In Silico Medicine in Italy: adoption pathways

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The role of In Silico Medicine in diabetes. Rome, 26-5-2022

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In Silico medicine

- Living organisms can be investigated *in vitro*, *in vivo*, or *in silico*
- *In Vitro* studies ("within the glass"), are done in a laboratory environment using cell cultures, test tubes, Petri dishes, etc.
- *In Vivo* studies ("within the living"), are those in which the effects of various biological entities are tested on whole, living organisms, whether animals or humans
- *In Silico* ("within the silicon, e.g. a computer chip) studies are done using computer modelling and simulation

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In Silico Medicine in Italy

- “Seeding the Europhysiome” – 2007: 16% of International experts who contributed to the roadmap were from Italy, more than from UK
- The first in silico replacement of an animal experimentation for regulatory purposes accepted by the FDA in 2008 was co-developed by the University of Padova
- Since then Italy has been very active in the field: internationally recognised research groups are active in Padova, Milano, Bologna, Pavia, Roma, Catania, Torino, Genova, etc
- Major EU-funded projects in the field were coordinated by Italian organisations, including: SCARLET, CARDIOWORKBENCH, STEP (FP6); ORAMOD, VPHOP, VPH-FET, MD-Paedigree, IRENE, CARDIOPROOF (FP7), STriTuVaD, In Silico World, MY-ATRIA, EXSCALATE4CoV, SYMBIONIC, LIGATE, (H2020)

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The story so far

- The National Health Council (CSS) is the Italian Health Minister's technical and scientific consulting body
- In 2019 the chair of the 1st section of CSS, Prof Bruno Dallapiccola, invited Prof Claudio Cobelli and Prof Marco Viceconti to establish a working group on In Silico Medicine
- In 2020 the report "Adoption pathways for In Silico Medicine in Italy" is submitted to the Minister; the document is approved but its publication is delayed to 2021 due to Covid-19 pandemics
- In 2022, a dialogue with AIFA was established to investigate potential areas of collaboration with the aim of improving mutual exchange of expertise and aligning on regulatory requirements for the adoption of In Silico methodologies in drug development

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Why diabetes?

- Diabetes Mellitus is a complex, multi-organ disease, for which a good quantitative mechanistic understanding is available.
- Diabetes is the disease for which for the first time a regulator accepted a computer model prediction based on cohorts of virtual patients as a possible replacement for animal testing
- Diabetes is a world pandemic and poses a huge socioeconomic burden to Italy: the overall cost for the national healthcare service is estimated in €8.1. billion/year (Marcellusi, 2016)

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CSS work group /1

- Prof. **Claudio Cobelli** Coordinatore GdL - Consigliere Sezione I CSS, Professore Emerito di Bioingegneria, Dipartimento di Ingegneria dell'informazione (DEI), Università degli Studi di Padova
- Prof. **Marco Viceconti** Co-coordinatore GdL, Professore ordinario di Biomeccanica Computazionale, Dipartimento di Ingegneria Industriale, Università di Bologna
- Prof. **Andrea Cavalli**, Professore ordinario di Chimica Farmaceutica presso il Dipartimento di Farmacia e Biotecnologie dell'Università di Bologna. Direttore di Ricerca presso la Fondazione Istituto Italiano di Tecnologia di Genova.
- Prof. **Francesco Migliavacca**, Professore Ordinario di Bioingegneria Industriale e coordinatore sezione Ingegneria biologica, Dipartimento Chimica, Materiali e Ingegneria Chimica 'Giulio Natta', Politecnico di Milano.
- Prof. **Francesco Pappalardo**, Professore associato di Informatica. Dipartimento di Scienze del Farmaco, Università di Catania
- Prof.ssa **Maria Chiara Carrozza**, Professore Ordinario di Bioingegneria Industriale - Istituto di Biorobotica della Scuola Superiore Sant'Anna, Pisa. Presidente del Gruppo Nazionale di Bioingegneria (Associazione Gruppo Nazionale di Bioingegneria)

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CSS work group /2

- Prof. **Sara Cabodi**, Professore associato di Biologia Applicata. Dipartimento di Biotecnologie Molecolari e Scienze per la Salute, Università di Torino.
- Dott. **Luca Emili**, Imprenditore, co-fondatore e CEO di sicurezza informatica con Emaze Networks e creatore del primo portale per in In Silico Trials.
- Prof.ssa **Laura Palazzani**, Professore Ordinario di Filosofia del Diritto e Biogiuridica, Presidente del Comitato Etico per la Ricerca Scientifica (CERS) della LUMSA. Vice Presidente del Comitato Nazionale per la Bioetica (CDBI).
- Dott. **Raffaele Tuccillo**, Magistrato amministrativo, Tar Lazio
- Prof. **Sergio Abrignani** Consigliere Sezione I CSS, Professore ordinario di Patologia generale – Dipartimento di Scienze Cliniche e di Comunità, Università degli Studi di Milano. Direttore scientifico dell'Istituto Nazionale di Genetica Molecolare "Romeo ed Enrica Invernizzi", Milano.
- Prof. **Francesco Longo** Consigliere Sezione I CSS, Professore Associato in Management pubblico, Dipartimento Analisi delle politiche e management Pubblico, Università Bocconi di Milano

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“Percorsi di adozione della In Silico Medicine in Italia”

Coordinatore: Prof. Claudio Cobelli

Co-coordinatore: Prof. Marco Viceconti


Ministero della Salute

Consiglio Superiore di Sanità

Sessione LII (2019-2022)

Presidente: Prof. Franco Locatelli
Segretario generale: Dott.ssa Daniela Rodorigo

Sezione I

Presidente: Prof. Bruno Dallapiccola
Segretario tecnico: Dott. Stefano Moriconi

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15 maggio 2020

https://www.salute.gov.it/portale/documentazione/p6_2_2_1.jsp?lingua=italiano&id=3095

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CSS Report: recommendations /1

- R1. Introduce the concept of "clinical data donor for research use" and a new informed consent model that authorizes, indefinitely or until the consent is revoked, the use of the donor's clinical data in the research databases.

- R2. Invite the National Bioethics Committee to draw up an opinion, on an ethical and legal level, on the subject of "data donation", in the light of the new orientations of digitized research.

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CSS Report: recommendations /2

- R3. Adoption of in Silico strategies that reduce:
  - geographic and wealth inhomogeneity in access and quality of care;
  - costs of research and development of new treatments;
  - animal experimentation with the improvement of animal welfare and the provision of resources destined for the abandonment of animal testing.

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CSS Report: recommendations /3

- R4. To finance pilot projects aimed at the development and clinical transfer of Digital Patient technologies to be adopted at national level, thus offering a better diagnostic / prognostic action, facilitating the personalized therapeutic choice (precision medicine) especially in relation to diseases of social importance (eg. chronic diseases - oncology - rare diseases).

- R5. Fund pilot projects aimed at In Silico trials for the evaluation of the safety and efficacy of new drugs and medical devices thus reducing animal testing and making human experimentation safer with undeniable benefits, including economic ones.

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CSS Report: recommendations /4

- R6. Promote an interoperability standard for the creation of a single information system for the management of the electronic health record (standard HL7 FHIR)

- R7. Create a scenario of total integration of digital clinical data where every citizen can access or give access to the treating staff to all of their medical data, from birth to today. This level of total integration, albeit very ambitious, is already active in some EU countries, and we believe it should definitely be explored.

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Conclusions

- There is a need to promote the development of best practices to improve the adoption of In Silico methodologies
- Italian biomedical industry, mostly made agile medium-sized companies, could benefit most by such radical innovation
- Early dialogue and cooperation is pivotal between regulatory authorities, academia, and industry to define an appropriate regulatory framework and increase the adoption of In Silico methodologies

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Any questions?

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