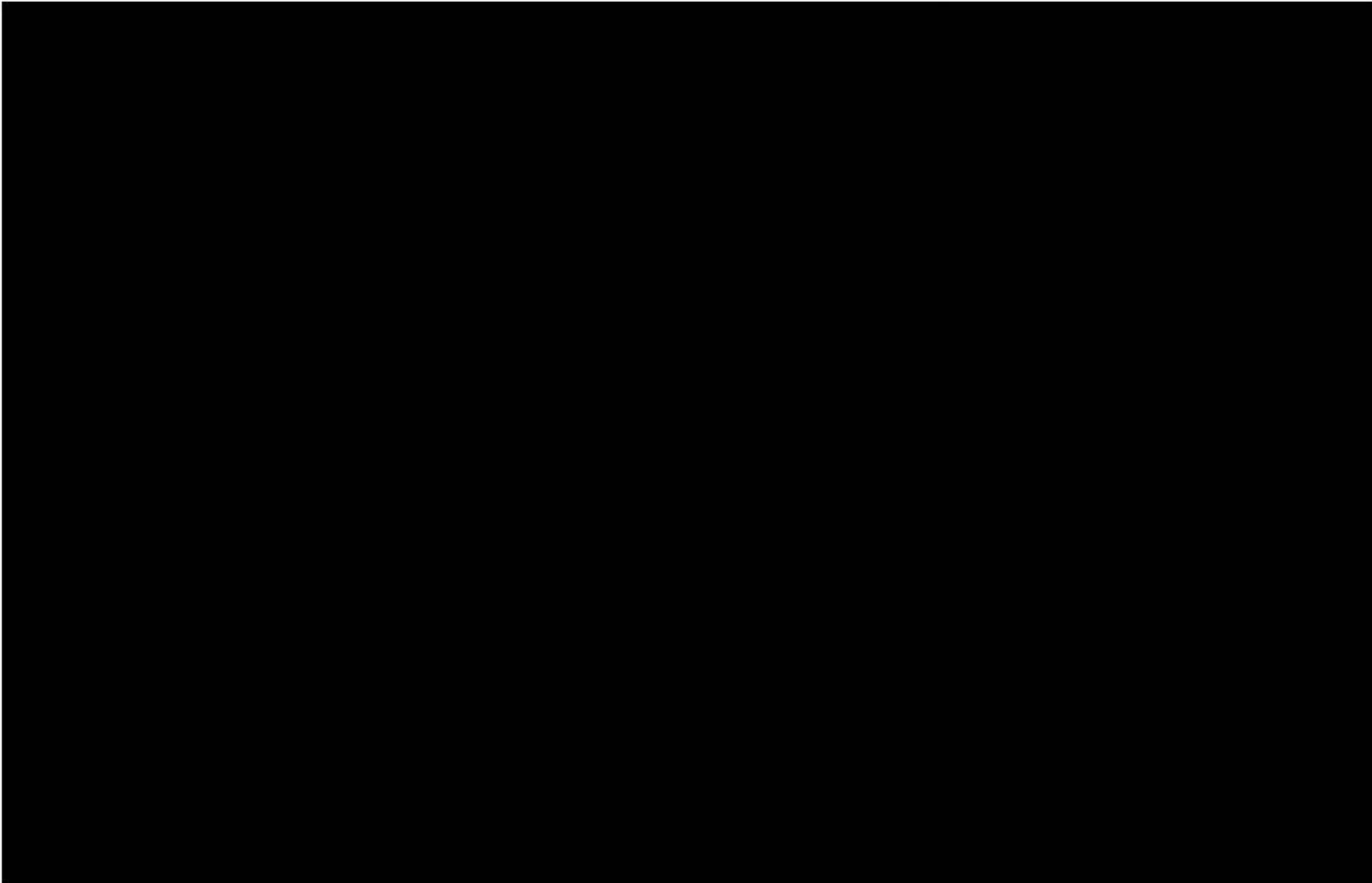
PartnERship to
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Attachment 1: Background included

According to the Grant Agreement (Article 16.1) Background is defined as “data, know-how or information (...) that is (...) needed to implement the Action or exploit the results”. Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the Project. This is the purpose of this attachment.

PARTY 1

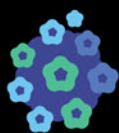
As to Istituto Superiore di Sanità is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)
Electronic submission System		

This represents the status at the time of signature of this Consortium Agreement.

As to:

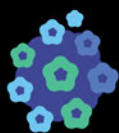
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- **HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH)**
- **USTAV ZDRAVOTNICKYCH INFORMACI A STATISTIKY CESKE REPUBLIKY (UZIS)**
- **TERVISE ARENGU INSTITUUT (TAI)**
- **INSTITUT NATIONAL DU CANCER GIP (INCA)**
- **BUNDESZENTRALE FUR GESUNDHEITLICHE AUFLARUNG (BZgA)**
- **1ST YGEIONOMIKI PERIFEREIA DYPE ATTIKIS (1ST YPE)**
- **NEMZETI NEPEGESZSEGUGYI KOZPONT (NNK)**
- **NACIONALINIS VISUOMENES SVEIKATOS CENTRAS PRIE SVEIKATOS APSAUGOS MINISTERIJOS (NVSC)**
- **FOLKEHELSEINSTITUTTET (NIPH)**



- **NARODOWY INSTYTUT ZDROWIA PUBLICZNEGO PZH – PANSTWOWY INSTYTUT BADAWCZY (NIZP-PZH)**
- **INSTITUTUL NATIONAL DE SANATATE PUBLICA (INSP)**
- **MINISTERSTVO ZDRAVOTNICTVA SLOVENSKEJ REPUBLIKY (SK MoH)**
- **ONKOLOSKI INSTITUT LJUBLJANA (IOL)**
- **INSTITUT CATALA D'ONCOLOGIA (ICO)**
- **FOLKHALSOMYNDIGHETEN (FOHM)**
- **UNIVERSITA CATTOLICA DEL SACRO CUORE (UCSC)**
- **UNIVERSITA DEGLI STUDI DI PADOVA (UNIPD)**
- **CENTRO DI RIFERIMENTO ONCOLOGICO DI AVIANO (CRO AVIANO)**
- **AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL RE)**
- **CONSIGLIO NAZIONALE DELLE RICERCHE (CNR)**
- **ISTITUTO PER LO STUDIO E LA PREVENZIONE E LA RETE ONCOLOGICA (ISPRO)**
- **UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI)**
- **MINISTERO DELLA SALUTE (IT MoH)**
- **TERVISEAMET (HB)**
- **ECOLE DES HAUTES ETUDES EN SANTE PUBLIQUE (EHESP)**
- **ROBERT KOCH-INSTITUT (RKI)**
- **NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)**
- **FUNDACIO INSTITUT D'INVESTIGACIO BIOMEDICA DE BELLVITGE (IDIBELL)**
- **KAROLINSKA INSTITUTET (KI)**

it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of

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- **KAROLINSKA INSTITUTET (KI)**

is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

This represents the status at the time of signature of this Consortium Agreement.



Attachment 2: Accession document

ACCESSION

of a new Party to

PERCH Consortium Agreement, version [..., YYYY-MM-DD]

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Grant Agreement]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

ISTITUTO SUPERIORE DI SANITA

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

ISTITUTO SUPERIORE DI SANITA

Signature(s)

Name(s)

Title(s)



Attachment 3: List of Affiliated Entities

The following entities which are linked to a beneficiary will participate in the action as 'affiliated entities':

- **UNIVERSITA CATTOLICA DEL SACRO CUORE (UCSC)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **UNIVERSITA DEGLI STUDI DI PADOVA (UNIPD)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **CENTRO DI RIFERIMENTO ONCOLOGICO DI AVIANO (CRO AVIANO)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **AZIENDA UNITA SANITARIA LOCALE DI REGGIO EMILIA (AUSL RE)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **CONSIGLIO NAZIONALE DELLE RICERCHE (CNR)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **ISTITUTO PER LO STUDIO E LA PREVENZIONE E LA RETE ONCOLOGICA (ISPRO)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **UNIVERSITA DEGLI STUDI DI FIRENZE (UNIFI)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **MINISTERO DELLA SALUTE (IT MoH)** linked to ISTITUTO SUPERIORE DI SANITA (ISS)
- **TERVISEAMET (HB)** linked to TERVISE ARENGU INSTITUUT (TAI)
- **ECOLE DES HAUTES ETUDES EN SANTE PUBLIQUE (EHESP)** linked to INSTITUT NATIONAL DU CANCER GIP (INCA)
- **ROBERT KOCH-INSTITUT (RKI)** linked to BUNDESZENTRALE FUR GESUNDHEITLICHE AUFKLARUNG (BZgA)
- **NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ)** linked to ONKOLOSKI INSTITUT LJUBLJANA (IOL)
- **FUNDACIO INSTITUT D'INVESTIGACIO BIOMEDICA DE BELLVITGE (IDIBELL)** linked to INSTITUT CATALA D'ONCOLOGIA (ICO)
- **KAROLINSKA INSTITUTET (KI)**, linked to FOLKHALSOMYNDIGHETEN (FOHM)



Attachment 4: Non-Disclosure Agreement¹

PartnERship to Contrast HPV

CONFIDENTIAL DISCLOSURE AGREEMENT

This confidentiality agreement (hereinafter "Confidentiality Agreement") is entered into between:

A) ISTITUTO SUPERIORE DI SANITA as Coordinator of the PartnERship to contrast HPV PERCH (the Disclosing Party), and

B) _____ who has signed this Confidentiality Agreement in his capacity of appointed member of the Scientific Advisory Board and Governance Advisory Board the PartnERship to contrast HPV_PERCH (the Receiving Party).

(Hereinafter also, each individually, Party, and jointly, Parties).

1. Purpose.

In order to ensure a proper implementation of the European PartnERship to contrast HPV_PERCH and of its activities, within the scope of the Scientific Advisory Board and Governance Advisory Board" which is extensively outlined in the corresponding Terms of Reference that are attached to this Agreement, the Parties must exchange information of a confidential nature ("Confidential Information" as defined in Article 2 below) and would like to ensure that it remains confidential. Each Party may, as the Partnership progresses, provide technical and/or scientific information to the other Party and they may want this information to be treated as confidential under the terms and conditions set out below,

2. "Confidential Information".

"Confidential Information" includes any information, and/or documentation, and/or material and/or instrument and/or research and development program provided by either Party, or furthermore acquired by one of the Parties, directly or indirectly, by any means (for example, paper copies or electronic form), clearly declared as "confidential", "proprietary", or similar phraseology that indicates the privileged and/or confidential nature of the information. The confidential nature of the information may also regard studies and analyses prepared by one Party, on the basis of Confidential Information provided by the other Party. All oral information must be treated as confidential, as must any information regarding any third party.

¹ Only for use of the Coordinator according to the provisions set forth in Articles 6 and 8 of the Consortium Agreement



Information that does not qualify as Confidential Information includes information that:

- (I) was in the public domain prior to the transfer of the same information from one Party to the other or information that has become publicly available without violating this Confidentiality Agreement;
- (II) has become available after being published by one Party to the other for reasons not attributable to the receiving Party;
- (III) was available to the receiving Party prior to the communication, as can be demonstrated by the date of communication on previous documents;
- (IV) is legitimately obtained by one of the Parties from a third party who has no obligation of confidentiality;
- (V) was developed independently by the receiving Party without use or reference to information from the communicating Party, as can be demonstrated by documents and other evidence in possession of the receiving Party; or
- (VI) was delivered by one Party to a Judicial or Administrative Authority in compliance with laws or regulations, or as required by the same Judicial or Administrative Authority, in which case the receiving Party shall promptly notify the communicating Party, in writing, prior to such disclosure or, if this is not possible, immediately following the disclosure of the information, as well as the method of disclosure in such a way as to limit its dissemination as much as possible.

3. Non-use and non-disclosure.

Each Party agrees not to use the Confidential Information for purposes other than those allowed in paragraph 1 above, either directly and/or indirectly.

Each Party agrees to not disclose Confidential Information to third parties or employees and/or different types of third-party coworkers, except when these third parties or their employees and/or different types of third-party co-workers are directly involved in the analysis of the project or as consultants to a Party.

If it is mandatory that a third party be involved in carrying out any of the activities listed above in paragraph 1, the Party requesting this involvement must require these third parties to sign a confidentiality agreement with content that reflects the obligations of and is similar to this Confidentiality Agreement.

Employees and/or co-workers of either Party and/or employees and/or co-workers of audit companies responsible for auditing financial statements of either Party are not considered third parties.

The receiving Party has the right to disclose Confidential Information to its consultants. If there is unlawful disclosure of Confidential Information by these consultants, or by members of the governing bodies of each of the Parties, the liability for damages will be the responsibility of the receiving Party.



4. Maintaining Confidentiality.

Each Party will take reasonable measures to protect the confidentiality of and prevent the dissemination of Confidential Information received under the terms of this Confidentiality Agreement.

When handling Confidential Information received from the other Party, each Party should use the same means they use for their own confidential documents and ensure that all persons who have access to the Confidential Information are bound to confidentiality.

Each Party must assess, through normal standards of reason and diligence, which must be measured based on the nature and type of information processed and/or received, the methods used for the protection of the confidentiality of restricted and sensitive information. If this assessment reveals that the methods used for the protection of Confidential Information are inadequate for the nature and type of information received and processed, the Party will be required to take measures that, according to normal standards of reason and diligence, are sufficient to safeguard the confidentiality of the type of information received. Failure to do so will result in liability for all damages caused to the other Party, as a result of the disclosure of Confidential Information received by the other Party.

5. Limitations.

Neither obligation nor commitment nor right, even of an additional pre-contractual nature, with respect to what is contained in this Confidentiality Agreement arises on either Party, as a result of signing this Confidentiality Agreement.

Where each Party has the right to unilaterally terminate this Agreement at their own discretion, the ceasing Party continue to be required to respect the terms and conditions of this Confidentiality Agreement with respect to any Confidential Information acquired during execution of the activities described in paragraph 1 above for a period equal to 12 (twelve) months, effective from the date of signing of this Confidentiality Agreement.

No additional obligation may arise from this Confidentiality Agreement for the Parties as a result of the termination of assignments related to PartnERship to contrast HPV_PERCH

6. Invalidity.

The declaration of nullity or invalidity of one or more provisions contained in this Confidentiality Agreement does not determine the invalidity or nullity of the Confidentiality Agreement as a whole or of the remaining provisions contained herein, which must be interpreted in such a way as to yield economic and substantial effects similar as much as possible to those arising from the original text of the Confidentiality Agreement.

7. Return of materials.

All Confidential Information communicated by one Party to the other, in any material form, and all copies owned by the other Party, remain property of the communicating Party and must be returned or destroyed promptly upon written request from the communicating Party. Nevertheless, the obligation to preserve the confidentiality of the content as stated in the last part of paragraph 5 above remains binding.



8. Amendments.

Any amendment to this Confidentiality Agreement must be made in writing and be approved by appropriate undersigning by both Parties.

9. Termination.

The duration of this Confidentiality Agreement is of 84 months from the date of its undersigning by both Parties.

10. Remedies.

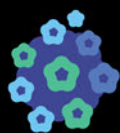
The receiving Party acknowledges that every violation of the provisions contained in this Confidentiality Agreement may cause irreparable damage to the Disclosing Party, reserving the right to claim monetary reparation, and any other legal remedy provided for from time to time by current regulation.

11. Applicable Law and Jurisdiction.

The Parties agree that this Agreement and all disputes arising hereunder shall be governed by the existing laws in Belgium. The Parties shall endeavor to amicably settle any disputes arising out of or in connection with the performance of this Agreement. If an amicable settlement cannot be reached, the parties may apply to the competent jurisdiction according to the above-mentioned principle.

This document constitutes the complete agreement between the Parties with respect to Confidential Information.

The Parties acknowledge and agree to the terms and conditions contained in this Confidentiality Agreement, as evidenced by the signatures appearing below.



PERCH
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DISCLAIMER

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the Executive Agency can be held responsible for them.