IT Future of Medicine

Medical Platform
Challenges of using medical and genetic data

- Broad spectrum of differently structured data
- How to achieve data interoperability
- Complex ethical, legal and societal frameworks
## IT Future of Medicine

<table>
<thead>
<tr>
<th>Data type</th>
<th>Examples</th>
<th>Structure</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Text</strong></td>
<td>Diagnosis, anamnesis, life style, medication, therapy, ...</td>
<td>INVASIVES MAMMAKARZINOM VOM DUCTULO-LOBULAEREN MISCHTYP, G-2, PT-2, FIBROESE MASTOPATHIE. OESTROGENREZEPFOREN: HOCHGRADIG (SCORE 12)</td>
</tr>
<tr>
<td><strong>Numeric</strong></td>
<td>Laboratory data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Age, BMI, disease-free survival, ...</td>
<td><strong>$3.75,\text{TA}$</strong> $3.70,\text{g/l}$ $235,\text{g/l}$ $11.9,\text{g/dl}$ $35.4%$</td>
</tr>
<tr>
<td><strong>Categoric</strong></td>
<td>staging, grading, score</td>
<td></td>
</tr>
<tr>
<td><strong>Image</strong></td>
<td>Histologic image</td>
<td><a href="image">Histologic image</a></td>
</tr>
<tr>
<td><strong>Array</strong></td>
<td>cDNA data</td>
<td></td>
</tr>
<tr>
<td><strong>Composite</strong></td>
<td>DNA sequences, polymorphisms, PCR, molecular signatures</td>
<td></td>
</tr>
<tr>
<td><strong>Hierarchic (tree)</strong></td>
<td>Family history</td>
<td></td>
</tr>
</tbody>
</table>
IT Future of Medicine

The garbage in – garbage out problem

Patient → Data → Knowledge

Sample
Pre-analytics

Computational modelling

Basic research
Biomarker
Targets for therapy
Reliability of medical and lifestyle data

<table>
<thead>
<tr>
<th>Reliability of measurement</th>
<th>Lifestyle/environmental factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥0.95</td>
<td>Body mass index (BMI) calculated from measured height and weight in various studies(^76)</td>
</tr>
<tr>
<td>~0.9</td>
<td>Measured hip or waist circumference(^76,77)</td>
</tr>
<tr>
<td>~0.7</td>
<td>Blood pressure measurement in the Intersalt Study(^78)</td>
</tr>
<tr>
<td>~0.5</td>
<td>Many nutritional components in a dietary recall study, mean of four 24h assessments(^79)</td>
</tr>
<tr>
<td>~0.3</td>
<td>Many nutritional components in a dietary recall study, a single 24h assessment(^79)</td>
</tr>
</tbody>
</table>

from P. Burton et al., Int J Epidemiol 2008
Impact of parameter reliability

Case control study: 1 case 4 controls

from P. Burton et al., Int J Epidemiol 2008
IT Future of Medicine

SPIDIA
Standardisation and improvement of generic pre-analytical tools and procedures for in-vitro diagnostics

Home | About Us | About the Project | News and Press | Events and Trainings | Downloads

NEWSLETTER
Subscribe to our newsletter to receive latest news about the project.

CONTACT US
Visit our contact form to submit comments and questions about this website.

ABOUT SPIDIA
SPIDIA is a 4-year project, funded by the European Union FP7 programme to the value of 9 million Euros, which brings together a consortium of 16 leading academic institutions, international organisations and life sciences companies.

The project is coordinated by QIAGEN GmbH and aims to tackle the standardisation and improvement of pre-analytical procedures for in-vitro diagnostics. The proposed research and standardisation activities cover all steps from creation of evidence-based guidelines to creation of tools for the pre-analytical phase to testing and optimisation of these tools through the development of novel assays and biomarkers.

+++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++

Read our most recent Newsletter

including important information about SPIDIA’s project progress and where to meet us!

+++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++ LATEST NEWS +++
IT Future of Medicine

Gene expression data variability

_genes (sorted by cryo ct)_

| 1 | sample duplicate (12mo) |
| 2 | cDNA duplicate |
| 3 | PCR duplicate |
| 4 | PCR |
| 5 | FFPE24h (6mo) |
| 6 | Cryo |
The ethical and legal framework

EU Legislation (examples)

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;


- The Charter of Fundamental Rights of the EU, December 2009.
International Conventions and Declarations (Examples)

- Biomedicine on Biomedical Research (CETS No.:195, 2005);
- Helsinki Declaration in its latest version (2008);
- OECD guidelines on human biobanks and genetic research databases (Oct 2009)
- Recommendation (97) 5 of the Committee of Ministers to Member States on the protection of medical data
- Recommendation R (79) 5 of the Committee of Ministers to member States concerning international exchange and transportation of human substances.
- Recommendation R (94) 1 of the Committee of Ministers to member States on human tissue banks
- The Council of Europe additional Protocol to the European Convention on Human Rights
- The Council of Europe recommendation regarding the use of human biological samples in research (Rec (4) 2006)
- Universal Declaration on the human genome and human rights adopted by UNESCO (1997);
## IT Future of Medicine

### Comparison Chart of Guidelines

For each guideline, the table addresses biobanking development steps in either of the following three levels of detail:

- mentioned, or
- guidelines (detailed enough to dress a protocol/model), or
- protocols/model (ready to be followed, to be used)

<table>
<thead>
<tr>
<th>Author (s)/organization</th>
<th>OECD</th>
<th>ISBER</th>
<th>IARC, WHO</th>
<th>NCIC, NIH, HHS</th>
<th>ABN</th>
<th>EHRM</th>
<th>RAND</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>International (28 countries)</td>
<td>International Forum based in United States</td>
<td>Worldwide Directors of National Cancer Centres</td>
<td>United States</td>
<td>Australia</td>
<td>Finland</td>
<td>United States</td>
</tr>
<tr>
<td>Document link</td>
<td>guidelines</td>
<td>guidelines</td>
<td>guidelines</td>
<td>guidelines</td>
<td>guidelines</td>
<td>guidelines</td>
<td>guidelines</td>
</tr>
<tr>
<td>Sample type(s)</td>
<td>Wide: human, animal and plant, and micro-organism</td>
<td>Human: blood, urine, tissues, nails, saliva, breast milk etc</td>
<td>Human: blood (plasma, serum, white blood cells), buffy coat, urine, buccal cells, saliva, bronchoalveolar lavage, bone marrow aspirate, fine needle aspirate, cerebrospinal fluid, semen, cervical and urothral swabs, hair, nail</td>
<td>Human: blood and solid tissue mentioned but not extensively</td>
<td>Human: blood, (serum, plasma, white blood cells, buffy coat), Urine, buccal cells, bone marrow</td>
<td>Human: blood</td>
<td>Human: blood, serum, tumor, tissue</td>
</tr>
</tbody>
</table>

*from P3G*
IT Future of Medicine

A pan-European infrastructure to provide access to high quality human biological samples and data

Solutions for:
• Sample management
• Data management
• ELSI issues
• Governance
• Financing
IT Future of Medicine

BBMRI legislation WIKI
IT Future of Medicine

Sample/data exchange navigator
IT Future of Medicine

Public engagement (BBMRI)

- Focus groups (AT, NL, GR, DE)
- Eurobarometer (15,600 people, 32 countries)
- European Patient Organisations
- Hearing in the European Parliament
Public perception (Eurobarometer 2010)
IT Future of Medicine

Medical and genetic data issues

- IT-FoM will build on many previous and ongoing leading EU initiatives (examples)
  - BBMRI
  - ELIXIR
  - ESBI
  - ESGI
  - SPIDIA
  - P3G
  - BioSHaRE
  - Biomedbrigdes
  - PHGEN
  - OncoTrack
  - ....

- Work will focus on integration into data management concept
The project outcomes will enable the prediction of health, disease, therapy and its effects for individual patients and through application in the clinic will change the future of medicine.

For more information:
Website: http://www.itfom.eu
Email: info@itfom.eu
Twitter: @itfom
Facebook: I.T. Future of Medicine
LinkedIn: IT Future of Medicine