IMI2 821520 - ConcePTION

ConcePTION

WP8 – Scientific coordination, project management & sustainability

D8.1 Project management plans

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	V1.0	01 April 2019

Document History

Version	Date	Description	Non-contributor reviewers (if applicable)
V1.0	31 July 2019	First Draft	NA
V1.1	27 Aug 2019	Draft	Managing Board
V1.2	27 Aug 2019	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 progress of the project, on time, on budget, towards its planned objectives and in line with all contractual commitments. In order to fulfil the project management objective, the Project Management Office (PMO) has developed a detailed project management plan that, alongside with the Description of Action (DoA), will form the core of the project management plans for ConcePTION.

Methods

The de DoA is the detailed project plan of the consortium. This document includes all the relevant information about the project, the partners and the work packages (WPs). Also, all tasks, deliverables and milestones are described in great detail. Therefore, the DoA will be a core document for all project management activities. In addition to the DoA, the PMO developed a detailed project management plan, which is an Excel file where the current status of work will be monitored and regularly updated. The detailed project management plan consists of three sections: Tasks and Deliverable overview (Figure 1), Deliverable and Milestone tracker (Figure 2) and a Project Chart (Figure 3).

Task and Deliverable overview

The task and deliverable overview is sorted per WP and includes information on the WP-leads, the tasks and their scheduled project months and the specific task lead(s). Also, the linked deliverables and deliverable due-dates are included. Furthermore, when applicable, interdependencies on other tasks or WPs are provided.

Deliverable and Milestone tracker

The deliverable and milestone tracker is sorted on the due dates; this provides a clear overview of the upcoming deadlines and the responsible organisations. The PMO will continuously update the status of the deliverables; 'Completed', 'On track', 'On track but potential issue' and 'Attention Management Team (MT) required'. In addition to regular updates from the WPs, the PMO will send a gentle reminder to the task leads six weeks before a deliverable due date. Since all the deliverable reports of ConcePTION are public, the Managing Board (MB) has decided to review a selection of the deliverables reports before submission for quality assurance. Information on which deliverable reports will be review by the MB is also included in the tracker. The exact review procedure will be described in the D8.4 'Detailed project plan, plus tracking tools, to be maintained throughout the life of the project'.

Project chart

The project chart is a Gantt Chart displaying all tasks and subtasks for each WP. The chart is based on the detailed work plans developed by the work packages (**Fout! Verwijzingsbron niet gevonden.**). In combination with the detailed work plans from the WPs the Gantt Chart will enable the PMO to effectively monitor progress and timelines.

Discussion

No deviations from the description of work for this deliverable.

Annex

Status variables
- Completed
- Ongoing
- Delayed

Project plan — Overview work packages, deliverables and milestones
Deadlines, responsibilities and status'

WP1 Moving beyond pregnancy registries to enhance our understanding of disease-related pregnancy outcomes, medication use and safety of use during pregnancy
WP lead public: Helen Dolk (h.dolk@ulster.ac.uk)
WP lead industry: Anja Geldhof (ageldho1@its.jnj.com)

		Months	Leads	Linked Deliverable	Deadline	Status (deliverable)	Input required from	Output needed for	Notes
Task 1.1	Identifying new data sources to update the ConcePTION data source catalogue and assess its functionality for use in demonstration projects	M1-M60	ULTS, Sanofi	D1.1: Spreadsheet containing all additional data sources for the ConcePTION Data Source Catalogue	M12 - March 2020	Ongoing		Task 1.5 (potentially) D1.1 is input for WP7 (task 7.4, searchable data source catalogue)	WP7 will transform data to FAIR data source catlogue
Task 1.2	Define core data elements to allow assessment of medication utilisation and safety in pregnancy to meet regulatory requirements and standards for inclusion in product label	M1-M12	CHUT, GSK	D1.2: Report on the core data elements and analytical standards for informing HCP and patients on risks associated with exposure during pregnancy and lactation as agreed during stakeholder consultation meeting	M13 - April 2020	Ongoing		Output stakeholders meeting is input for Task 1.3 and Task 1.6	In collaboration with WP2, WP6 and WP7 multi-stakeh consultation meetings will be prepared.
Task 1.3	Develop definitions and validate proposed algorithms to identify outcomes of interest, exposure and confounders and produce background and disease-specific prevalence rates	M12-M36	SGUL, Lilly	D1.4: Report on algorithms and validations to define maternal, perinatal and childhood outcomes	M40 - July 2022		Task 1.2 WP7 (Data characterization activities will guide this task)	Task 2.2	Outcome Validation Task Force (across WP1, WP2 and will ensure compatibility and collaboration across WF
Task 1.4	Establishing medication utilisation for newly approved products	M12-M54	THL	D1.5: Submitted manuscript of a guidance document outlining standards for conducting medication utilisation studies in pregnant women (data collection and analytic standards) for established and newly marketed product	M54 - September 2023			Task 1.6	Collaboration with WP2 and WP7 to establish the best strategy and innovative methodologies
Task 1.5	Execute five demonstration projects for established and newly marketed products to tackle methodological/data source issues where progress and innovation is needed	M12-M54	UOSLO, Jan, Lilly	D1.3: Final study protocols for demonstration projects submitted to EU PAS register	M24 - March 2021		Task 1.3	Task 1.6 Task 5.2	Collaboration with WP7 in implementation of demonstration projects; back and forth process. Set up: joint statistical method working group (with W
				D1.6: Report and submitted manuscripts of all five demonstration projects	M54 - September 2023				
Task 1.6	Prepare guidance documents	M48-M60	FERR, Jan	D1.7: Submitted manuscript of a guidance document outlining standards for conducting medication safety studies based on secondary data sources in pregnancy	M54 - September 2023		Task 1.2 Task 1.4 Task 1.5 (demonstration studies) Knowledge gained from WP1 and WP2		WP6 will facilitate stakeholder consultation
				D1.8: Submitted manuscript of an overall guidance on the application of different data and analytic approaches (both primary and secondary sources) to generate evidence for medication safety in pregnancy	M60 - March 2024				

WP2: Improving the collection, analysis and interpretation of pregnancy pharmacovigilance data
WP lead public: Laura Yates (lauraashersonyates@gmail.com)
WP lead industry: David Lewis (david-1.lewis@novartis.com)

		Months	Leads	Linked Deliverable	Deadline	Status (deliverable)	Input required from	Output needed for	Notes
Task 2.1:	Information and process needs, barriers and requirements	M1-M8	UKZN	D2.1 Report on stakeholder meeting describing the model for a 21st century pregnancy data collection and signal detection system which should be able to replace traditional pregnancy registries	M8 - November 2019	Ongoing		Workshop output is input for task 2.5 and 2.6	In collaboration with WP1 prepare stakeholder worksh
Task 2.2:	Catalogue structure of industry and publicly held data sources and handling processes	M1-M16	LAREB	D2.2 Report describing the metadata model (variables) for data collection on pregnancy data sources, as basis for the catalogue collection of exposed pregnancies	M8 - November 2019	Ongoing	Using WP1 literature mining tool (task 1.3)	D2.2 is input for WP7 (task 2.4, data source catalogue)	Collaboration with WP7

Tasks and linked Deliverables | Deliverable and Milestone track | Project Chart | Project months

Figure 1 Screenshot of the Task and Deliverable overview

Work Package	Deliverable	Description	Month	Due Date		Deliverable status	Task lead	Review by MB	Comments
WP8	D8.1	Project management plans	2	May 2019	🟢	On track	UMCU	Yes	Slight delay, due to required input from other WPs Expected date: End July/Begin August
WP7	D7.18	Report confirming that all the relevant documents for using, producing or collecting human cells or tissues (e.g., ethics approval, import licence, accreditation/designation/authorisation/licensing) prior to the start of the research activity raising ethics issue and that they are kept on file	3	June 2019	🟢	On track	UMCU	No	
WP7	D7.22	Report confirming that all the relevant documents for using animal experiments (WP3) prior to the start of the research activity raising ethics issue and that they are kept on file	3	June 2019	🟢	On track	UMCU	No	
WP8	D8.2	Collaborative website (intranet)	3	June 2019	✅	Completed	UMCU	No	Uploaded in portal
WP1	M1.1	First Joint Workshop with WP1,2,7	3	June 2019	✅	Completed	-		Workshop took place in Basel, 3-4 June 2019 --> signed off in portal
WP8	M8.1	Successful launch of project	3	June 2019	🟢	On track	UMCU	-	Project plans and website are part of the deliverable, still to be completed. In justification, include the month in wich the different parts were ready.
WP8	D8.3	Contact database (stakeholders and key project contacts)	4	July 2019	✅	Completed	UMCU	No	Internal contact database completed. Contact list wil be a living document and along the course of the project the stakeholder database will be created/added.
WP8	D8.4	Detailed project plan, plus tracking tools, to be maintained throughout the life of the project	4	July 2019	🟢	On track	UMCU	No	
WP8	D8.5	Data Management Plan	4	July 2019	🟡	On track, but potential issu	UMCU	Yes	
WP3	D3.1	Report on scope and limitations of in vivo and in vitro non-clinical and computational models for drug milk excretion and breastfed infant exposure; Selection of a panel of at least 10 model compounds for initial evaluation of non-clinical models	6	September 2019	🟢	On track	KUL	Yes	First work on task 3.1 has started
WP7	D7.1	User requirements and meta-data model for the FAIR data catalogue from WP1&2	6	September 2019	🟢	On track	BBMRI-ERIC	Yes	
WP7	D7.2	Description of the operational platform for data sharing and task management plus instructions	6	September 2019	🟢	On track	UMCU	Yes	
WP8	D8.6	Public website and social media plan	6	September 2019	🟢	On track	UMCU	Yes	Website ongoing, Social Media to start
WP8	D8.7	Additional third party selection procedure description	6	September 2019	🟡	On track, but potential issu	UMCU	No	
WP2	D2.1	Report on stakeholder meeting describing the model for a 21st century pregnancy data collection and signal detection system which should be able to replace traditional pregnancy registries	8	November 2019	🟢	On track	UKZN	Yes	
WP2	D2.2	Report describing the metadata model (variables) for data collection on pregnancy data sources, as basis for the catalogue collection of exposed pregnancies	8	November 2019	🟢	On track	LAREB	Yes	
WP3	D3.2	Report on lactation characteristics of animal species (rodent, rabbit, (mini)pig, dog, non-human primate, etc.; anatomy/histological structures, milk composition, duration of lactation, etc.); Selection of the animal species to be used in in vivo studies	9	December 2019	🟢	On track	UNIBO, TEVA	Yes	
WP7	M7.2	Draft governance models for WP1-5 ready	9	December 2019				-	
WP1	M1.2	Workshop on core data elements (Task 1.2)	10	January 2020				-	
WP1	D1.1	Spreadsheet containing all additional data sources for the ConcePTION Data Source Catalogue	12	March 2020	🟢	On track	ULTS, Sanofi	Yes	
		Report describing existing coding systems, schemes and							

Figure 2 Screenshot of the Deliverable and Milestone Tracker

Figure 3 Screenshot of the Project Chart