IMI2 821520 - ConcePTION

ConcePTION

WP8 – Scientific coordination, project management & sustainability

D8.4 Detailed project plan, plus tracking tools, to be maintained throughout the life of the project

Lead contributor	Florian van der Nolle (1 – UMC Utrecht)
	f.l.vandernolle-raven@umcutrecht.nl
Other contributors	Pieter Stolk (1 – UMC Utrecht)
	Juul Klaassen (1 – UMC Utrecht)

Document History

Version	Date	Description	Non-contributor reviewers (if applicable)
V0.1	26-9-2019	First Draft	NA
V0.2	3-4-2020	Second Draft	NA
V1.0	6-4-2020	Final version	NA

Publishable Summary

The objective of WP8 is to run an effective project management for the ConcePTION consortium and to guarantee the project's long-lasting impact. Effective project management will ensure the progress of the project, on time, on budget, towards its planned objectives and in line with all contractual commitments. To achieve the project management objective, the Project Management Office (PMO) has developed a detailed project plan that, alongside with the Description of Action (DoA) and in combination with the tracking tools, will be instruments to monitor the progress and successes of the project.

Methods

As described in D8.1 (Project management plans) the DoA will be the core document for all project management activities. As part of the project management plans the PMO developed a deliverable and milestone tracker. To build on the existing documents, the PMO developed a template for a detailed work package (WP) work plan and a communication tracker, risk registry and amendment log. Besides the trackers, multiple procedures have been developed and an internal Project Handbook is written.

Results

Detailed work package work plan

The PMO team developed a template for each work package to complete as a WP work plan. The template was circulated to all work package leaders (WP leads) before the kick off meeting (2-3 April 2019). The WP leads were asked to complete the work plans, at least for the first year of the project, together with their WP members during the kick off meeting and the first month following. The information of these work plans feeds into the project management plans (D8.1).

The WP work plans are divided per tasks. Per task the WPs are asked to determine and describe: the subsequent activities leading up to completion of the task, the responsible instruction, collaborating institutions, names of involved members, output, dependencies, uncertainties and needs for clarification. Figure 1 in the Annex gives an example of a completed work plan (WP7) for year 1.

<u>Procedure</u>

The WP leads are asked to keep their work plan up to date over the course of the project themselves. The PMO will request an updated version of the work plan regularly.

Project Handbook

Due to the size of the consortium and the diversity of partners, in both background and experience with IMI/H2020 projects, it was decided to develop a project handbook. This handbook will act as an initial reference document for consortium members. The project handbook explains, among other things, the governance and decision making procedure, reporting obligations and process and the amendment method. The table of contents of the project handbook depicts all the topics currently included in the project handbook and can be found in the Annex (Figure 2). The project handbook will be an evolving document and will be regularly updated when procedures change. Also, on request of the consortium members, additional topics can be included.

The project handbook can be shared upon request.

Communication tracker*
All consortium members are requested to inform the PMO of all dissemination and communication activities. As soon as the PMO is informed they will update the tracker.

The tracker is based on the 'Dissemination and Communication Activities' section of the periodic report in the EU-portal. In this way, we ensure that all necessary activities are tracked and differentiated properly. Therefore, the different sections in the communication tracker are Abstract submission; Participation to a conference; Participation to/Organisation of a workshop (not part of a conference); Participation to/Organisation of an event (not a conference or workshop); Press release; Presentation (not a conference); Scientific publication/research paper; Popularized publication (non-scientific and peer-reviewed); Promotional material (flyers, posters, …); Websites and webpages; Media (TV, Radio, Podcast, Press, etc.); Social media (active accounts); Other (please specify).

A screenshot for the communication tracker can be found in the Annex.

**Open to change*
Activities related to external communication are divided over multiple work packages, as stated in the DoA:

"We have dedicated WPs to address specific stakeholder groups and their needs. ***WP5*** *will take the lead in engaging HCPs and pregnant and breastfeeding women to stimulate pregnancy and breastfeeding pharmacovigilance reporting.* ***WP6*** *will reach out to healthcare professionals, societies, regulators and build relationships and co-creation models, while* ***WP8*** *will coordinate information dissemination on the project as a whole."*

During the first year of the project, we experienced a great need for alignment between these groups. To ensure this, a Communication Task Force will be put in place. WP5, 6 and 8 will play a major role in the Task Force but representatives from all WPs will be included. The Commination Task Force may decide to change the communication tracker and tracking procedure.

Risk Registry

Risk management tracking is performed by the PMO with a continuous contribution of the MT and MB. Nonetheless, risk management activities benefit from the participation of all involved parties. Therefore, open communication that allows contribution from all participants involved is encouraged. The PMO will include all assessed risk in a 'Risk Registry'. The risk registry is an excel table containing the following columns: ID; Date raised; WP; Risk title; Risk description (including impact description); Likelihood; Impact; Severity; Owner; Action; Progress on actions; Status/Change; Date; Closed and Comments. The likelihood and impact will be assessed on a 3 point scale low, medium, high. Based on the likelihood and impact the severity will be assed.

		Likelihood		
		1	2	3
Impact	1	Low	Low	Medium
	2	Low	Medium	High
	3	Medium	High	Critical

A screenshot for the Risk Registry can be found in the Annex.

<u>Procedure</u>
The risk management process can be summarised as follows:

1. A risk is detected by a consortium member, can be WP leader (WPL) but doesn't have to be
2. The WP leaders of the associated WP will introduce the risk in the bi-monthly MB meeting and the MB will assess the risk *(when an acute risk arises the risk owner can contact the MT directly. The MT will assess the risk in their weekly meetings).*
3. During the assessment, the following topics will be addressed
    - Type of risk; <u>Threat</u> to successfully achieve project objects OR Risk of missing an <u>opportunity</u>
    - Assess the likelihood and severity of the risk (low-medium-high)

- Propose initial actions
- Identify Risk Owner; the consortium member in the best position to recommend mitigation strategies for the risk, develop and document a contingency plan and monitor the status of the risk.

4. Risk owner completes the risk documentation form, see Annex *(when the risk owners is not a WPL, the associated WPL will support the risk owner in the completion of the risk documentation form)*
5. The Risk owner shares the risk documentation form with the MT and PMO
6. The PMO will include the risk in the risk registry
7. Risks are regularly monitored and updated by the MT assisted by the PMO. WP leaders/Risk owners are regularly consulted for monitoring purposes.

Amendment log

The PMO will be responsible for the coordination and preparation of the amendments during the project. Overall one single amendment request will be submitted per project year (if necessary) after the completion of the periodic report. Special timeliness will apply in case of major or urgent changes. The PMO will keep track of all non-urgent amendment requests in an amendment log. The log is an excel file containing the following columns: Title amendment, Partners involved, Precise change, Contact and Notes.

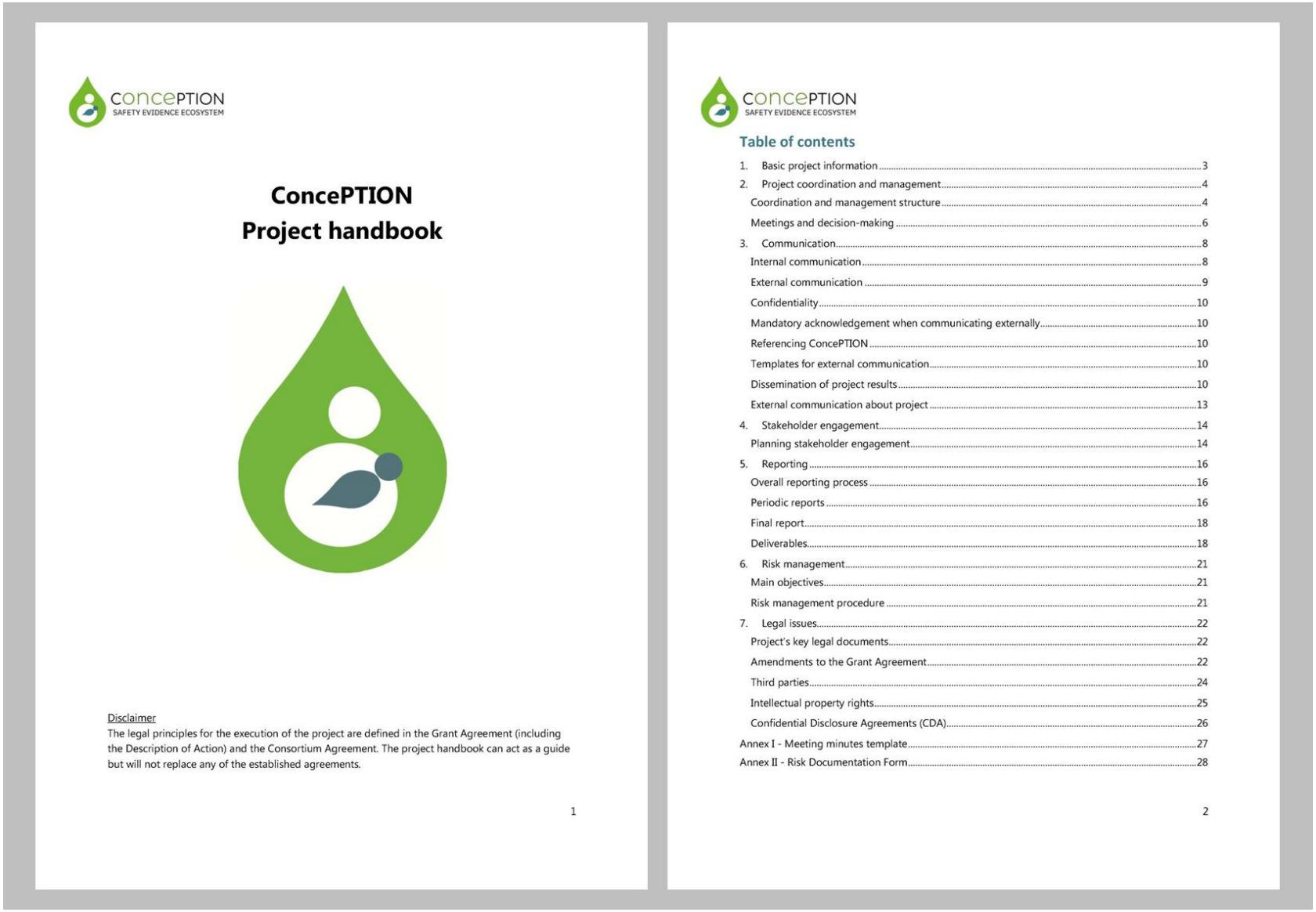
Procedure
In general, the amendment procedure will be as follows:

1. The PMO will keep track of all the needed amendments. To compile all necessary documentation the PMO will reach out to the affecting participants/beneficiaries. Please note, validation of a legal entity (e.g. when adding a new beneficiary or linked third party) needs to be done before the coordinator will 'submit an amendment request'.
2. A list with all the modifications and a new version of the related Grant Agreement (including Annexes) with tracked changes will be circulated to the General Assembly (GA) for their information and approval.
3. Members of the GA have 2 weeks to raise objections (review period can be extended to 4 weeks by a formal request)
4. Once the GA has accepted the modification, the PMO will prepare the official documentation for the amendment request and will include the changes in the Funding & Tenders Portal.
5. The Coordinator will submit, on behalf of the Consortium, the amendment request. Please note, a signed and submitted amendment request cannot be changed — only accepted, rejected or withdrawn.
6. The IMI2 JU will assess the request and must accept or reject the request within 45 days
7. The IMI2 JU may request additional information/documents, which will not change the amendment itself.
8. The coordinator must upload the requested information within 15 calendar days
9. Hereafter, the IMI2 JU has (a new) 45 days to assess the request
10. The amendment request gets accepted or rejected
11. The amendment enters into force on the day the IMI2 JU signs it
    - The amendment takes effect (i.e. the changes to the grant agreement start to apply) either:
        i. On a specific date agreed by the parties (clearly specified in the amendment)
            - This date should normally be after the entry into force. In justified cases it may – exceptionally - be before that date.
        ii. On the date it enters into force (i.e. the date on which the amendment was signed by IMI2 JU).

Annex

		Step	Activity	month 1	2	3	4	5	6	7	8	9	10	11	12	responsible instution	collaborating institutions	names of persons: Institution/name	output	dependencies	details	uncertainties	needs for clarification
Task 7.1 Defining the rules and collaboration models for data reuse		1	developing the questionnaire/interview													UMCU	SGUL / KI / iHD / EIWH GSK	UMCU: Miriam S, Rieke de G, PhD (tbd). SGUL: Joan Morris : ..... KI Helle Kieler...., iHD.....; GSK Marianne Cunnington	Interview template	none		framework for the questions	are there existing questions, models?
		2	testing the interview																adapted interview and script	draft interview and test		whom to test on	
		3	compiling a list of contacts /interviewees													SGUL?	SGUL/KI	Joan Morris	List with scientific contacts of relevant databases	none			how many should we interview?
		4	training interviewer(s)													UMCU			set of interviewers that went through test interviews	availability of interview			how many interviewers?
		5	invitations and scheduling of interviews																appointments				
		6	Conduct of GOTO interviews																data				
		7	Analysis & interpretation of data													GSK		Marianne Cunnington					
		8	Focus groups proposing reward models													UMCU	third parties and other DAPs		Series of award models to be proposed to DAPS			money for f2f meeting	are there available reward models? How many?
		9	Drafting deliverable 7.3													UMCU	SGUL / KI / iHD / EIWH GSK	SGUL Joan Morris, GSK Marianne Cunnington EUWH Rebecca Moore	report				
		10	Review of deliverable 7.3 and updates													consortium & MB							
		11	Submission to IMI													UMCU							
Task 7.2 Definition governance framework for responsible re-use of data		1	Identify, collate and compare existing instruments														i~HD, UMCU, UPPS, EFCGP, EIWH, KI, GSK, SANOFI	Sanofi Chuntao Wu	Comparative analysis				
		2	Develop collated requirements set as basis for common standard approaches																Collated requirements				
		3	Develop standard operating rules & identify common procedures																SOR document				
		4	Initiate DPIA discussions, project brief and produce high level DPIA with agreed recommendations																Initial high-level DPIA				
		5	Development of local DPIA template based on initial high-level DPIA - along with guidance on completion																Local DPIA template & guidance over completion				
		6	GDPR Compliance guidance including information security management and policy development																GDPR compliance guidance				
		7	Development of high-level DPIA recommendations into planned activities, system functions, and associated procedures																Task/ activity plan				
		8	develop information and consent procedures and templates for biobanking																Draft procedures & templates				
		9	Monitoring of local DPIA development, including advice & support																Summary analysis				
		10	2nd formal high-level DPIA draft with agreed recommendations, based on tasks achieved to date and feedback from local DPIAs																Revised high-level DPIA				
		11	D7.4 - Report on initial information and research governance for WP1-5																Initial report				
		12	Regulatory & legal horizon-scanning												+				Annual update report				
7.3 Ethical research		1	Literature study													UMC Utrecht		PhD student, Rieke, Ghislaine					
		2	Topic list interviews													UMC Utrecht	UPPS, EFGCP, EIWH, GSK, San	Rieke, Ghislaine, Marianne, Chuntao Wu					
		3	Waiver REC approval													UMC Utrecht	UPPS?	Matts?				conduct of 2nd focus group outside Netherlands, Sweden?	
		4	Interviews													UMC Utrecht		PhD student, Rieke, Ghislaine					
		5	Conceptual analysis													UMC Utrecht	UPPS	Rieke, Ghislaine, Matts, PhD stud	Report				
		6	Interim report													UMC Utrecht							
e		1	requirements analysis for catalogue													UMCG	BBMRI, UMCU	Morris, David, Petr, ???					
		2	prototype metadata model for catalogue													UMCG	UMCU	David + data manager					
		3	prototype catalogue to evaluate model													UMCG	-	Morris, David + developers					
		4	evaluate prototype with pilot datasets													UMCG	BBMRI, UMCU	David, ??? => pilots???				who will be pilots?	

Figure 1 Screenshot of the detailed work plan of WP7



conceptION
SAFETY EVIDENCE ECOSYSTEM

ConcePTION Project handbook

Disclaimer
The legal principles for the execution of the project are defined in the Grant Agreement (including the Description of Action) and the Consortium Agreement. The project handbook can act as a guide but will not replace any of the established agreements.

1

conceptION
SAFETY EVIDENCE ECOSYSTEM

Table of contents

2

Figure 2 Screenshot of the cover page and table of contents of the project handbook

Ongoing and completed communication								
Type of communication	Name conference, workshop, etc.	Contact person	Work Package	Title (if applicable)	Date	Completed/Ongoing	Link to source/output	Comment
Abstract submission								
1								
2								
...								
Participation to a conference.								
1								
2								
...								
Participation to/Organisation of a workshop (not part of a conference).								
1								
2								
...								
Participation to/Organisation of an event (not a conference or workshop)								
1								
2								
...								
Press release								
1	Press release, start of the project	Florian van der Nolle	WP8	ConcePTION; 'Building a pan-European ecosystem for gen	29-5-2019	Completed	https://www.prnewswire.com/ne	Note; consoritum members distributed the me
2								
...								
Scientific publication/research paper								
1								
2								
...								
Popularized publication (non-scientific and peer-reviewed)								
1								
2								
...								
Promotional material (flyers, posters, ...)								
1								
2								
...								
Websites and webpages								
1	ConcePTION - public webstie	Florian van der Nolle	WP8	https://www.imi-conception.eu	TBD	Ongoing	https://www.imi-conception.eu	
2	ConcePTION - member area	Florian van der Nolle	WP8	https://files.imi-conception.eu	1-4-2019	Completed	https://files.imi-conception.eu	
...								
Media (TV, Radio, Podcast, Press, etc.)								
1	Interview: statnews.com	Miriam Sturkenboom	MT	How Europe is building a sweeping system to study medi	21-6-2019	Completed	https://www.statnews.com/2019/	Based on the kick-off press release
2								
...								
Social media (active use)								
1	Twitter	Florian van der Nolle	WP8	@IMIConcePTION	19-6-2019	Completed	https://twitter.com/IMIConcePTION	
2								
...								
Other (please specify)								
1								
2								
...								

Figure 3 Screenshot of the communication and dissemination tracker

concePTION
SAFETY EVIDENCE ECOSYSTEM

ID	Date raised	WP	Risk title	Risk description (including impact description)	Likelihood	Impact	Severity	Owner	Action
R1	01 April 2019	WP1	Alignmet	There is not sufficient alignment between WP1,2 and 7 projects to provide overall recommendations across data approaches					Ongoing alignment efforts between WP1, WP2 and WP7, dialogue and outcomes task force plus statistical task force
R2	01 April 2019	WP1,2,7	Data access	Limited data access and restrictions to data access					Use a mix of data sources with different access restrictions to phase data access. Be ready with protocols early to allow time for data permissions and ethics approvals in WP7. Early assessment of access rule in Task 7.1
R3	01 April 2019	WP1,2,4	Budget	Budget constraints for demonstration studies					Select carefully and prioritise tasks in demonstration that can provide enough data for popPK analyses and prioritise tasks in each demonstration study
R4	01 April 2019	WP1,2	Divergent views	Divergent views amongst stakeholders and/ or consortium members on the framework for a pregnancy exposure data collection system or pregnancy PV model of the future					Stakeholder consultation and involvement initiated at the very start of the project to enable early identification of contentious areas that will require further discussion and arbitration
R5	01 April 2019	WP2	Failure to validate data fields	Failure of demonstration project to validate proposed data fields for prospective long-term follow-up of neurodevelopment					Stakeholder consultation to agree on approach to long term surveillance for neurobehavioral teratogens
R6	01 April 2019	WP3	Model drugs	Difficulties encountered with the model drugs selected in Task 3.1, e.g. cost and availability of model drugs, bioanalytical challenges, stability issues, etc					with comparable physicochemical properties will be pursued early on in the project. With the involvement of
R7	01 April 2019	WP3,4	Bioanalytical assays	Difficulties in developing bioanalytical assays for drugs in breast milk					Leveraging and combining expertise of multiple partners involved with experience in bioanalysis of milk samples. The consortium partners have ample and complementary expertise in the bioanalysis (including sample preparation strategies) of drugs (and their metabolites) in various complex matrices including breast milk.
									Consider cell lines that can serve as surrogates to mimic the blood-milk barrier in terms of drug passage. Initial use of transport data generated in alternative cell lines will enable to meet

Figure 4 Screenshot of the Risk Registry

Risk Documentation Form

Risk Title			
Type of Risk	Threat / Missing opportunity		
Associated Work Package			
Detection Date		Risk reporter	
Likelihood (high-medium-low)			
Impact (high-medium-low)			
Risk Owner			

Description
(Summarise the risk, indicating causes and consequences. Where possible identify the stakeholders that may be impacted). Indicate whether other Work Packages may be affected.

Risk timing and monitoring
(Summarize in what timeframe will the risk evolve, how the Risk owner will activity monitor the risk and on what frequency is interaction between the Risk Owner and MT required)

Actions to prevent/conquer the Risk
(Summarise the initial actions (to be) taken to prevent the risk of happening or to conquer an ongoing risk)

Risk progress indicators
(List indicators that the risk is becoming an increasing problem or that the risk is eliminated)