

## FWO DMP Template - Flemish Standard Data Management Plan

### Version KU Leuven

Project supervisors (from application round 2018 onwards) and fellows (from application round 2020 onwards) will, upon being awarded their project or fellowship, be invited to develop their answers to the data management related questions into a DMP. The FWO expects a **completed DMP no later than 6 months after the official start date** of the project or fellowship. The DMP should not be submitted to FWO but to the research co-ordination office of the host institute; FWO may request the DMP in a random check.

At the end of the project, the **final version of the DMP** has to be added to the final report of the project; this should be submitted to FWO by the supervisor-spokesperson through FWO's e-portal. This DMP may of course have been updated since its first version. The DMP is an element in the final evaluation of the project by the relevant expert panel. Both the DMP submitted within the first 6 months after the start date and the final DMP may use this template.

The DMP template used by the Research Foundation Flanders (FWO) corresponds with the Flemish Standard Data Management Plan. This Flemish Standard DMP was developed by the Flemish Research Data Network (FRDN) Task Force DMP which comprises representatives of all Flemish funders and research institutions. This is a standardized DMP template based on the previous FWO template that contains the core requirements for data management planning. To increase understanding and facilitate completion of the DMP, a standardized **glossary** of definitions and abbreviations is available via the following [link](#).

1. General Project Information	
Name Grant Holder & ORCID	Anne Smits, ORCID 0000-0002-0710-6698
Contributor name(s) (+ ORCID) & roles	Not applicable
Project number <sup>1</sup> & title	Personalized pharmacotherapy in neonates: from (patho)physiology to innovative pharmacokinetic and pharmacodynamic tools
Funder(s) GrantID <sup>2</sup>	FWO, Senior Clinical Investigator, 18E2H24N
Affiliation(s)	<input checked="" type="checkbox"/> KU Leuven <input type="checkbox"/> Universiteit Antwerpen <input type="checkbox"/> Universiteit Gent <input type="checkbox"/> Universiteit Hasselt <input type="checkbox"/> Vrije Universiteit Brussel <input type="checkbox"/> Other: ROR identifier KU Leuven: 05f950310

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<sup>1</sup> "Project number" refers to the institutional project number. This question is optional. Applicants can only provide one project number.

<sup>2</sup> Funder(s) GrantID refers to the number of the DMP at the funder(s), here one can specify multiple GrantIDs if multiple funding sources were used.

Please provide a short project description	<p>In Flanders 8834 of all 63899 live-born neonates (14%) needed a neonatal or neonatal intensive care unit admission in 2021, because of prematurity, adaptation, critical illness, infections, or congenital malformations. Drugs play a pivotal role in the care of these highly vulnerable patients, but have been introduced without standard regulatory drug development process. Consequently the neonate remains a ‘therapeutic orphan’. Lack of evidence-based drug dosing and physiological immaturity make it challenging to predict pharmacokinetics (PK, drug concentration-time relation) and pharmacodynamics (PD, drug concentration–effect relation) in the individual neonate. This puts neonates at risk for toxicity or therapy failure. The goal of my proposal is to reach personalized pharmacotherapy, by developing and applying innovative, predictive PK and PD modeling tools for 3 clinical settings: 1) a translational physiology-based PK model for perinatal asphyxia treated with cooling, 2) an electronic-health record embedded model-informed precision dosing tool for vancomycin in neonatal sepsis, and 3) a bedside neuromonitoring PD tool for integrated PKPD models in neonatal respiratory failure. These new tools have in common that implementation of documented key PK and PD covariates and biomarkers in dose predictions will result in improved target attainment and clinical outcomes in neonates. The workflow generated can also serve to support dosing for other drugs or neonatal subpopulations.</p>
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## 2. Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data <sup>3</sup>.

Dataset Name	Description	New or Reused	Digital or Physical	ONLY FOR DIGITAL DATA	ONLY FOR DIGITAL DATA	ONLY FOR DIGITAL DATA	ONLY FOR PHYSICAL DATA
				Digital Data Type	Digital Data Format	Digital Data Volume (MB, GB, TB)	Physical Volume
WP1 (PBPK)	In vitro experimental	<input checked="" type="checkbox"/> Generate new data <input type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input type="checkbox"/> Audiovisual <input checked="" type="checkbox"/> Images <input type="checkbox"/> Sound <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual <input type="checkbox"/> Model <input type="checkbox"/> Software <input type="checkbox"/> Other:	.xlsx, .csv, .doc, .pdf, .txt	<input type="checkbox"/> < 1 GB <input checked="" type="checkbox"/> < 100 GB <input type="checkbox"/> < 1 TB <input type="checkbox"/> < 5 TB <input type="checkbox"/> > 5 TB <input type="checkbox"/> NA	
	In vivo observational	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	<input checked="" type="checkbox"/> Images <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual	.xlsx, .csv, .doc, .txt	<input checked="" type="checkbox"/> < 100 GB	Blood-and urine samples of minipigs and humans (e.g. human blood 0.5 mL/sample; urine 5 mL/sample)
	Simulated data	<input checked="" type="checkbox"/> Generate new data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input checked="" type="checkbox"/> Images <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual <input checked="" type="checkbox"/> Model	.xlsx, .csv, .doc, .pdf, .txt, .R, simulation software specific formats (e.g. PK-Sim)	<input checked="" type="checkbox"/> < 100 GB	

<sup>3</sup> Add rows for each dataset you want to describe.

<b>WP2 (MIPD)</b>	In vivo experimental and observational	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	<input checked="" type="checkbox"/> Images <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual	.xlsx, .csv, .doc, .pdf, .txt	<input checked="" type="checkbox"/> < 100 GB	Remnants of blood samples from routine clinical care. Plasma will be stored (0.2 mL/sample)
	Simulated data	<input checked="" type="checkbox"/> Generate new data <input checked="" type="checkbox"/> Reuse existing data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input checked="" type="checkbox"/> Images <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual <input checked="" type="checkbox"/> Model	.xlsx, .csv, .doc, .pdf, .txt, .R, simulation software specific formats	<input checked="" type="checkbox"/> < 100 GB	
<b>WP3 (PKPD)</b>	In vivo experimental and observational, and time-logged extracted central-server data	<input checked="" type="checkbox"/> Generate new data	<input checked="" type="checkbox"/> Digital <input checked="" type="checkbox"/> Physical	<input checked="" type="checkbox"/> Images <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual <input checked="" type="checkbox"/> Audiovisual	.xlsx, .csv, .doc, .pdf, .txt, .EDF (EEG)	<input checked="" type="checkbox"/> < 100 GB	Remnants of blood samples from routine clinical care. Plasma will be stored (0.2 mL/sample)
	Simulated data	<input checked="" type="checkbox"/> Generate new data	<input checked="" type="checkbox"/> Digital <input type="checkbox"/> Physical	<input checked="" type="checkbox"/> Images <input checked="" type="checkbox"/> Numerical <input checked="" type="checkbox"/> Textual <input checked="" type="checkbox"/> Model	.xlsx, .csv, .doc, .pdf, .txt, .R, simulation software specific formats	<input checked="" type="checkbox"/> < 100 GB	

**GUIDANCE:**

*The data description forms the basis of your entire DMP, so make sure it is detailed and complete. It includes digital and physical data and encompasses the whole spectrum ranging from raw data to processed and analysed data including analysis scripts and code. Physical data are all materials that need proper management because they are valuable, difficult to replace and/or ethical issues are associated. Materials that are not considered data in an RDM context include your own manuscripts, theses and presentations; documentation is an integral part of your datasets and should be described under documentation/metadata.*

[RDM Guidance on data](#)

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type.

- PharmaCool and Albino study datasets with in vivo observational data will be reused in WP1. EC approval and data transfer agreements (DTA) for reuse are available, and the FAIR principles for scientific data management will be applied (<https://www.go-fair.org/fair-principles>).
- The PharmaCool study protocol is published as DOI: 10.1186/1471-2431-12-45 (PMID: 22515424), and the Albino trial study protocol as DOI: 10.1186/s12887-019-1566-8 (PMID: 31248390).

<p>Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.</p>	<p><input checked="" type="checkbox"/> Yes, human subject data; provide SMEC or EC approval number:  <b>WP1:</b> EC Research UZ Leuven,  <ul style="list-style-type: none"> <li>▪ S64850 (approval 15/02/2021)</li> <li>▪ AMEND-Id: 001 (approval 14/10/2022)</li> </ul> <b>WP2:</b> EC submission documents are in preparation   <b>WP3:</b> Doxa-trial, EC Research UZ Leuven, EudraCT-nr 2019-003666-41,  <ul style="list-style-type: none"> <li>▪ S63834 (approval 16/04/2021, 22/04/2021)</li> <li>▪ AMEND-Id 0001 notification only</li> <li>▪ AMEND-Id 0002 (approval 25/03/2022)</li> <li>▪ AMEND-Id 0003 notification only</li> </ul> Dexmedetomidine trial, EC submission documents are in preparation</p> <p><input checked="" type="checkbox"/> Yes, animal data; provide ECD reference number:  <b>WP1:</b> ECD U Antwerpen, 2020-62 (approval 17/12/2020)</p> <p><input type="checkbox"/> Yes, dual use; provide approval number:  <input type="checkbox"/> No  Additional information:</p>
<p>Will you process personal data<sup>4</sup>? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).</p>	<p><input checked="" type="checkbox"/> Yes (provide PRET G-number or EC S-number below)  <input type="checkbox"/> No  Additional information: S-numbers already obtained are S64850 (WP1) and S63834 (WP3).  In both studies personal data will be collected e.g. name, birth date, birth weight, current weight, gestational age, postnatal age, postmenstrual age, diagnosis on admission, co-medication of included neonates. Data will be pseudonymized. Inclusion of neonates is only possible after informed written parental consent, and in agreement with the General Data Protection Regulation.</p>

<sup>4</sup> See Glossary Flemish Standard Data Management Plan

<p>Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, ...)?</p> <p>If so, please comment per dataset or data type where appropriate.</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>If yes, please comment:</p>
<p>Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material/Data transfer agreements, research collaboration agreements)?</p> <p>If so, please explain to what data they relate and what restrictions are in place.</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If yes, please explain:</p> <ul style="list-style-type: none"> <li>- Data transfer, data sharing and data analyses of PharmaCool or ALBINO datasets for reuse in the I-PREDICT project (WP1), will occur according to DTA between PharmaCool or ALBINO and I-PREDICT PI/Researchers. PharmaCool and ALBINO remain owner of these original datasets.</li> <li>- Also for data sharing as part of the neuromonitoring substudy of the Doxa-trial (WP3), DTA will be provided.</li> </ul>
<p>Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use?</p> <p>If so, please explain to what data they relate and which restrictions will be asserted.</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p>If yes, please explain:</p> <p>Concerning data ownership, cfr. response mentioned to the previous question.</p>

### 3. Documentation and Metadata



<p>Clearly describe what approach will be followed to capture the accompanying information necessary to keep <b>data understandable and usable</b>, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, Codebook.tsv etc. where this information is recorded).</p> <p><a href="#"><i>RDM guidance on documentation and metadata.</i></a></p>	<p><b>Documentation</b></p> <ul style="list-style-type: none"> <li>▪ <b><u>In vitro (WP1)</u></b>: Documentation of the in vitro experiments by the PhD students involved in WP1 will consist of notes in the laboratory notebook that refer to specific experiments and datasets. These notes will describe and document the experimental set-up, biological samples used (certificates of in vitro systems), protocols used, and the names of the respective databases. Initials of the person who conducted the experiments will be noted.</li> <li>▪ <b><u>In vivo human documentation (WP1, WP2, WP3)</u></b>: Research methods and practices (including sampling material, volumes, timing, bioanalytical methods used etc) will be documented in the study protocols as word files (EC templates), and additional study SOPs (Standard Operating Procedures) where needed. The same holds true for vital signs collection, near-infrared spectroscopy (NIRS) and electroencephalography, (a)EEG, data collections in WP 3. A blank copy of the informed consent form will also be stored.</li> <li>▪ <b><u>In vivo animal documentation (WP1)</u></b>: Research methods and practices (including sampling material, volumes, timing, bioanalytical methods used etc) will be documented in the study protocols as word files (EC templates), and additional study SOPs (Standard Operating Procedures) where needed. Additionally, data sheet with clinical parameters monitored during experiments will be completed.</li> <li>▪ <b><u>Software (WP1, WP2, WP3)</u></b>: Models, algorithms, scripts and software usage (e.g. PBPK software in WP1) will be documented in e-notebook / logbook by the PhD students involved. Final versions of algorithms and scripts will be implemented in manuscripts / research papers, and the PBPK models of WP1 may be provided in open source platforms e.g. Github (<a href="http://github.com/Open-Systems-Pharmacology">http://github.com/Open-Systems-Pharmacology</a>).</li> <li>▪ <b><u>General (WP1, WP2, WP3)</u></b>: All databases (e.g. excelfiles) will contain definitions of variables and units in a legend section to make it easy and uniform to understand. For prospective clinical studies, REDCAP (WP1, WP2) or Castor (WP3, DOXA-trial) will be used as electronic case report form (eCRF), from which excelfiles can be generated. Excelfiles as well as other documentation that needs to be accessible to dedicated research team members will be stored on shared, but pass-word protected, drives like the KU Leuven J-drive. The latter has currently been installed for the I-PREDICT project (WP1).</li> </ul>
<p>Will a metadata standard be used to make it easier to <b>find and reuse the data</b>?</p> <p>If so, please specify which metadata standard will be used. If not, please specify which</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p>If yes, please specify (where appropriate per dataset or data type) which metadata standard will be used:</p> <p>If no, please specify (where appropriate per dataset or data type) which metadata will be created:</p>

metadata will be created to make the data easier to find and reuse.

*REPOSITORIES COULD ASK TO DELIVER METADATA IN A CERTAIN FORMAT, WITH SPECIFIED ONTOLOGIES AND VOCABULARIES, I.E. STANDARD LISTS WITH UNIQUE IDENTIFIERS.*

### Metadata

- The PRIDE metadata standards will be used **for proteomics data** in WP1:
  - <http://www.dcc.ac.uk/resources/implementations/pride-proteomics-identifications-database>
- **For in vitro data for human neonatal & animal research** in WP1, no metadata standards are available. The in vitro databases will contain the following metadata (some examples, not exhaustive, the full list will be available in the resulting publications):
  - In vitro model system: species, type (suspended/cultured hepatocytes, microsomes, S9 fractions), protein content (mg/mL), cell density (million cells/mL), other donor-specific characteristics (if applicable and available, e.g. specific enzyme activities, number of donors pooled,...)
  - Experimental conditions: model drug, incubation time, incubation concentration, sample volume, incubation temperature, extracellular protein content (type/concentration), sampling scheme, number of replicates.
  - Samples generated: type (activity/abundance), volumes, dilutions, processing steps (centrifugation, filtration or precipitation,...)
  - Endpoints: Activities towards model drugs (uptake and/or metabolic rates or clearance values normalised for protein content or number of cells, protein abundances (pmol/mg protein).
- **For clinical data in the field of neonatal pharmacology**, in WP1, WP2, WP3, no predefined metadata standards are available. The databases on human subjects will contain the following metadata (some examples, not exhaustive, the full list will be available in the resulting publications):
  - Patient: study ID, gestational age (GA), postnatal age (PNA), postmenstrual age (PMA), birth weight (BW), current weight (CW), diagnosis on admission.
  - Biomarkers: sampling time, concentration in blood (e.g. 4β-OHC, ng/ml) for WP1. For each biomarker (WP1, WP2) this information will be documented.
  - Drug: dose, date and time of administration, route and rate of administration, sampling time, concentration in blood (WP1, WP2, WP3).
  - Biochemical data: e.g. albuminemia (g/L), creatininemia (mg/dL), total bilirubin (mg/dL), direct bilirubin (mg/dL), ...
  - Clinical data: e.g. respiratory support (yes/no), mechanical ventilation (yes/no), sepsis (no/suspected/confirmed), co-medication.
- **For animal pharmacology research** in WP1, no metadata standards are available. The databases on

	<p>animal studies will contain the following metadata (some examples, not exhaustive, the full list will be available in the resulting publications):</p> <ul style="list-style-type: none"> <li>➤ Animal: Animal ID, postnatal day (PND), birth weight (BW), terminal weight (TW).</li> <li>➤ Biomarkers: sampling time, concentration in blood (e.g. 4β-OHC, ng/ml) for WP1. For each biomarker (WP1) this information will be documented.</li> <li>➤ Drug: dose, date and time of administration, route and rate of administration, sampling time, plasma concentration.</li> <li>➤ Biochemical data: e.g. blood glucose levels, blood gas analysis,...</li> <li>➤ Clinical data: respiratory support &amp; mechanical ventilation (yes) sepsis, hypotension (no/suspected/confirmed), co-medication.</li> </ul> <ul style="list-style-type: none"> <li>▪ <b><u>For vital sign, NIRS and EEG data</u></b> in WP3, no metadata standards are available. For NIRS, we apply to the recommendations as provided by Vesoulis et al (<a href="https://pubmed.ncbi.nlm.nih.gov/33589724/">https://pubmed.ncbi.nlm.nih.gov/33589724/</a>).</li> </ul>
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#### 4. Data Storage & Back-up during the Research Project

<p>Where will the data be stored?</p> <p><i>Consult the <a href="#">interactive KU Leuven storage guide</a> to find the most suitable storage solution for your data.</i></p>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Shared network drive (J-drive) – password protected</li> <li><input type="checkbox"/> Personal network drive (I-drive)</li> <li><input type="checkbox"/> OneDrive (KU Leuven)</li> <li><input type="checkbox"/> Sharepoint online</li> <li><input type="checkbox"/> Sharepoint on-premis</li> <li><input type="checkbox"/> Large Volume Storage:</li> <li><input type="checkbox"/> Digital Vault</li> <li><input checked="" type="checkbox"/> Other: <ul style="list-style-type: none"> <li>▪ UZ Leuven network drive (P-drive, H-drive) – password protected</li> <li>▪ Signed informed consent forms of WP1, WP2, WP3 will be stored in a binder in a lockable room at the NICU department UZ Leuven. Only authorized personnel will have access.</li> <li>▪ Human blood/urine samples will be stored in UZ Leuven biobank.</li> <li>▪ Animal plasma samples will be stored in a badge-access room at the U Antwerpen research unit.</li> </ul> </li> </ul>
<p>How will the data be backed up?</p> <p><i>WHAT STORAGE AND BACKUP PROCEDURES WILL BE IN PLACE TO PREVENT DATA LOSS?</i></p>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Standard back-up provided by KU Leuven ICTS for my storage solution</li> <li><input type="checkbox"/> Personal back-ups I make (specify)</li> <li><input checked="" type="checkbox"/> Other (specify): <ul style="list-style-type: none"> <li>▪ Data stored at UZ Leuven network drives (P-drive, H-drive) will have automatic and daily back-up provided by UZ Leuven.</li> <li>▪ The promotor of respective PhD students will have access to his/her student data.</li> </ul> </li> </ul>
<p>Is there currently sufficient storage &amp; backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.</p>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Yes, there is currently sufficient storage and back-up capacity on both the KU Leuven and UZ Leuven servers and drives used for this project.</li> <li><input type="checkbox"/> No</li> </ul> <p>If no, please specify:</p>

<p>How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?</p> <p><i>CLEARLY DESCRIBE THE MEASURES (IN TERMS OF PHYSICAL SECURITY, NETWORK SECURITY, AND SECURITY OF COMPUTER SYSTEMS AND FILES) THAT WILL BE TAKEN TO ENSURE THAT STORED AND TRANSFERRED DATA ARE SAFE.</i></p> <p><a href="#">Guidance on security for research data</a></p>	<ul style="list-style-type: none"> <li>▪ The J-drive is only accessible for members of the study team, and using a personal login / password.</li> <li>▪ The P-drive and H-drive (UZ Leuven) is individual, and only accessible with personal login / password.</li> <li>▪ REDCap and Castor are only accessible for members of the study team, and with a personal login.</li> <li>▪ Storage of the signed informed consent forms occurs in a lockable room, to which access can only be granted to members of the study team by the PI (A. Smits).</li> <li>▪ Access to the stored samples at U Antwerpen can only be granted to members of the study team by S. Van Cruchten.</li> </ul>
<p>What are the expected costs for data storage and backup during the research project? How will these costs be covered?</p>	<ul style="list-style-type: none"> <li>▪ The J-drive and its back-up has a yearly cost of 51,9 euro.</li> <li>▪ REDCAP has a cost of 80 euro per project.</li> <li>▪ The costs mentioned will be covered by existing grant funding (e.g. FWO I-PREDICT grant G0D052N for WP1, DOXA-trial ZOnMW funding WP3), and personal UZ Leuven D-krediet of A.Smits.</li> </ul>

5. Data Preservation after the end of the Research Project	
<p>Which data will be retained for at least five years (or longer, in agreement with other retention policies that are applicable) after the end of the project? In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).</p> <p><a href="#">Guidance on data preservation</a></p>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> All data will be preserved for 10 years according to KU Leuven RDM policy</li> </ul> <p><i>Clarification:</i> approved study documents for WP1 clarifies data storage up to 20 years.</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> All data will be preserved for 25 years according to CTC recommendations for clinical trials with medicinal products for human use and for clinical experiments on humans</li> </ul> <p><i>Clarification:</i> approved study documents for WP3 Doxa-trial clarifies data storage up to 25 years.</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Certain data cannot be kept for 10 years (explain)</li> </ul>

<p>Where will these data be archived (stored and curated for the long-term)?</p> <p><i><a href="#">Dedicated data repositories</a> are often the best place to preserve your data. Data not suitable for preservation in a repository can be stored using a KU Leuven storage solution, consult the <a href="#">interactive KU Leuven storage guide</a>.</i></p>	<p> <input type="checkbox"/> KU Leuven RDR  <input type="checkbox"/> Large Volume Storage (longterm for large volumes)  <input checked="" type="checkbox"/> Shared network drive (J-drive)  <input checked="" type="checkbox"/> Other (specify):         <ul style="list-style-type: none"> <li>UZ Leuven network drive, P-drive and H-drive.</li> <li>Signed informed consent forms of WP1, WP2, WP3 will be stored in a binder in a lockable room at the NICU department UZ Leuven. Only authorized personnel will have access.</li> <li>Human blood/urine samples will be stored in UZ Leuven biobank.</li> <li>Animal plasma samples will be stored in a badge-access room at the U Antwerpen research unit.</li> </ul> </p>
<p>What are the expected costs for data preservation during the expected retention period? How will these costs be covered?</p>	<p>During the studies, all costs are covered by the existing respective grant funding (e.g. FWO I-PREDICT grant G0D052N for WP1, DOXA-trial ZOnMW funding WP3). Afterwards, and also for the WP2-related activities, costs will be covered by the personal UZ Leuven D-krediet of A.Smits.</p>

## 6. Data Sharing and Reuse

<p>Will the data (or part of the data) be made available for reuse after/during the project? Please explain per dataset or data type which data will be made available.</p> <p><i>NOTE THAT 'AVAILABLE' DOES NOT NECESSARILY MEAN THAT THE DATA SET BECOMES OPENLY AVAILABLE, CONDITIONS FOR ACCESS AND USE MAY APPLY. AVAILABILITY IN THIS QUESTION THUS ENTAILS BOTH OPEN &amp; RESTRICTED ACCESS. FOR MORE INFORMATION: <a href="https://wiki.surfnet.nl/display/STANDARDS/INFO-EU-REPO/#INFOEUREPO-ACCESSRIGHTS">https://wiki.surfnet.nl/display/STANDARDS/INFO-EU-REPO/#INFOEUREPO-ACCESSRIGHTS</a></i></p>	<p> <input type="checkbox"/> Yes, as open data  <input type="checkbox"/> Yes, as embargoed data (temporary restriction)  <input checked="" type="checkbox"/> Yes, as restricted data (upon approval, or institutional access only)  <input type="checkbox"/> No (closed access)  <input type="checkbox"/> Other, please specify:         </p> <p>New pseudonymized data, generated during the project, will be made available after publication upon request with the principle investigator (PI) and all co-supervisors involved. The PBPK model code and source data will be provided upon publication and afterwards in an open source platform (Github (<a href="http://github.com/Open-Systems-Pharmacology">http://github.com/Open-Systems-Pharmacology</a>)). Reuse of data of prospectively included neonates will be possible if parents granted permission for reuse and after new EC approval in case of research initiatives not directly related to the scope of the initial project.</p>
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<p>If access is restricted, please specify who will be able to access the data and under what conditions.</p>	<p>Data are only accessible for researchers involved in the respective WP projects. Informed consent will ask parents of included neonates if data can be reused, both by the research group or by other researchers in case of purposes related to the project. For other research initiatives, new approval needs to be asked to the ethical commission. Data of patients of whom parents granted permission, can only be shared with other research groups after written request to our research group and with a Data Transfer Agreement (DTA).</p>
<p>Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)? Please explain per dataset or data type where appropriate.</p>	<p> <input checked="" type="checkbox"/> Yes, privacy aspects  <input type="checkbox"/> Yes, intellectual property rights  <input checked="" type="checkbox"/> Yes, ethical aspects  <input type="checkbox"/> Yes, aspects of dual use  <input type="checkbox"/> Yes, other  <input type="checkbox"/> No         </p> <p>If yes, please specify: Since most (sensitive) data originate from patients, privacy and ethical regulations have to be taken into account, and restrict data sharing. Therefore, DTA will be used for data sharing between research groups, when applicable.</p>
<p>Where will the data be made available? If already known, please provide a repository per dataset or data type.</p>	<p> <input type="checkbox"/> KU Leuven RDR  <input checked="" type="checkbox"/> Other data repository (specify): As mentioned above, the PBPK model code and source data (WP1) will be provided upon publication and afterwards in an open source platform (Github (<a href="http://github.com/Open-Systems-Pharmacology">http://github.com/Open-Systems-Pharmacology</a>)). For the other studies, data will be made available after publication upon request with the principle investigator (PI) and all co-supervisors involved.  <input type="checkbox"/> Other (specify)         </p>
<p>When will the data be made available?</p>	<p> <input checked="" type="checkbox"/> Upon publication of research results  <input type="checkbox"/> Specific date (specify)  <input type="checkbox"/> Other (specify)         </p>

<p>Which data usage licenses are you going to provide? If none, please explain why.</p> <p><i>A DATA USAGE LICENSE INDICATES WHETHER THE DATA CAN BE REUSED OR NOT AND UNDER WHAT CONDITIONS. IF NO LICENSE IS GRANTED, THE DATA ARE IN A GREY ZONE AND CANNOT BE LEGALLY REUSED. DO NOTE THAT YOU MAY ONLY RELEASE DATA UNDER A LICENSE CHOSEN BY YOURSELF IF IT DOES NOT ALREADY FALL UNDER ANOTHER LICENSE THAT MIGHT PROHIBIT THAT.</i></p> <p>Check the <a href="#">RDR guidance on licences</a> for data and software sources code or consult the <a href="#">License selector tool</a> to help you choose.</p>	<p><input type="checkbox"/> CC-BY 4.0 (data)</p> <p><input checked="" type="checkbox"/> Data Transfer Agreement (restricted data)</p> <p><input type="checkbox"/> MIT licence (code)</p> <p><input type="checkbox"/> GNU GPL-3.0 (code)</p> <p><input type="checkbox"/> Other (specify)</p>
<p>Do you intend to add a PID/DOI/accession number to your dataset(s)? If already available, please provide it here.</p> <p><i>INDICATE WHETHER YOU INTEND TO ADD A PERSISTENT AND UNIQUE IDENTIFIER IN ORDER TO IDENTIFY AND RETRIEVE THE DATA.</i></p>	<p><input type="checkbox"/> Yes, a PID will be added upon deposit in a data repository</p> <p><input type="checkbox"/> My dataset already has a PID</p> <p><input checked="" type="checkbox"/> No</p> <p>At present, no specific data identifiers are available. If needed during deposit of data in a data repository, we will comply with the requested procedure.</p>
<p>What are the expected costs for data sharing? How will these costs be covered?</p>	<p>No costs are expected for data sharing. If costs would occur, this has to be mentioned in the respective DTA agreements and will be covered by the requesting parties.</p>

7. Responsibilities	
Who will manage data documentation and metadata during the research project?	The PhD students associated with the studies described in this Senior Clinical Investigatorship research proposal, will be responsible for data documentation and metadata, under supervision and final responsibility of the respective (co-)promotors where the studies take place.
Who will manage data storage and backup during the research project?	The PhD students associated with the studies described in this Senior Clinical Investigatorship research proposal, will be responsible for data storage and back-up, under supervision and final responsibility of the respective (co-)promotors where the studies take place.



Who will manage data preservation and sharing?	The principal investigator of the respective studies described in this Senior Clinical Investigatorship research proposal, will be responsible for ensuring data preservation and reuse.
Who will update and implement this DMP?	Anne Smits will update and implement the DMP for this Senior Clinical Investigatorship research proposal.