ICPerMed Workshop 2023-2 Concept – 14-15 November, 2023

Type of document

Draft Concept

General background of the ICPerMed event – focus on workshop format

- *Type of event:* Workshop
- *Format:* one day and a half, i.e.one whole day sessions followed by a morning session on two consecutive days; on-site meeting, including the (hybrid) possibility to participate virtual to follow presentations and discussions (potentially chat function and interactive tools)
- *Participation:* on invitation only (for both, on-site and online participation), 100-150 participants, international
- *Overall Aim*: Exchange on research, policies and strategies relating to development and implementation of personalised medicine.
- *General topic/s*: Active discussions about new and highly relevant PM topics.
- *Potential output*: Workshop report; Development of recommendations for the promotion of the workshop topic.

Specific indications focussing on the ICPerMed workshop 2023_2

1. **Goals of the workshop in November 2023**
   - To explore the latest developments in technology and innovation that are driving the field of personalised medicine.
   - Showcase experiences of researchers, clinicians, biotech and industry leaders to share their experiences and insights on how to drive PM-related innovation in the healthcare sector.
   - To gather and disseminate present technologies/tools that are close to application or already implemented, e.g. companion diagnostics, etc.
   - To share good practices regarding the methodologies applied to obtain regulatory approval of innovation (particularly in the field of PM with sometimes small clinical sample sizes).

2. **Key words**

#personalisedmedicine, #technology, #innovation, #healthcare, #goodpractices, #evidence

3. **Participants**

ICPerMed members, ICPerMed stakeholders and experts in PM (academic researchers, clinicians and healthcare professionals, SMEs and industry, funding agencies, payers, regulators, policymakers, patient representatives, medical societies representatives).

Foster participation and discussions with international, non-European, stakeholders.

Other potential participants: ERA PerMed partners, ICPerMed family members, international funders.

4. **Format**

The workshop will be a mixture of keynote presentations, panel discussions, and interactive sessions. Only plenary sessions, no breakout rooms.

5. **Workshop title**

"Advancing Personalised Medicine through Technology Development"

6. **Date: 14-15 November 2023**

- 1 ½-day workshop. End of the workshop latest around 14:00 (day 2).
- Number of participants: 100-150
- Workshop participants can leave in the afternoon of day 2.
- Option: Social event in the afternoon day 2 (workshop participants and ExCom).
- ExCom starts the internal meeting in the morning of 16 November. Potentially, keep the same venue for the ExCom meeting (TBD).
- Satellite meetings possible, e.g. working groups, ICPerMed Secretariat, AB, etc. at the same or closely located venue.

	Monday	Tuesday	Wednesday	Thursday	Friday
Date (Nov.)	13	**14**	**15**	16	17
Morning		**Workshop**	**Workshop**	ExCom	
Afternoon		**Workshop**	**End max. 14:00**		
Location		**Siena**	**Siena**	Siena	

7. **Venue:** Strada del Petriccio e Belriguardo, 53100 Siena, Italy
(C/O Toscana Life Sciences)

8. **Local host:** Toscana Life Sciences (TLS) with the endorsement of Tuscany Regional Government (ICPerMed Executive Committee member organisation)

9. **General content, agenda points:**

   - Registration
   - Welcome session (regional minister of health government, local host: TLS president, EC, ICPerMed chair)
   - 4 keynote lectures (external speakers or “internal talk”) presenting concrete technology examples in personalised medicine:

- **Innovation perspective:** A look to the future of personalised medicine, current innovation/s in the field and the role of technology in driving innovation into the healthcare sector.
  Speaker profile: Industry leader (or biotech).
- **Clinical perspective:** A clinical perspective on personalised medicine, how technology/ies are implemented in primary healthcare settings, and how they facilitate the practice of healthcare providers. This can cover topics like technology supporting diagnosis, treatment, and monitoring for personalised medicine, electronic health records or patient reported outcome integration and telemedicine.
  Speaker profile: Clinician or practitioner.
- **European regional perspective**: Presentation of activities concerning PM development and implementation
  Speaker profile: Tuscany Region representative, could be biotech, research or policy level.
- **International perspective:** Current practices, advantages and needs as well as challenges for personalised medicine technology development and implementation in healthcare and clinical practice.
  Speaker profile: expert participating e.g. in a transnational initiative, project or clinical trial

- ICPerMed Recognition – award ceremony
- 3 topic specific plenary sessions – 2-3 introductory talks, followed by panel discussions
- Wrap up & closing remarks (ICPerMed chair)

10. Specific content: Plenary sessions

Session 1: Technologies in Personalised Medicine

- **Content:** Provide an overview on different technologies implemented in the field of PM (e.g. single nucleotide polymorphism genotyping, haplotyping, gene expression studies by biochip/microarrays and proteomics, sequencing, epigenomics, metabolomics, imaging, etc.) and how those (can) contribute to facilitating the prescription of specific therapeutics that are best suited for an individual e.g. based on pharmacogenetic and pharmacogenomic information.
- **Speakers** (international and European experts, up to 3) are invited to give a talk (10 min as impulse for panel discussion following the impulse talks):
  - Presentation of 3 different technology examples
  - To be further developed
- Panel discussion: Experts will discuss obstacles and facilitators for developing, implementing and using these kind of personalised medicine technologies (data collection, logistics, …) and the potential need for initiating new technologies or developing existing ones.

Session 2: Research and regulatory perspectives for technology development

- **Content:** Presentation of case studies or examples of HTA assessments of personalised medicine technologies and interventions, and support of personalised medicine technology developments through adequate regulatory and legal framework/s.
- **Speakers** (international and European experts, up to 3) are invited to give a talk (10-15 min as impulse for panel discussion following the impulse talks):
    - Clinical perspective: Value of PM diagnostic or decision support tools for clinical practice and for the practitioners. Challenges for PM technology development in clinical settings.
    - Regulatory perspective: Overview of the regulatory landscape for personalised medicine research [in-vitro, medical devices, Clinical Trials Regulation (CTR) and HTA, conducting clinical trials] and how existing regulations interact. Role of regulatory authorities in ensuring patient safety and efficacy of personalised medicine products/technologies, and related-clinical trials.
    - Research perspective: How to develop an appropriate research framework (incl. methodology)? How to create relevance in research (e.g. concerning data needed for approval)?
- **Panel discussion**: Regulatory experts from government agencies, research/clinics and industry discuss current practices in technology development and implementation in healthcare and clinical practice, advantages and challenges: The role of HTA in this process, including the importance of considering patient and societal values in HTA. Challenges and opportunities for navigating the regulatory landscape for personalised medicine products and clinical trials.

Session 3: Collaboration of research and healthcare providers to foster innovations

- **Content:** Innovation is not a linear process from research to clinical application but also requires a feedback loop back to research after implementation of a technology in clinical practice.
- **Panellists** (international and European experts): Instead of having introductory talks, this session can be interactive with 3-4 panellists (option 1: the keynote speakers of day 1; option 2: new set of panellists, each having a short 5 min presentation to outline their background and expertise) discussing questions concerning collaboration of research (, industry?) and healthcare providers to foster innovations. Animated by the moderator, the panellists discuss predefined topics (e.g. coming from sessions 1 and 2) together with the audience.
- **Panel discussion:** Researchers, international experts, industry representatives, clinicians and regulators discuss the need of close and bidirectional collaboration between research (, industry?) and healthcare professionals to foster innovation. Research supports innovation and their future implementation (with support of the private sector) in healthcare practice. Vice-versa, healthcare professionals should report back to research (e.g. data use and collection, hospital data streams, technology transfer needs etc.). How can this process being supported, e.g. through research or research-supporting activities, to allow efficient technology development and refinement of implemented technologies?

11. ICPerMed Workshop November 2023 draft/preliminary agenda:

14-11-2023; Sienna, Italy

09:00 – 09:30	Registration
09:30 – 10:10	Welcome and opening session (specific names to be listed later) Regional minister of health government, Local host: TLS president, EC, ICPerMed chair (Overview of ICPerMed and Introduction to workshop)
10:10 – 10:40	Keynote lecture 1: Innovation perspective (Keynote subject TBC) – 25 min talk and 5 min Q&A
10:40 – 11:20	Coffee break
11:20 – 11:50	Keynote lecture 2: Clinical perspective (Keynote subject TBC) – 25 min talk and 5 min Q&A
11:50 – 12:20	Keynote lecture 3: European regional perspective (Keynote subject TBC) – 25 min talk and 5 min Q&A
12:20 – 14:00	Lunch break
14:00 – 14:30	Keynote lecture 4: International perspective (Keynote subject TBC) – 25 min talk and 5 min Q&A
14:30 – 16:00	Session 1: Technologies in Personalised Medicine (Session TBC) 30 min impulse talks and 1h discussions (panel and audience)
16:00 – 16:40	Coffee break
16:40 – 18:00	ICPerMed 'Best Practice in Personalised Medicine' Recognition 2022-2023 Introduction by IT-MoH (15 mins); 3 talks by project experts to be identified later on (15 min talk and 5 min discussion each)
18:00 – 18:10	Closing day 1
20:00	Dinner

15-11-2023; Siena, Italy:

08:30 – 09:00	Registration
09:00 – 09:10	Opening day 2 remarks
09:10 – 10:40	Session 2: Research and regulatory perspectives for technology development (Session TBC) 30 min impulse talks and 1h discussions (panel and audience)
10:40 – 11:20	Coffee break
11:20 – 12:50	Session 3: Collaboration of research and healthcare providers to foster innovations (Session TBC) Short 5 min input per panellist (15-20 min. in total) followed by discussions (panel and audience)
12:50 – 13:00	Closing remarks Local host ICPerMed chair
13:00 – 14:00	Lunch