AGENDA

1. **Short introduction recalling the precursor sessions** (P6, P7, P8, P9) and **Issues description** [15'], Edwin Morley-Fletcher, Lynkeus, and Yannis Ioannidis, Athena RC.

2. **Facilitating reproducibility within Biomedical Science and Health Data Domain** [30'], Leslie McIntosh Borrelli, Washington University School of Medicine and Executive Director of RDA.

3. **Diverging data protection regulations and security standards referring to health data** [30']: Ludovica Durst, Rome University La Sapienza and Lynkeus.

4. **Open discussion** and further themes in view of P11 in Berlin [15']

research data sharing without barriers
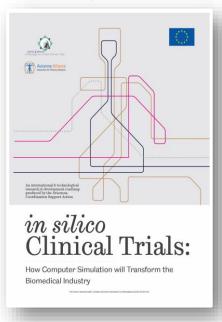rd-alliance.org

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Background (1)

- IG idea rooted in EU projects in biomedical informatics
  - Health-e-Child www.health-e-child.org
  - Sim-e-Child www.sim-e-child.org
  - Cardioproof http://www.cardioproof.eu
  - MD-Paedigree www.md-paedigree.eu
  - p-medicine www.p-medicine.eu
  - Avicenna www.avicenna-isct.org
  - MyHealthMyData www.myhealthmydata.eu

VPHi:
The International
Society for In Silico
Medicine

75+ universities
100+ research groups

research data sharing without barriers
rd-alliance.org

Background (2)

- Two successful BoFs at RDA P6 (Paris) and P7 (Tokyo)
    - Each attended by numerous researchers and professionals from diverse backgrounds who expressed interest in IG formation
    - Charter / IG approved – growing number of members on the website

- Two IG meetings at RDA P8 (Denver) and RDA P9 (Barcelona)

- As yet, the Health Data IG has 140+ members

Having research data at the service of healthcare innovation[5]
Some User scenarios/Focus areas

- **Data access and protection**
  - sharing best practice on pseudonymisation and anonymization (or "qualified anonymisation")
  - developing models for consent that protect patients while enabling research
  - providing a forum for discussing, explaining and responding to data protection regulation
  - secure opening up of data to facilitate research
- **Data-based healthcare for personalised medicine**
  - disease signatures identification
  - stratification of patient groups
  - patient-specific simulation and prediction
- **Data literacy in Health care**
  - providing materials for education of healthcare professionals on use and misuse of data
- **Patient data repositories/patient-centric data gathering systems**
- **In-silico drug development and clinical trials**
  - representing interests of the data-based healthcare community to policy makers
  - identifying and discussing related challenges, interdisciplinary research needs and potential roadmaps.
- **Blockchain applications to health data**

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Tackling Wasteful Spending on Health

- A significant share of health spending in OECD countries is at best ineffective and at worst, wasteful.

- **One in ten patients is adversely affected during treatment by preventable errors, and more than 10% of hospital expenditure is allocated to correcting such harm**.

- Many more patients receive unnecessary or low-value care. A sizable proportion of emergency hospital admissions could have been equally well addressed or better treated in a primary care setting or even managed by patients themselves, with appropriate education.

- Large cross-country variations in antibiotic prescriptions reveal excessive consumption, leading to wasted financial resources and contributing to the development of antimicrobial resistance.

- The potential for generic medicines remains underexploited.

- Finally, a number of administrative processes add no value, and money is lost to fraud and corruption.

- Overall, existing estimates suggest that **one-fifth of health spending could be channelled towards better use.**

according to the May 2017 Friends of Europe Discussion Paper

- "If healthcare could be transformed by the kind of 'disruptive innovation' that has revolutionised other sectors of the economy, the potential efficiency and cost gains would be huge".

- "Healthcare has not achieved the types of productivity increases that most other industries have experienced. In fact, healthcare ranks near the bottom in terms of productivity improvements since 1990".

- "In healthcare we lag at least ten years behind virtually every other area in the implementation of IT solutions".

- "Implementation is inconsistent due to the fragmented nature of the system and because of incentives that support the status quo".

- "Transaction-based systems don't provide citizens with an incentive to promote their own health, or medical professionals to keep patients well".

- "The importance of building trust into the system so that people feel comfortable sharing their health data".

- Eventually, what is needed is "a radical shift in the fundamental approach to digital health: establishing an innovation ecosystem with a central platform at its heart".

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Big Data Healthcare

- Big Data Healthcare is the drive to capitalise on growing patient and health system data availability to generate healthcare innovation.

- By making smart use of the ever-increasing amount of data available, new insights can be found by re-examining the data or combining them with other information.

- In healthcare this means not just mining patient records, medical images, biobanks, test results , etc., for insights, diagnoses and decision support advice, but also continuous analysis of the data streams produced for and by every patient in a hospital, a doctor's office, at home, and even while on the move via wearables and mobile devices.

Personalised Medicine

- Personalised Medicine refers to a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring:
    - the right therapeutic strategy
    - for the right person
    - at the right time
    - and/or to determine the predisposition to disease
    - and/or to deliver timely and targeted prevention.
- The future vision is to move towards prevention and prediction (right living, right care, right provider, right value, right innovation) .

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CDSSs

- Big data, provided for bio-medical and clinical researchers to mine for patterns and correlations, are meant to trigger a process of "data-intensive scientific discovery".

- This can go far beyond the traditional uses of empirical description.

- It can lead to CDSSs based on computerised models that provide predictive simulations of complex pathophysiological phenomena.

The need of specialised analytics

- To integrate bioinformatics and systems biology information with clinical observations at tissue, organ and organisms scales

- To define the "physiological envelope" during the daily life of each patient.

The need of advanced health data repositories

In order to reap this growing value there is the need not only for clinicians and researchers to acquire Big Data analytics skills and services, but also for patients, and for industrial stakeholders, to develop a framework for data repositories which:

- adheres to international standards for the preservation of data

- sets common storage protocols and metadata

- protects the integrity of data

- establishes sound privacy criteria for different levels of access

- defines common rules that facilitate the combining of datasets and improve interoperability.

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- Here comes now Leslie's presentation on how a better understanding of the current practices of research transparency and accessibility, regarding:
  - research design and aim
  - database and data collection methods
  - data mining and data cleaning
  - data analysis
  - data sharing and documentation
- can be crucial for providing better data for better decisions.

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- Some examples:
- **FAIRsharing**
- **Biosharing**
- The *Scientific Data* (natureresearch)peer-reviewed, open-access journal for descriptions of scientifically valuable datasets, aims to promote wider data sharing and reuse, and to credit those that share.

- The open source **ISA TAB** for standardizing metadata for scientific experiments and the **ISA Framework** managing an increasingly diverse set of biomedical experiments employing one or a combination of technologies.

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The need for better data decisions

- After Leslie's will also come Ludovica's presentation on diverging data protection regulations and security standards referring to health data

RDA P11 in Berlin

- We would like our IG to prepare for the Berlin plenary two reports on these subjects

- Our final discussion should also focus on how to get organised for attaining this goal.