Présentation from ValérieBarbié

Personalized medicines fieldis a promising area but we have not shown much evidence so far that it represents a **true added-value for the society**→ time to do so.

Life cycle of data:

- **Data generation**: not only about genomics
  High throughput technologies has grown in the past 10 years
  High quality is a requirement
  What is missing is annotation, phenotypic annotation but also qualitative annotation
  Data have to fit for purpose. Data generated needs to be clearly labelled.
- **Storage and processing**: huge costs behind the data generation
- **Sharing and integration**: we can have interoperable systems but accessible data is another thing , we are lacking some data even if we have the systems. →then only we can speak of integrating.
- **Analysis and interpretation**: need of good data to have good interpretation – common criteria are crucial to streamline the way we understand the results.

Shared interpretation results! Feedback on the treatment given after the decision taken thanks to the collected data is very important. More often there is no follow-up, therefore no feedback to research. The only feedback is usually from clinical trials or post-marketing studies , but rarely from routine healthcare →**iterative feedback loop is crucial.**

The whole chain has to be **economically sustainable**. If medical outcomes are not tracked, it is very difficult to justify a cost-effective investment.

Adherence of the society is needed to keep the momentum therefore health authority, healthcare professional and citizens need to be convinced.

Exemple of the Swiss Personalized Health Network – where all the key stakeholders are involved in the governance: Government – Health – Research – Patients.

Discussion

- Focus: **From bed to bench and back to bed**.
- Ascertainment: Research is too much disconnected from healthcare and patients... or healthcare is too much disconnected from research.
- Personalized healthcare starts from bed – need of a cultural shift / data

- Need of a **definition of Personalized Medicines** maybe more precise to better define the scope

- **Data Quality**: has to be a given because if not, is misleading at every steps (research and clinics) and data have no value. **But** should be guaranteed even more when data are cycling back (Example of Biobanks). Quality of data per se, but also quality of data depending on what you want to achieve.

→Recommendation: capturing experimental processes, best documentation / data management plan

- Data are a way to **generate Knowledge** which has then to be re-used – implementation of this knowledge. (FAIR principles)
  ➔ Recommendations: applying FAIR principles, national implementation of GDPR has to be harmonized, mapping of legal framework, best practices in the different countries and data sharing initiatives, publication of a report / state-of-play

- **Informed consent** (EU-wide consent / default consent / dynamic consent) – IC PerMed to take a position? Or to have it as a reflection point – survey/spread the work already done.

- **Feedback loop on decision outcomes** (diagnostics and therapeutic): if no feedback, then no way to show positive outcomes of Personalized Medicines compared to physician's choice. Follow-up systems have to be embedded in healthcare systems. Iterative process – from bed to bench, and back to bed. (also necessary for machine learning systems)
  ➔ Recommendations:real life data are needed – also from lifestyle & environment, need of text mining tools to use unstructured data.
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- **Standards** on raw data, standards and **clinical relevance** in annotation (double signature technique and clinic) – to be regulated by funding agencies (at least in research setting).
  ➔ Recommendations: workshops + recommendations from IC PerMed + showcase of best practices + requirement in calls for funding.

- **Incentives/Governance/Support**for **data collection**, for **sharing**,**re-use** of data.
  Culture of data sharing in research. Are incentives needed for data collection? – Need to identify **stakeholders' practices**.Are **incentives/guidelines/facilitation** needed for data collection for **clinicians**? Right tools and resources would help, especially for the data sharing aspects.
  Key actors: **Infrastructure**/ministries of health/political will, **editors**, **funding agencies**
  ➔ Recommendations: guidelines (writing or dissemination) + showcase the return of investment of putting data together for the various stakeholders- information and training - **'bring your own data'** in NL + mandatory requirement **(regulators/reimbursement bodies)**

- **Multi-stakeholder dimension / stakeholder mapping**–patients, researchers, clinicians, bioinformaticians, funding agencies, health/research authorities, insurance/payers , patient advocacy groups, editors, regulators, pharma/diagnostic industry, IT industry
  →Recommendations: mapping/perspective to be provided by IC PerMed, engagement plan, people to bring together to write guidelines

- **Call for 'case studies'**- at least two participating countries (prospective or retrospective studies) – for one particular medical area or more (Israel, Vienna EXACT) – collaboration between different structure.

- →Recommendations: Call for funding – case studies showing the value generated by personalized medicines + work on Workflow of personalized medecines: meaning of data / impact at every step in the Value Chain
- **Increase collaboration** of IC PerMed with BBMRI (consent and phenotypic annotation), RD-Connect, ELIXIR, IRDiRC (Interdisciplinary Scientific Committee), EMA/FDA, Health-RI (NL) on Biobanks

- **Education and training**, spreading the culture of personalized medicines, for clinicians, research nurses, patients, public/citizens, etc
  ➔ Recommendations: investment in training + workshop on best practices in Europe / at national level

- **Project proposals evaluation**
  ➔ Give **priority** to projects that contains medical records-based, broader, critical size, etc
  →Studies Patient Preferences / Patient-Relevant Outcomes

- **Public-private partnerships?**
  - With several pharmaceutical companies (ex: for Combination therapies)
  - With IT industry → recommendations on how to interact