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Innovations to accelerate vaccine development and manufacture

WP12 – 3D in vitro Models and assays: Roadmap, standardisation and guidelines

D12.1 Stakeholder meetings organised, and workshop reports available

D12.1.1 Report of Workshop 1 (Applications)

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Document History

Version	Date	Description
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Introduction

Inno4Vac Subtopic (ST) 3 (MERMAID) aims to develop next-generation human in vitro 3D models for gastro-intestinal, respiratory and urovaginal mucosae that include relevant immune-system components as for infectious disease, and then test & validate the in vitro 3D models for use in nonclinical or clinical vaccine R&D applications. In vitro 3D models have the potential to not only fulfil the 3R Principle – that is to reduce, refine and replace animal experiments – for a variety of clinically relevant pathogens, but also to allow assessment of pathogens for which no human or animal model exists. The focus of Work package (WP) 12 (**3D in vitro Models and assays: Roadmap, standardisation and guidelines**) is to facilitate the acceptance of the models developed in ST3 into regulatory frameworks.

The specific objectives of WP12 are:

- To accompany and underpin the scientific-technical development of the in vitro 3D mucosa models and assays by developing a strategy and roadmap for the ultimate integration of the models and assays into pharmaceutical vaccine development and to sustain project outputs long term;
- To promote acceptance of the in vitro model concept and methodology in infectious disease and vaccine R&D by researchers, vaccine developers and regulators; and
- To develop case-study based guidance for the use of next-generation in vitro systems and assays.

One of the tasks of WP12 (Task 12.1) is to organise workshops with relevant experts and stakeholders covering four main topics:

- Application, specification and qualification.
- Standardization.
- Production and upscaling.
- Potential use of the models to reflect heterogeneity of the population (tissue, immune components) and the pathogens (strains).

By the end of the project, WP12 aims to design a roadmap for the integration of novel in vitro mucosal models and assays into the pharmaceutical development process for vaccines, that will be published. Findings from the workshops (alongside regulatory discussions undertaken in Tasks 12.3 and 12.5) are critical to the preparation of the roadmap.

This report summarizes aspects **of the 1st Regulatory Stakeholder Workshop of Work Package 12 of the Inno4Vac Project**, entitled "A Regulatory Exchange on the Inno4Vac MERMAID Project" held on 08 June 2022 in Brussels, Belgium at the Park Inn by Radisson Hotel from 09:00-16:30. This first workshop covered the topic of model applications, specification and quantification. It was organized during the first year of the project as a means to orient model development around the future context of use and to collect feedback on the essential tissue and infection parameters of the MERMAID models. Project modellers, industry representatives, key opinion leaders and international regulatory experts were brought together to give presentations and hold discussions on how to best take regulatory concerns into account when developing the specific Subtopic 3 models. There were 47 workshop attendees, with 10 attending in-person. The workshop provided an opportunity for stakeholders to discuss and consider criteria for regulatory acceptance of a novel technology in a very complex context of use. Developers gained feedback on potential regulatory obstacles and how to overcome them, while regulators had a chance to see the capabilities and limitations of complex in vitro models and consider the applications to which they are most appropriate.

Methods

Identification of external stakeholders and outreach

ST3 members and the WP12 team identified relevant regulatory and modelling experts to take part in the workshop. The main outreach target were EU countries (national regulatory agencies). The WP12 team additionally reviewed the global landscape and identified that advice from Canada and USA will be of relevance for the project. Please see below in the Table 1 the final list of the experts with relevant regulatory and 3D model expertise from organisations representing multiple countries in Europe and North America who attended the workshop. A complete list of attendees is included in Appendix 1.

Table 1 External experts in attendance

Name	Organisation	Expertise	Country
External Experts			
Armin Braun	Fraunhofer Institut of Toxicology and Experimental Medicine (ITEM)	Respiratory models	Germany
Dean Smith	Health Canada (HC)	Regulator, vaccines	Canada
Dasja Pajkrt	Amsterdam University Medical Center (AUMC)	Respiratory models, technology transfer	Netherlands
James McBlane	UK Medicines and Healthcare Products Regulatory Agency (MHRA)	Regulator, vaccines	UK
Marcel Hoefnagel	Dutch Medicines Evaluation Board (MEB)	Regulator, vaccines	Netherlands
Marcela Juarez-Hernandez	Paul-Ehrlich-Institut (PEI)	Regulator, vaccines	Germany
Margherita Turco	Friedrich Miescher Institute for Biomedical Research (FMI)	Uterine models	Switzerland

Mary Estes	Baylor College of Medicine (BCM)	Gastrointestinal	USA
Peter Theunissen	Dutch Medicines Evaluation Board (MEB)	Regulator, risk assessment	Netherlands
Sonja Beken	Belgian Federal Agency for Medicines and Health Products (FAMHP)	Regulator, 3R approaches	Belgium
Yuansheng Sun	Paul-Ehrlich-Institut (PEI)	Regulator, vaccines	Germany

Workshop agenda and preparation

The workshop agenda (Appendix 1) was developed to facilitate a hybrid meeting format and included variety of presentations on regulatory considerations and lessons learned from other modelling approaches, as well as model-specific discussion of specifications, potential use and challenges. The keynote and closing address were provided by regulators and offered information on regulatory resources available to new 3R testing approaches as well as general regulatory concerns to consider when attempting to replace an in vivo testing approach. Throughout the day, several "Lessons Learned" presentations were given by external experts sharing their expertise on various topics relevant to the project.

Description and potential uses of the MERMAID in vitro 3D models

The aim of the MERMAID models is to accurately depict the human in vivo conditions during mucosal infection and reliably predict mucosal immune protection.

Three mucosal surfaces were selected for modelling (the gastrointestinal, respiratory and uro-vaginal mucosae), and the resulting models are intended for use in combination with some of the most relevant pathogens of these tissues. Specifically, these are the nosocomial enteric pathogens *Clostridioides difficile* and Norovirus, the respiratory pathogens influenza and RSV, and the sexually transmitted pathogens *Neisseria gonorrhoea*, HSV-2 and *Chlamydia trachomatis*. Please see Table 2 for descriptions of the models and their potential benefits.

Table 2 3D in vitro mucosal model descriptions

	Gastrointestinal Models (WP13)	**Respiratory Models (WP14)**	**Urogenital Models (WP15)**
Description	Gastrointestinal (GI) mucosal models will present organotypic architecture and include functional tissue-resident immune cells. The models will be infected with *C. difficile* and Norovirus to investigate infection parameters and ultimately evaluate immunisation strategies.	Respiratory epithelial infection models for influenza and respiratory syncytial virus (RSV) will include immunological components (e.g. antibodies, monocytes, NK cells, and/or T cells) to mimic and evaluate vaccine- or infection-induced protective or detrimental immune responses.	Scaffold-based infection models of the urogenital mucosa include typical human architecture and physiology as well as innate and adaptive immune cells to investigate protective effector immune mechanisms for *N. gonorrhoea*, *C. trachomatis* and Herpes Simplex 2 under static and dynamic flow conditions.
Model Formats	Organoid culture based on human induced pluripotent stem cells (hiPSC)	Air-liquid interface differentiated primary nasal/bronchial epithelial cells,	Air-liquid interface based on primary cells isolated from donor tissues, and

	Gut-on-chip based on human induced pluripotent stem cells (hiPSC)	Alveolar/bronchial lung organoids, and Lung-on-chip	UV-on-chip based on primary cells isolated from donor tissues.
Benefits	Improved translation of preclinical to clinical results due to more accurate cellular diversity in tissue models, allowing deep understanding of immunopathogenesis. Possibility of relevant investigation of infections where no model currently exists. Opportunity to evaluate donor-specific characteristics in a controlled fashion earlier in the vaccine discovery and development process.	Improved predictivity of preclinical and clinical studies by augmenting the read-outs relevance and identification of biomarkers. Improved knowledge of the mechanism of action of infection, host pathogen interactions and mechanisms of action of the immune response (including safety effects) induced by vaccines.	Improved knowledge of the mechanism of action of infection, host pathogen interactions and mechanisms of action the immune response induced by vaccines. More accurate representation of the cell types in human tissue, enabling identification of relevant infection receptors, pathways and immunopathology. Inclusion of human genetic diversity, providing an opportunity for real life infection dynamics studies.

Models can be used in the discovery stage to accurately recapitulate host-pathogen interactions for development of rationale-based medicines (prophylactic or therapeutic) as well as to screen and prioritize the most promising therapeutic/vaccine candidates. However, the MERMAID consortium is focused on their applicability in the later stages of vaccine development. They are particularly well-suited to serve to reduce, refine and replace animal experiments in nonclinical studies due to their physiological accuracy and immunological functionality. They are also well-suited to provide supplementary information about the immune responses in clinical trial subjects.

The potential applications proposed and discussed at the workshop included:

- Assessment of efficacy/functionality of immune modalities (such as neutralizing antibodies) induced by natural infection or vaccination against infection or disease.
- A characterization test for antigen-antibody interactions and the mechanism of action. Models would support and provide additional characterization for the development of a potency assay but would not be intended as a potency assay themselves.
- Determination of the precise mechanism of action of medicines for critical attributes identification and future quality control strategy definition.
- Exploratory clinical readouts to assess the mechanism of action of vaccine-induced antibodies.
- Verification of specific Ab functionality properties in relation with an identified biomarker.
- Complete or partial replacement of clinical lot-to-lot consistency studies
- Acceleration of clinical development by complementing trial data (e.g., expanding cohorts with in vitro living human replica)

For each type of 3D mucosal model (respiratory, gastrointestinal and UV), a separate, in-depth session was held. Subtopic 3 model developers gave a brief presentation of their models' attributes, construction and

potential benefits. This was followed by a round-table discussion with regulators and experts on proposed and possible applications of the models. To support a lively and productive discussion of potential model applications, model descriptions, along with preliminary validation concepts and model-specific questions, were shared with external regulators before the workshop.

Meeting venue and format

A meeting room was reserved at the Park Inn by Radisson Hotel in Brussels, Belgium, and communications technology was utilized to broadcast the workshop in a hybrid format through Microsoft Teams, enabling effective interaction between in-person and virtual attendees. Virtual participants were able to give presentations, provide feedback, and participate in round-table discussions. A transcript was made of the meeting to assist in the preparation of summary reports.

Results

Regulators who participated in this workshop shared their personal experiences and viewpoints on the Inno4Vac Subtopic 3 project and models. An important disclaimer is that their feedback cannot be taken as a policy statement or recommendation by any regulatory agency. Specific questions regarding a particular model in a particular context of use should be addressed to the responsible national competent agency.

Regulatory interest in animal study alternatives

There is a legal framework in Europe supporting the replacement of animal studies with in vitro testing approaches. This is evidenced by Directive 2010/63/EU on The Protection of Animals Used for Scientific Purposes, particularly in Articles 4 and 30. The EMA and the national regulatory agencies responded to this call not only with working groups and guidance documents, but also with efforts to raise awareness and engage in dialogue on the contexts of use, endpoints, and reference compounds for 3R testing approaches, and to establish communication channels to allow implementation of novel 3R methods. The following pathways to obtain regulatory feedback on a novel 3R testing approach were identified:

- **EMA Innovation Task Force (ITF) for 3Rs**- the 3Rs ITF offers briefings designed to provide an informal exchange of information and non-legally binding guidance on the testing approach very early in the development process. Briefings are free, and are offered to wide variety of stakeholders, including not only industry, but SMEs, academics, end users and private/public consortia.
- **EMA Guideline on the principles of regulatory acceptance on testing 3R approaches** - although this document defines regulatory acceptance as inclusion of the method in the European pharmacopeia or other regulatory testing guideline, it acknowledges that acceptance may also occur on a case-by-case basis, allowing a regulatory decision to be made for a particular dossier on the basis of a 3R testing approach. The guideline spells out the criteria a 3R testing approach must meet to be considered eligible for regulatory acceptance.
- **Safe harbor submission of data** – the EMA Guideline on the principles of regulatory acceptance on testing 3R approaches also allows the submission of data from non-accepted 3R testing approaches in parallel with data from existing approaches. The 3R data are then evaluated to assess the future possibility of acceptance of the 3R testing approach. This process can be used to gain feedback concurrently with additional data collection or product development.

Key parameters in convincing regulators to accept non-animal models

Despite regulatory interest in 3R testing approaches and channels for interaction between regulators and developers, uptake of 3R testing approaches has been slow. This is not due to a fundamental problem with 3R approaches – regulators pointed out that in the vaccine arena, appropriately designed in vitro assays can be superior to animal assays in terms of speed, efficacy, precision and reproducibility. The difficulty lies in convincing regulators that the particular in vitro approach in question is superior to existing methods. The workshop identified the following recommendations for complex in vitro systems, such as the Organ-on-Chip, organoid and air-liquid interface models of Inno4Vac:

- **Emphasize a science-driven agenda.** A more complete understanding of the science of the system can identify natural opportunities for new 3R testing approaches and provide justification for an innovative approach.
- **Increase the scientific relevance, predictability and number of insights over that of the existing approach.** The more accurate and relevant information that a novel approach can provide, the more valuable it becomes, and the more likely it will be able to displace a less relevant and less accurate method.
- **Standardize functional assays.** In a vaccine context, standardized functional assays allow for correlate of protection analyses, validation, and demonstration of comparability to in vivo models, which are key steps to regulatory acceptance.
- **Add value over existing approaches.** In vivo models have many weaknesses and do not work in every context. An in vitro testing approach able to provide accurate and relevant information that an in vivo approach cannot is more likely to find regulatory acceptance.

Regulators pointed out that the use of complex in vitro systems in vaccine development may pose additional challenges. Infection biology and vaccine immunology are often poorly understood, and additional work to identify relevant readouts or correlates of protection may be necessary before a 3R testing approach can be successful. Furthermore, technical and biological validation of the models and qualification of the methodology for the specific context of use are needed.

Role of early communication between developers and regulators

A new technology presents new regulatory challenges. Both regulators and developers at the workshop stressed the need for frequent and early communication not only as a means to raise awareness about complex in vitro systems, their potential usages and reproducibility and validity of information originating from these models, but also to address implications for approval and licensure pathways. Early exchanges can help to identify hurdles and adapt development to regulatory feedback and demands. This can occur both within the scope of the Inno4Vac work packages and outside them. Within the scope of Inno4Vac, communication can occur via:

- **Soliciting regulatory feedback on a particular model and application.** An ITF briefing is likely most suited to the current stage of development of the Inno4Vac models, but the safe harbor submission of 3D mucosal model data may also provide valuable early insight.

- **Inclusion of regulators upfront.** Although regulators cannot participate in the development of an item they may one day regulate, their inclusion in regulatory work packages and workshops allows them to provide insight into the specifications that are needed or identify gaps in proposed approaches.

Communication outside the scope of Inno4Vac was also encouraged:

- **Attending or hosting meetings.** The EMA hosted a workshop in 2017 with micro-physiological system (MPS) developers and discovered a need for specific qualification guidance for this field. Attending joint meetings or including joint sessions allows education to occur on all sides of the issue.
- **Technology transfer with regulators.** A recent example is the FDA adoption of MPS. Hands-on exposure to complex in vitro systems is a powerful way for regulators to develop expertise in the capabilities and limitations of the technology and to provide informed feedback on its applications.
- **Scientific training with regulators.** Inviting regulatory researchers to the laboratory at the very early stages of development provides an opportunity to familiarize them with the technology and also for them to provide early development advice.

Finally, the importance of standardized assays cannot be overstated. Industry involvement at an early stage of technology development can start necessary conversations about future uses and needs and lay the groundwork for successful assay standardization. The Inno4Vac consortium includes industry members with a vested interest in the 3D mucosal models in each work package, but additional forums such as EUROoCs, CEN-CENELEC and the IQ MPS Affiliate may also provide valuable insight.

Suitability of 3D mucosal models for preclinical and clinical applications

A theme that repeated itself throughout the workshop was that complex in vitro models excel at describing defined situations. A wealth of information about the mechanisms underlying the pathogenicity and vaccine immune response or about correlates of protection could be obtained from in vitro systems such as the 3D mucosal models of Inno4Vac. Two external participants presented their work with complex in vitro models in this area. Dr. Armin Braun (Fraunhofer ITEM) explained his work with the imSAVAR consortium to identify inflammatory-related adverse outcome pathways that may occur during immuno-oncology or immuno-inflammatory therapies and develop nonclinical in vitro models to assess these events. Dr. Mary Estes (Baylor College of Medicine) presented her work to develop human enteroids capable sustaining Norovirus replication and subsequent efforts to establish a Norovirus correlate of protection assay. Both presentations were well-received by regulators and the following attributes were singled out as reasons why each model was well-suited to its chosen application:

- Models focused on a precise set of interactions – an adverse event pathway and a correlate of protection, respectively
- Models assessed a situation that was not possible to measure accurately in animals
- Model readouts were specific and relevant to the question at hand
- Models were reproducible, well-characterized systems

Additional case studies specific to the Inno4Vac models clarified that, in their current state, 3D mucosal models would not be able to serve as a replacement for or reduce the size of a clinical trial. The use of these models to assess immunological readouts from vaccine trials is possible, though likely not feasible at large scale. A more appropriate application would be the collection of supplemental data for secondary endpoints in a trial or for analysis of correlates of protection.

General regulatory considerations before choosing an application

A variety of possible vaccine applications for 3D mucosal models were proposed at the workshop and discussed among the group. Although some specific advice was obtained, much advice was applicable to all models and should be considered as a preliminary step to choosing a specific application.

- **Consider the model's strengths (and limitations).** A one-to-one replacement of an existing assay may not be possible or desirable. A single model cannot capture systemic immunity or safety in humans. However, a single model could measure a key component of the response, and a well-designed combination of models might be a very powerful tool to investigate a multi-factorial or complex response. Models may be especially well-suited to investigate new correlates of protection. Although many vaccines do not have an established correlate of protection, usually at least some information is available about the factors that may mediate protection. A well characterized in vitro model that is able to incorporate such factors could support the identification of and mechanism of action studies on new correlates of protection.

- **Define the context of use for the model.** A 3D mucosal model will not be used to replace a particular animal or human study, but rather as a tool to collect more predictive information about how a vaccine candidate will behave in humans. To do this well, model developers must first identify specific, clear readouts or functions that can be measured accurately and reproducibly. Developers must then decide which system characteristics are critical and must be incorporated to accurately capture the desired readout(s). Other characteristics should be excluded or de-prioritized. Finally, developers must form a clear understanding of the limitations of the model. Without a clear context of use, it is difficult (if not impossible) to evaluate a proposed application. Moreover the (extent of) qualification requirements will be dependent upon the identified context-of-use.

- **Model humans, not animals.** The problem with many animal models is that they do not replicate the human response. If an in vitro model also does not replicate the human response, it is unlikely to add value over existing assays and it may be difficult to show the superiority of the in vitro method. Instead, models should improve their relevance and predictability by using human data (e.g. those collected from clinical/challenge trials or medical practice) as reference data to demonstrate relevance or for correlation studies defining what model attributes reflect. Comparative work can be challenging but may be invaluable when attempting to demonstrate comparability and predictability of a model.

One possibility suggested by regulators was to make model replicates for subjects in concurrent clinical or challenge trials and use the resulting data as a way to assign meaning to model readouts and allow model validation.

Conclusion

The in vitro models of ST3 are a new, complex technology attempting to model one of the most complicated human systems (immunity). This is an ambitious goal that will face many challenges. Chief among them is the difficulty in demonstrating how specific model readouts correlate with in vivo outcomes, when the in vivo system is so poorly understood. However, many regulatory fundamentals remain the same. The relevance of the data collected by a model must be clear. Developers must have a well-characterized system and be able to demonstrate a thorough understanding of their model's outputs and limitations. Standardization of model functional assays is always valuable.

The workshop concluded with the following general suggestions for immediate future work with 3D mucosal models:

- A learning process is necessary for all stakeholders to become familiar with the technology and regulatory expectations for vaccine work.
- Begin small, with correlate of protection or mechanism studies as a means to start establishing model credibility. Work up to more ambitious goals as data are gathered to support more ambitious uses.
- Think carefully about how to reduce animal and human participation using 3D mucosal models. Full replacement is probably not an option, but reduction certainly might be.

In light of the insights gathered by this workshop, a technical roadmap outlining key aspects to consider when choosing an application for a model was developed. Subtopic 3 models used this roadmap to identify gaps in existing testing approaches, areas where their models could be potentially more relevant, and readouts and standards necessary to begin the subsequent process of in-depth characterization and qualification of their models.

The next steps for the MERMAID models include more interactions with regulators via additional workshops on such topics as standardization and human and pathogen diversity. Input from these ongoing interactions can be used to improve the models simultaneously with the ongoing development process. In Year 3, models that meet basic criteria for successful infection will transition to a second stage of development that focuses on the inclusion of immune components and establishment of relevant immunological readouts. Simultaneously, models will begin preparation for a final validation stage by creating standard operating procedures for finalized model procedures and manipulations.

Appendices

Appendix 1_WP12_Meeting Agenda and Attendees

Appendix 1_WP12 Workshop 01 (Applications)_Attendees and Meeting Agenda

Participants	Institution
Alexander Dobly	Sciensano
Anke Huckriede	University Medical Center Groningen (UMCG)
Apurva Kulkarni	Takeda Pharmaceuticals International AG (Takeda)
Armin Braun	Fraunhofer Institut of Toxicology and Experimental Medicine (ITEM)
Barbro Melgert	University of Groningen (RUG)
Daniel Reem	European Vaccine Initiative (EVI)
David Kessie	University of University of Wurzburg (UWB)
Dasja Pajkrt	Amsterdam University Medical Centers (AUMC)
Dean Smith	Health Canada (HC)
Elke Walter	Takeda Pharmaceuticals International AG (Takeda)
Emanuele Montomoli	Vismederi
Fabienne Piras-Douce	Sanofi Pasteur SA (SP)
Giulia Piccini	Vismederi
Hristina Koceva	Jena University Hospital (JUH)
Irina Meln	European Vaccine Initiative (EVI)
Isabel Delany	GlaxoSmithKline Biologicals SA (GSK)
Isabelle-Bekeredjian-Ding	Paul-Ehrlich-Institut (PEI)
James McBlane	UK Medicines and Healthcare Products Regulatory Agency (MHRA)
Karl Melber	CureVac
Katie Huber	Paul-Ehrlich-Institut (PEI)
Katrien Pletinckx	CureVac
Kevin Buno	GlaxoSmithKline Biologicals SA (GSK)
Kimberly Veenstra	European Vaccine Initiative (EVI)
Lorenzo Tesolin	Sciensano
Luisa Borgianni	Sclavo Vaccines Association (SCLAVO)
Marcel Hoefnagel	Dutch Medicines Evaluation Board (MEB)
Marcela Juarez Hernandez	Paul-Ehrlich-Institut (PEI)
Margherita Turco	Friedrich Miescher Institute for Biomedical Research (FMI)
Mary Estes	Baylor College of Medicine (BCM)
Maxime Vermeulen	Sciensano
Nathalie Mantel	Sanofi Pasteur SA (SP)
Nathalie Reveneau	Sanofi Pasteur SA (SP)

Nick Hannan	University of Nottingham (UoN)
Nicole Engert	Jena University Hospital (JUH)
Peter Loskill	University of Tubingen (EKUT)
Peter Theunissen	Dutch Medicines Evaluation Board (MEB)
Puck van Kasteren	Dutch National Institute for Public Health and the Environment (RIVM)
Rob Vandebriel	Dutch National Institute for Public Health and the Environment (RIVM)
Sandra Morel	GlaxoSmithKline Biologicals SA (GSK)
Sapna Sheth	BioSci Consulting
Silvia Rossi Paccani	GlaxoSmithKline Biologicals SA (GSK)
Sonja Beken	Belgian Federal Agency for Medicines and Health Products (FAMHP)
Stefan Jungbluth	European Vaccine Initiative (EVI)
Stephane Temmerman	GlaxoSmithKline Biologicals SA (GSK)
Thomas Rudel	University of Wurzburg (UWB)
Tiziana Spadafina	Sclavo Vaccines Association (SVA)
Yannick Vanloubbeeck	GlaxoSmithKline Biologicals SA (GSK)
Yuansheng Sun	Paul-Ehrlich-Institut (PEI)

Inno4Vac Sub Topic 3 (MERMAID), Work Package 12 (Regulatory)

"A Regulatory Exchange on the Inno4Vac MERMAID Project"

08 June 2022, 9:00- 16:30 CEST

Park Inn by Radisson Brussels Midi (Place Marcel Broodthaers, 3, 1060, Brussels, Belgium)

Agenda

	Topic	Who
09:00-09:05	Welcome from Project Co-ordinator	Dr Kimberly Veenstra (EVI)
09:05-09:20	Introduction of the Inno4Vac Project and ST3 MERMAID	Dr Fabienne Piras-Douce (Sanofi) - ST3 EFPIA Lead Dr Katie Huber (PEI) – WP12 (Regulatory Roadmap) Lead
09:20-09:40	Keynote Speaker (20 min)	Dr Sonja Beken (FAMHP)
09:40-09:55	Respiratory Models (15 min)	Dr Kevin Buno (GSK) - WP14 (RESP) EFPIA Lead
09:55-10:40	Feedback from Regulators on Respiratory Models (45 min)	External Experts Chair: Dr Rob Vandebriel (RIVM)
10:40-11:00	Coffee Break (20 min)	
11:00-12:00	Lessons Learned (20 min + 5 min questions each) "How to develop a model we trust for safety prediction" "What is a good model for research and for an application?"	 Prof Armin Braun (Fraunhofer ITEM / imSAVAR) Prof Dasja Pajkrt (AUMC / OrganoVIR)
12:00-13:00	Lunch	
13:00-13:15	Uro-Vaginal Models (15 min)	Dr David Kessie (UWB) - WP15 (UV) Research Scientist
13:15-14:00	Feedback from Regulators on Urovaginal Models (45 min)	External Experts Chair: Dr Isabel Delany (GSK)

14:00-14:15	Gastrointestinal Models (15 min)	Dr Nicole Engert (JUH) - WP13 (GI) Research Scientist Dr Nick Hannan (UoN) – WP13 (GI) PI
14:15-15:00	Feedback from Regulators on Gastrointestinal Models (45 min)	External Experts Chair: Prof Mary Estes (BCM)
15:00-15:20	Coffee Break (20 min)	
15:20-16:20	Lessons Learned (20 min + 5 min questions each) "Organoids: Mini-organs or Avatars to Understand Human GI Health and Disease" "What Regulators Need to Leave Animal Models Behind"	Prof Mary Estes (BCM) Dr Dean Smith (Health Canada)
16:20-16:35	Wrap Up (15 min)	Dr Katie Huber (PEI) - WP12 (Regulatory Roadmap) Lead