

Workload & Costs

ACTIVITIES	Work capacity allocation				Total Cost
	Resources	Number of units	Unit	Unit Cost	
A. STUDY DOCUMENTS					
1 BASIC STUDY DESIGN - consultation & updating	CRM		hour		0 Kč
2 PROTOCOL	CRM		hour		0 Kč
3 LOCAL ADAPTATION OF PROTOCOL	CRM		hour		0 Kč
4 PROTOCOL AMENDMENTS	CRM		hour		0 Kč
5 RANDOMIZATION SCHEDULE	NA		hour		0 Kč
6 MASTER INFORMED CONSENT FORM (ICF) in Czech	CRM		hour		0 Kč
7 LOCAL ADAPTATION OF ICF	CRM		hour		0 Kč
8 ENGLISH TRANSLATION OF the Czech MASTER ICF	CRM		hour		0 Kč
9 CRF (Case Report Form) DESIGN	CRM	■	hour		■ ■
10 CRF INSTRUCTIONS FOR INVESTIGATOR	CRM	■	hour		■ ■
11 SUBJECT DIARY	CRM		hour		0 Kč
12 SUBJECT QUESTIONNAIRE (1)	CRM		hour		0 Kč
13 SUBJECT QUESTIONNAIRE (2)	CRM		hour		0 Kč
14 INVESTIGATOR STUDY FILE (ISF)	CRM	■	hour		■ ■
15 USER MANUAL TO IP / MD	CRM		hour		0 Kč
16 PRINTING OF STUDY DOCUMENTS	CRA	■	hour		■ ■
17 DOCUMENT DELIVERY TO SITE / TO SPONSOR	CRA	■	hour		■ ■

ACTIVITIES	Work capacity allocation				
	Resources	Number of units	Unit	Unit Cost	Total Cost
18 TRANSLATION of documents - if applicable	CRM		hour	██████	0 K
19 STUDY MANUAL - if applicable	CRA		hour	██████	0 K
20 MONITORING PLAN	CRM	█	hour	██████	██████
21 NEWSLETTERS	CRM		hour	██████	0 K
22 ADVERTISING TOOLS	CRM		hour	██████	0 K
23 PHARMACIST FILE	CRM		hour	██████	0 K

B. DRUG SUPPLY AND INVENTORY MANAGEMENT, BIOLOGICAL SAMPLES ████████

1 SUPPLY TEST IP/ MD	CRA	█	hour	██████	██████
2 PACKAGE DRUG / ASSEMBLY DEVICE	CRA		hour	██████	0 K
3 LABEL DRUG	CRA		hour	██████	0 K
4 LOCAL LAB management, start up and management	CRM		hour	██████	0 K
5 COORDINATION OF BIOLOGICAL SAMPLES SHIPMENT BETWEEN SITES AND CENTRAL DEPO	CRA		hour	██████	0 K
6 SHIP USED/UNUSED DRUGS FROM SITES TO SPONSOR, PERFORM IP ACCOUNTABILITY	CRA		hour	██████	0 K

C. REGULATORY ACTIVITIES ████████

1 ETHICS COMMITTEE (EC) initial submission	CRM		hour	██████	0 K
1 Communication before/during EC review process	CRM		hour	██████	0 K
1b ETHICS COMMITTEE amendment submission	CRM	█	hour	██████	██████
2 COMPETENTY AUTHORITY (CA) initial submission	CRM		hour	██████	0 K
2 Communication before/during CA review process	CRM		hour	██████	0 K

ACTIVITIES	Work capacity allocation				
	Resources	Number of units	Unit	Unit Cost	Total Cost
2b COMPETENT AUTHORITY amendment submission	CRM	█	hour	█ █	█ █ █
3 INITIAL and FINAL REPORTS TO EC and CA	CRA	█	hour	█ █	█ █ █ █

D. STUDY SET-UP ACTIVITIES

1 IDENTIFY INVESTIGATIONAL SITE, PERFORM QUALIFICATION VISIT, PREPARE REPORT	CRM		hour	█ █	0 K
2 NEGOTIATE and CONCLUDE INVESTIGATOR AGREEMENT	CRM		hour	█ █	0 K
2 INVESTIGATOR'S FEE (payment for the study, to be included in agreement)	CRM		hour	█ █	0 K
3 SET UP INVESTIGATOR FILE	CRM	█	hour	█ █	█ █ █
4 ICF printing and distribution	CRA		hour	█ █	0 K
5 SITE PRE-SELECTION CONTACT AND VISIT	CRM		hour	█ █	0 K

E. MEETINGS / STUDY UPDATES

1 INTERNAL MEETING	CRM/CRA		hour	█ █	0 K
2 CRO/SPONSOR MEETING	CRM	█	hour	█ █	█ █ █
3 INVESTIGATOR MEETING (Start up)	CRM/CRA	█	hour	█ █	█ █ █
4 GCP Training (site staff)	CRM	█	hour	█ █	█ █ █
5 CRA TRAINING	CRA		hour	█ █	0 K
6 TELECONFERENCES / WEEKLY UPDATES	CRA		hour	█ █	0 K
7 General local study & site supervising	CRA		hour	█ █	0 K

F. MONITORING

ACTIVITIES	Work capacity allocation				
	Resources	Number of units	Unit	Unit Cost	Total Cost
1 CONDUCT QUALIFICATION SITE VISIT	CRA		hour	■ ■	0 K
2 CONDUCT ON-SITE STUDY INITIATION VISIT	CRA	■	hour	■ ■	■ ■
3 CONDUCT INTERIM MONITORING VISITS	CRA	■	hour	■ ■	■ ■
4 CONDUCT STUDY CLOSURE VISITS	CRA	■	hour	■ ■	■ ■
5 MANAGEMENT of INVESTIGATOR FEE & INVOICING	CRA		hour	■ ■	0 K
6 Site oversight/communication between MVs	CRA		hour	■ ■	0 K

G. GLOBAL PROJECT MANAGEMENT					
PROJECT MANAGEMENT	CRM	■	hour	■ ■	■ ■

H. SAFETY REPORTING					
SAE reporting	CRA	■	hour	■ ■	■ ■

I. CLINICAL DATA MANAGEMENT					
CLINICAL DATA MANAGEMENT	DE/DM	■	hour	■ ■	■ ■

J. PROGRAMMING AND STATISTICS					
PROGRAMMING AND STATISTICS - if CRO is charged to ensure this task	NA				0 K

K. STUDY CLOSURE ACTIVITIES					
1 ARCHIVE, RETAIN, AND RETURN STUDY DOCUMENTS AND STUDY DATABASE	CRA	■	hour	■ ■	■ ■

Work capacity allocation

ACTIVITIES	Resources	Number of units	Unit	Unit Cost	Total Cost
2 CLINICAL STUDY REPORT (CSR)	CRM	█	hour	█ █	█ █ █ █
3 END OF STUDY REPORT TO EC AND CA	CRA	█	hour	█ █	█ █ █ █

L. OTHER ACTIVITIES					0 K
Office overhead	office				

L. PASS-THROUGH COSTS					
Mileage (company car) per 1 km		█	km	█ █	█ █ █ █

GRAND TOTAL					214 370 K
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CRO staff work

