



IMI2 821520 - ConcePTION

ConcePTION

WP8 – Scientific coordination, project management & sustainability

D8.1 Project management plans

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Deliverable type	R
Dissemination level	PU

Description of Work	Version	Date
	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



821520 - ConcePTION - D8.1



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

			-	-					
A	В	С	D	E	F	G	H	I	J
- '						Status variables			
						Completed			
						Ongoing			
						Delayed			
						Delayed			
⊢ て.	SAFETY EVIDENCE ECOSYSTEM								
Project pla	 Overview work packages, deliverables and milestones 								
	, responsibilities and status								
	, responsibilities and status								
WP1 Movi	ng beyond pregnancy registries to enhance our understanding of disease-related pregnanc	cy outcomes, m	nedication use and	I safety of use during pregnancy					
WP lead p	ublic: Helen Dolk (h.dolk@ulster.ac.uk)								
	ndustry: Anja Geldhof (ageldho1@its.jnj.com)								
in icuar	ladday, Anja delanor (ageranor englishing)	Months	Leads	Linked Deliverable	Deadline	Caraban (dallarandala)	In such as a submediate of the sum	Output and ad fee	Notes
		wonths	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							Task 1.5 (potentially)	
	and assess its functionality for use in demonstration projects							D1.1 is input for WP7 (task	
				D1.1: Spreadsheet containing all additional data sources for				7.4, searchable data source	
		M1-M60	ULTS Sanofi	the ConcePTION Data Source Catalogue	M12 - March 2020	Ongoing		catalogue)	WP7 will transform data to FAIR data source catlogu
Tech 1.2	Define core data elements to allow assessment of medication utilisation and	1112 11100	oers, sunon		W122 W101CH 2020	ongoing		corologue,	with with data to FAIN data source catloga
				D1.2: Report on the core data elements and analytical					
	safety in pregnancy to meet regulatory requirements and standards for inclusion	1		standards for informing HCP and patients on risks associated				Output stakeholders meeting	
	in product label			with exposure during pregnancy and lactation as agreed				is input for Task 1.3 and Task	In collaboration with WP2, WP6 and WP7 multi-stak
		M1-M12	CHUT, GSK	during stakeholder consultation meeting	M13 - April 2020	Ongoing		1.6	consultation meetings will be prepared.
Task 1.3	Develop definitions and validate proposed algorithms to identify outcomes of						Task 1.2		
	interest, exposure and confounders and produce background and disease-			D1.4: Report on algorithms and validations to define			WP7 (Data characterization		Outcome Validation Task Force (across WP1, WP2 ar
	specific prevalence rates	M12-M36	SGUL, Lilly	maternal, perinatal and childhood outcomes	M40 - July 2022		activities will guide this task)	Task 2.2	will ensure compatibility and collaboration across
Task 1.4	Establishing medication utilisation for newly approved products			D1.5: Submitted manuscript of a guidance document outlining					
				standards for conducting medication utilisation studies in					
				pregnant women (data collection and analytic standards) for					Collaboration with WP2 and WP7 to establish the be
		M12-M54	THL	established and newly marketed product	M54 - September 202	2		Task 1.6	strategy and innovative methodologies
Tech 1.C	Francisco di un deservazione e contrato della contrato i la contrato di secolo e contrato di	1012-1054	1116	established and newly marketed product	wow september 202	5		1038 1.0	
	Execute five demonstration projects for established and newly marketed							L	Collaboration with WP7 in implementation of
	products to tackle methodological/data source issues where progress and		UOSLO, Jan,	D1.3: Final study protocols for demonstration projects				Task 1.6	demonstration projects; back and forth process.
	innovation is needed	M12-M54	Lilly	submitted to EU PAS register	M24 - March 2021		Task 1.3	Task 5.2	Set up: joint statistical method working group (with
				D1.6: Report and submitted manuscripts of all five					
				demonstration projects	M54 - September 202	3			
Tack 1.6	Prepare guidance documents						Task 1.2		
1038 1.0	riepare guidance documents						Task 1.4		
				D1.7: Submitted manuscript of a guidance document outlining			Task 1.5 (demonstration studies)		
				standards for conducting medication safety studies based on			Knowledge gained from WP1 and		
		M48-M60	FERR, Jan	secondary data sources in pregnancy	M54 - September 202	3	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: Impr	oving the collection, analysis and interpretation of pregnancy pharmacovigilance data								
	ublic: Laura Yates (lauraashersonyates@gmail.com)								
WP lead i	ndustry: 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			D2.1 Report on stakeholder meeting describing the model for					
				a 21st century pregnancy data collection and signal detection					
								Markelan average in the state	
				system which should be able to replace traditional				Workshop output is input for	
		M1-M8	UKZN	pregnancy registries	M8 - November 2019	Ongoing		task 2.5 and 2.6	In collaboration with WP1 prepare stakeholder wo
Task 2.2:	Catalogue structure of industry and publicly held data sources and handling			D2.2 Report describing the metadata model (variables) for					
	processes			data collection on pregnancy data sources, as basis for the			Using WP1 literature mining tool	D2.2 is input for WP7 (task	
	processes	841 841C							
	piceses	M1-M16	LAREB	catalogue collection of exposed pregnancies	M8 - November 2019	Ongoing	(task 1.3)	2.4, data source catalogue)	Collaboration with WP7

Figure 1 Screenshot of the Task and Deliverable overview



Work Package	Deliverable	Description	Month 🗸	Due Date	-	 Deliverable status 	💌 Task lead	Review by MB	Comments		
					•				Slight delay, due to required input from other WPs		
WP8	D8.1	Project management plans	2	May 2019	-	On track	UMCU	Yes	Expected date: End July/Begin August		
		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									
WP7	D7.18	that they are kept on file	3	June 2019		On track	UMCU	No			
		Report confirming that all the relevant documents for using	,								
		animal experiments (WP3) prior to the start of the research			•						
WP7	D7.22	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	0	Completed	UMCU	No	Uploaded in portal		
WP1	M1.1	First Joint Workshop with WP1.2.7	3	June 2019		Completed	UNICO	-	Workshop took place in Basel, 3-4 June 2019> signed off in portal		
VVPI	1/11.1	Prist Joint Workshop with WP1,2,7	5	June 2019		completed		-	Project plans and website are part of the deliverable, still to be completed. In		
WP8	M8.1	Our second all second and second s	3	June 2019	0	On track	UMCU				
WP8	M8.1	Successful launch of project	5	June 2019		Un track	UNICU	-	justification, include the month in wich the different parts were ready.		
					0				Internal contact database completed. Contact list will be a living document and along the		
WP8	D8.3	Contact database (stakeholders and key project contacts)	4	July 2019		Completed	UMCU	No	course of the project the stakeholder database will be created/added.		
		Detailed project plan, plus tracking tools, to be maintained			•						
WP8	D8.4	throughout the life of the project	4	July 2019		Un track	UMCU	No			
WP8	D8.5	Data Management Plan	4	July 2019	0	On track, but potentia	l issi UMCU	Yes			
		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-									
WP3	D3.1	clinical models	6	September 20	19	On track	KUL	Yes	First work on task 3.1 has started		
		User requirements and meta-data model for the FAIR data									
WP7	D7.1	catalogue from WP1&2	6	September 20	19	On track	BBMRI-ERIC	Yes			
		Description of the operational platform for data sharing			-						
WP7	D7.2	and task management plus instructions	6	September 20	19	On track	UMCU	Yes			
WP8	D8.6	Public website and social media plan	6	September 20	19 🔘	On track	UMCU	Yes	Website ongoing, Social Media to start		
WP8	D8.7	Additional third party selection procedure description	6	September 20			l issi UMCU	No			
		Report on stakeholder meeting describing the model for a									
		21st century pregnancy data collection and signal									
		detection system which should be able to replace			•						
WP2	D2.1	traditional pregnancy registries	8	November 20	19	On track	UKZN	Yes			
		Report describing the metadata model (variables) for data									
		collection on pregnancy data sources, as basis for the			•						
WP2	D2.2	catalogue collection of exposed pregnancies	8	November 20		On track	LAREB	Yes			
VVF2	02.2	Report on lactation characteristics of animal species	0	November 20	19	Officials	DANED	165			
		(rodent, rabbit, (mini)pig, dog, non-human primate, etc.;									
					•						
		anatomy/histological structures, milk composition,									
		duration of lactation, etc.); Selection of the animal species									
WP3	D3.2	to be used in in vivo studies	9	December 20		On track	UNIBO, TEVA	Yes			
WP7	M7.2	Draft governance models for WP1-5 ready	9	December 20				-			
WP1	M1.2	Workshop on core data elements (Task 1.2)	10	January 2020				-			
		Spreadsheet containing all additional data sources for the			•						
WP1	D1.1	ConcePTION Data Source Catalogue	12	March 2020		On track	ULTS, Sanofi	Yes			
1		Report describing existing coding systems, schemes and									

Figure 2 Screenshot of the Deliverable and Milestone Tracker



A	В	С	D	E	F	G	н	I .	I K	L		N O	P	Q	R S	T	U	V	N X		Z AA	AB	AC	AD	AE	AF AC	a AF	H AI	AJ			AM	AN
							Į				Yea									Year 2										Yea			
							apr-19 me	i-19 jur	n-19 jul-	19 aug-1	9 sep-19	okt-19 nov	-19 dec-1	19 jan-20	feb-20 mrt-	20 apr-2	0 mei-20	jun-20 ju	I-20 aug-20	sep-20 ok	t-20 nov-2	0 dec-20	jan-21	feb-21 m	nrt-21 a	pr-21 mei	-21 jun-	-21 jul-2	1 aug-21	sep-21	okt-21 r	nov-21 d	ec-21 ja
							1	2	3	4	5 6	7	8	9 10	11	12 1	3 14	15	16 17	18	19 2	0 21	22	23	24	25	26	27 2	8 29	30	31	32	33
rk Package 1	Task	Sub-task	Deliverable	Leads	Start Month	End Month																											
	Task 1.1		D1.1	ULST / JA	M1	M60									D1.	.1																	
1		1.1.1		ULST	M1	M1																											
1		1.1.2			M1	M6																											
1		1.1.3			M1	M6							-•																				
1		1.1.4			M3	M3																											
1		1.1.5		NIHW, F		M3																											
1		1.1.6			M3	M3																											
1		1.1.7			M3	M3																											
1		1.1.7		USWAN		M3																											
1		1.1.8		UNEWC /		M3																											
1		1.1.9		INSERM		M3				-																							
-						M3																											
1		1.1.11			M3																												
-		1.1.12			M3	M3																											
1		1.1.13		Each par		M3																											
1		1.1.14			M4	M6																											
1		1.1.15		Maria Lo		M12																											
1		1.1.16		Maria Lo		M6																											
	Task 1.2		D1.2	CHUT, GS		M13										D1.2																	
1		1.2.1			M1	M3																											
1		1.2.2			M3	M11																											
1		1.2.3			M3	M11																											
1		1.2.4			M3	M11																											
1		1.2.5			M3	M11																											
1		1.2.6			M3	M12																											
1	Task 1.3		D1.4	SGUL, Lil	M12	M36																											
1	Task 1.4		D1.5	THL	M12	M54																											
1	Task 1.5		D1.3 / D1.6	UOSLO, J	M12	M54																				D1.3							
1	Task 1.6		D1.7 / D1.8	FERR, Jar	M48	M60																											
2 .	Task 2.1		D2.1	UKZN	M1	M8						D2.	.1																				
2 *	Taks 2.2	[D2.2 / D2.4 /D2.6	LAREB	M1	M16						D2	.2						2.4	D2.6													
2 '	Task 2.3		D2.3 / D2.7	UMAN	M1	M36									D2.	.3									D2.3								
2		2.3.1			M1	M12																											
							-																										
		2.3.2			M1	M36																											
2		2.3.2	D2.8	LAREB	M1 M6	M36 M12																			D2.8								
2	Taks 2.4	2.3.2	D2.8		M6	M12												D	2.5						D2.8								
2 2 1 2 1	Taks 2.4 Task 2.5	2.3.2	D2.5 / D2.9	LAREB	M6 M12	M12 M48												D	2.5						D2.8								
2 2 1 2 1 2 1 2 1	Taks 2.4 Task 2.5 Task 2.6	2.3.2		LAREB NUTH	M6 M12 M36	M12 M48 M48												D	2.5						D2.8								
2 2 1 2 1 2 1 2 1 2 1	Taks 2.4 Task 2.5 Task 2.6 Task 2.7	2.3.2	D2.5 / D2.9 D2.10	LAREB NUTH NUTH	M6 M12 M36 M48	M12 M48 M48 M54					D3.1		D3.0					D	2.5						D2.8								
2 2 1 2 1 2 1 2 1 2 1	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1		D2.5 / D2.9 D2.10	LAREB NUTH NUTH UNIBO,Te	M6 M12 M36 M48 M1	M12 M48 M48 M54 M6					D3.1		D3.2	2				D	2.5						D2.8								
2 2 1 2 1 2 1 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1	D2.5 / D2.9 D2.10	LAREB NUTH NUTH UNIBO,Te UNIBO,Te	M6 M12 M36 M48 M1 M4	M12 M48 M48 M54 M6 M6					D3.1		D3.2	2					2.5						D2.8								
2 2 1 2 1 2 1 3 3 3 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2	D2.5 / D2.9 D2.10	LAREB NUTH NUTH UNIBO,Te UNIBO,Te UNIBO,Te	M6 M12 M36 M48 M1 M4 M4 M4	M12 M48 M48 M54 M6 M6 M9					D3.1		D3.2	2					2.5						D2.8								
2 2 2 1 2 1 3 3 3 3 3 3 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3	D2.5 / D2.9 D2.10	LAREB NUTH NUTH UNIBO,Te UNIBO,Te UNIBO,Te	M6 M12 M36 M48 M1 M4 M7 M7	M12 M48 M54 M6 M6 M9 M12					D3.1		D3.2						2.5						D2.8								
2 2 7 2 7 3 3 3 3 3 3 3 3 3 3 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3 3.1.4	D2.5 / D2.9 D2.10	LAREB NUTH NUTH UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te	M6 M12 M36 M48 M1 M4 M7 M7 M7 M10	M12 M48 M48 M54 M6 M6 M9 M12 M12					D3.1		D3.2												D2.8								
2 2 2 7 2 7 3 7 3 3 3 3 3 3 3 3 3 3 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3	D2.5 / D2.9 D2.10 D3.1 / D3.2	LAREB NUTH NUTH UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te	M6 M12 M36 M48 M1 M4 M7 M7 M7 M10 M6	M12 M48 M48 M54 M6 M6 M9 M12 M12 M9					D3.1		D3.2												D2.8								
2 2 2 7 2 7 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3 3.1.4 3.1.5	D2.5 / D2.9 D2.10 D3.1 / D3.2	LAREB NUTH NUTH UNIBO, Te UNIBO, Te UNIBO, Te UNIBO, Te UNIBO, Te KUL, NVS	M6 M12 M36 M48 M1 M4 M7 M7 M7 M10 M6 M4	M12 M48 M48 M54 M6 M6 M9 M12 M12 M9 M48					D3.1		D3.2						2.5		3.3				D2.8								
2 2 2 7 2 7 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Taks 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3 3.1.4 3.1.5 3.2.1	D2.5 / D2.9 D2.10 D3.1 / D3.2	LAREB NUTH NUTH UNIBO, Te UNIBO, Te UNIBO, Te UNIBO, Te UNIBO, Te KUL, NVS KUL, NVS	M6 M12 M36 M48 M1 M7 M7 M7 M10 M6 M4 M7	M12 M48 M54 M6 M6 M12 M12 M12 M12 M12 M12 M12 M12					D3.1		D3.4								3.3				D2.8								
2 2 2 7 2 7 3 3 3 3 3 3 3 3 3 3 3 3 3 3	Task 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3 3.1.4 3.1.5 3.2.1 3.2.2	D2.5 / D2.9 D2.10 D3.1 / D3.2	LAREB NUTH UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te KUL, NVS KUL, NVS KUL, NVS	M6 M12 M36 M48 M1 M4 M7 M7 M10 M6 M4 M4 M7 M7	M12 M48 M48 M54 M6 M6 M9 M12 M12 M9 M48					D3.1		D3.4								3.3				D2.8								
2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3	Task 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3 3.1.4 3.1.5 3.2.1	D2.5 / D2.9 D2.10 D3.1 / D3.2 D3.3 / D3.4	LAREB NUTH NUTH UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te KUL, NVS KUL, NVS KUL, NVS	M6 M12 M36 M48 M1 M4 M7 M7 M7 M6 M4 M7 M7 M7	M12 M48 M48 M54 M6 M9 M12 M12 M12 M9 M48 M12 M12 M12					D3.1		D3.2								3.3				D2.8								
2 2 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3	Task 2.4 Task 2.5 Task 2.6 Task 2.7 Task 3.1	3.1.1 3.1.2 3.1.3 3.1.4 3.1.5 3.2.1 3.2.2	D2.5 / D2.9 D2.10 D3.1 / D3.2 D3.3 / D3.4	LAREB NUTH UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te UNIBO,Te KUL, NVS KUL, NVS KUL, NVS	M6 M12 M36 M48 M1 M7 M7 M7 M7 M10 M6 M4 M7 M7 M4 M4	M12 M48 M54 M6 M6 M12 M12 M12 M12 M12 M12 M12 M12					D3.1		D3.2								13.3				D2.8								

Figure 3 Screenshot of the Project Chart