A FET Flagship on Personalised and Patient Centred Healthcare

EXECUTIVE SUMMARY

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Leadership and Governance of the Preparatory Action

Under the leadership of Prof. Rui L. Reis, Director of 3B's Research Group[1], Vice-Rector of Research and Innovation at the University of Minho[2] and Global President of the Tissue Engineering and Regenerative Medicine International Society (TERMIS)[3], the University of Minho is coordinating an ambitious and large-scale proposal for a preparatory action targeting the health and life sciences area and specifically focused on Personalised and Patient Centred Healthcare. This proposal is the result of a merger of related initiatives that applied to the FET Flagship open consultation. The University of Minho is supported by a very strong Steering Committee of 16 organisations. The core and multidisciplinary partnership thus joins under a single initiative several of the leading scientific and technological leaders working in the health and life sciences fields. The partnership's extensive experience in these fields, coupled with a strategic vision for the future of health, will guarantee a disruptive approach in the definition and implementation of this action.

The context for personalised and patient centred healthcare

Despite significant advances in medicine, the current context and healthcare outcomes are still inadequate. The ageing population, which continues to grow; the manifestation of chronic diseases (e.g. heart diseases, type 2 diabetes), also related to the ageing population; and healthcare costs, which place a significant burden on national economies, all call for a revolutionary change in the healthcare landscape. This new landscape is possible in the near future, based on new science and technologies, where the healthcare system will be patient centred, treatments will be evermore personalised, and the patient will be involved in decision-making.

Existing fragmentation in health sciences and technological fields

There have been many recent developments in various health sciences and technological fields, including but not limited to tissue engineering, biomaterials, biofabrication, bionics, stem cells, nanotechnology, multi-OMICS, big data and imaging. These and many other fields, based on new knowledge and technological advancements, have the potential to generate impactful contributions for the development of new and improved therapies. However, many of these scientific areas and fields remain fragmented and have not yet been explored from an integrated approach. Developments are still achieved in isolation and within individual fields. Thus, there is an evident

[1] 3B's Research Group: https://3bs.uminho.pt/
[2] University of Minho: https://www.uminho.pt/EN
[3] TERMIS: https://www.termis.org/

opportunity for different fields to strategically work together under a common objective: to develop new solutions targeting personalised and patient centred healthcare.

Objective and Grand Challenge of the Flagship initiative

The objective of the proposed action is to drive a transformation in the current situation by developing a game changing strategy and promoting a paradigm shift in the health and life sciences field. The grand challenge is to restructure current research efforts, moving from multi to transdisciplinary, and also converging stakeholders (i.e. academia, research, industry, associations and societies, and authorities) through strategic interactions towards a more predictive rather than reactive healthcare. The challenge is to develop efficient, personalised and patient centred regenerative medicine therapies (rather than relying on substitution and treatment of symptoms), along with more effective early diagnosis tools and prevention care, patient empowerment and out-of-hospital/ remote care. The challenge is also to put the emphasis on patient involvement and responsibility, rather than only the providers' responsibility. This will lead to increasingly patient centred healthcare that will serve to improve the sustainability of healthcare systems.

Scientific and technological goals of the initiative

The main scientific goals of the project consist in the development of patient-matched therapies for treating diseases that have a great impact on society (e.g. those associated to ageing and chronic diseases) or on the patient (e.g. rare diseases). Other scientific and technological goals include the development of early and accurate diagnostic technologies and predictive and preventive tools that enable a paradigm change in healthcare.

To achieve these paradigm-changing goals, the Preparatory Action will support the design of a scientific and technological roadmap (see Figure 1) that foresees the concerted effort of leaders of different research fields going from basic to applied research on tissue engineering, biomaterials, biofabrication, biosensors, stem cells, nanotechnology, multi-omics, big data, imaging, etc. The development and implementation of the roadmap also includes the efforts of social sciences and economy experts to create awareness and acceptance of the new technologies, as well as experts to cope with the regulatory framework, marketing and costs supporting the new advanced therapies to be developed.

The roadmap will be implemented through three stages that include the *shifting*, *converging* and *integrating* of the various fields currently working in isolation or at a distance from each other. The three stages include:

1. *IDENTIFYING* synergies between an increasing number of scientific areas and technologies;
2. *SHIFTING* these by promoting specific challenges – *moonshot* projects. Along this process, the various fields will be shaped to accommodate the integrations with the other adjacent fields.
3. Increasing the complexity of the successive moonshots will require the *CONVERGING* of additional fields, until reaching a perfect orchestrated *INTEGRATION*.

Figure 1. Long-term scientific and technological roadmap

The roadmap focuses on overcoming fragmentation through a paradigm shift in the convergence of scientific fields and stakeholders into transformative and core platforms towards four patient centred healthcare pillars: (1) integrated diseases prevention, (2) multicentred diseases prediction, (3) personalized therapies and treatments and (4) participative society.

The roadmap's converging and integrative platforms

Defined during the one year Preparatory Action, the initiative will implement the developed scientific and technology roadmap and will identify strategic paths to move from fragmented areas to continuously converging areas, addressing both basic and applied research. In doing so, the action aims to achieve a number of key transformative platforms, including converging platforms and integrative platforms. These platforms mobilise multiple scientific areas and incorporate key future and emerging technologies.

Converging Platforms:

- Advanced Manufacturing: will be centred on the increasing integration of all the new/available innovative and relevant technologies including bioprinting, 3D biofabrication, microfluidics (lab-organ-on-a-chip), bioreactors, etc., centred on new developments of regenerative medicine therapies. It will also support the development of innovative devices, such as portable diagnostics tools, health sensors, wearables, etc.
- Imaging, Biosensing, and MultiOmics: will integrate knowledge generated by each of those technologies enabling the generation of real time data for supporting the development of patient-centred personalised and regenerative therapies. The integration of biosensing and imaging will enable following in real time the evolution of specific biomarkers identified in multiomics analysis, providing new insights into the onset and progression of diseases and efficacy of the therapies to be developed.

- MultiScaleBiology: will be based on the increasing awareness of the complexity of biological systems and the importance it assumes in the development and outcomes of engineered therapeutic strategies.

Integrative Platforms:

- Big Data and Deep Learning: will use artificial intelligence as a disruptive tool for the management and analysis of the big data generated by the transformative platforms. The development and application of algorithms allowing to learn from new data is expected to produce great developments in disease diagnosis and prevention, treatment options, the development of cures and drugs and the business of healthcare.
- Health Policies and Social Sciences: will assist in the definition and implementation of a series of coordinated and coherent actions from all sectors and the whole spectrum of society, as many of the main drivers of bad health lie outside the control of health ministries, systems and professionals.
- Health Economics and Regulatory Issues: will design health economic policies and a regulatory agenda considering the evidence-based technology approach, focusing on health applications in primary production, health, and industry. This platform will support the expected increase of the innovation rate in the areas of healthcare by providing adequate health economics policies and future regulatory perspectives for best defining a clear regulatory path of consumption, use and reimbursement in benefit of the Patient.

Involvement of stakeholders and mobilisation of critical mass

In addition to the core partnership, consisting of 16 organisations and covering 10 European countries of a wide geographical scope (see section 'Steering Committee'), the project has also mobilised many more than 300 stakeholders from various categories (detailed in the Sections below): Academia and Health Institutes (*ca.* 150), Research Institutes (*ca.* 45), Industry and Associations (*ca.* 95), and Authorities (ca. 25) from 31 countries (including 27 from the EU and Associated Countries).[4] With regard to Authorities, it should be emphasized the support of authorities at Ministry level, including the Ministry of Research (Greece), Ministry of Education and Science (Bulgaria), Ministry of Education, Science and Culture (Iceland), Ministry of Education, Science and Sport (Slovenia), Ministry of Science, Education and Culture (Germany), Ministry of Health (Italy), Ministry of Health (Portugal), and the Ministry of Science, Technology and Higher Education (Portugal). The full list of supporters is available at the project website.

[4] Numbers are as of February 1, 2018.

Activities of the one year Preparatory Action

As aforementioned, the implementation of the project and long-term scientific and technological roadmap and the will be based on the activities developed during the one-year Preparatory Action. Several activities are envisioned for the Preparatory Action. These will focus on defining how the Flagship initiative will function and be implemented, how it will be governed, how stakeholders will be mobilised and involved, how results will be exploited, among others.

Specific activities will include:

- Defining the Flagship's Strategy and operational framework, focusing on the operations, implementation of the S&T roadmap, financial approach and involvement of partners.
- Consolidating the long-term vision and unifying goal of the Flagship and defining measurable and realistic short to long-term S&T objectives and milestones.
- Defining the scientific and technological research roadmap, including how R&D will be promoted and implemented in the course of the initiative.
- Managing Scientific and industrial engagement, not only to receive their support, but to involve them in the project and development of the roadmap (through workshops, consultations and other activities).
- Defining the Governance of the initiative, including decision making and involvement of stakeholders.
- Defining the exploitation and impact potential of the initiative, including how results will be managed and supported on a market analysis.
- Managing dissemination and public outreach, focused on the one-year preparatory action, which will include the development of a plan, materials and implementation of specific events (e.g. a large conference).
- Ensuring the management and coordination of the one year Preparatory Action.

Impacts

The integration and convergence of fields will lead to a new era in healthcare based on regenerative, precision and personalised-medicine therapies centred on the patient. Furthermore, it will generate new avenues for predicting and preventing disease. The action will build on the critical mass of experts from different fields, which will generate the momentum to provide a continuous and tangible development of different advanced therapies for regenerative, precision and personalised medicine. The vision behind the emerging areas of predictive, preventive, personalised and participative healthcare is the radical improvement of the quality of life of billions of patients worldwide.

Economic benefits and impact

The new science and technologies developed as part of this initiative will contribute to a new way of thinking about healthcare, which will impact how it is managed. The promotion of personalised medicine, based on newly developed technologies will bring a long-term reduction in healthcare costs. Potential savings will vary depending on the diseases that are being addressed. For example, the use of personalised medicine tests can reduce hospitalisation rates by 30%[5] or provide $2.000 USD in savings per patient[6]. The market perspectives are also positive, with the personalised medicine market estimated to reach $2.4 trillion USD by 2022, and $130 billion just related to regenerative medicine[7].

Social benefits and impact

The initiative will result in new scientific and technological findings that, on the one hand, can underlie future investments in health-related infrastructure, and on the other, lead to the development of solutions and therapies with an impact on society and the patient. For example, the development of new therapies will allow a shift from reactive treatments to preventive ones; new tests will help identify targeted therapies that improve the outcomes of treatments, reduce potential side-effects and potential adverse drug reactions; personalised therapies can also increase patients' adherence to treatments. Another impact is the increased involvement of ICT in the sector and the importance of big data, which is relevant to society (considering the management and security of data). Lastly, advances in these scientific and technological fields have the potential to lead to new businesses and employment opportunities.

Effects on research, collaboration and research talent

The project will have an important impact on research, by converging and integrating R&D from the wide array of scientific areas and technologies related to the health and life sciences. This will be supported by the more than 300 associated partners and supporters involved in the project, which are fully committed to advancing transdisciplinary cross-border R&D aligned with the scientific and technological roadmap. The initiative will amalgamate diverse S&T disciplines into long-lasting platforms,

[5] In the case where heart patiens use a prescribed drugn based on availabiltiy of genetic information [Source: Lewensohn D (2010), Towards Personalised Healthcare (Karolinska Institutet, in association with Science Business) *http://www.sciencebusiness.net/sites/default/files/archive/Assets/5a9b0ad5-bd1e-4d99-92e8-8bec4a89574a.pdf*]

[6] In the case of breast cancer therapy [Source: Same as [5]]

[7] Regenerative medicine: The next generation of therapeutic products is set to shake up the pharmaceutical world. Roland Berger (2017). https://www.rolandberger.com/publications/publication_pdf/roland_berger_regenerative_medicine.pdf

which will nurture trans-disciplinary research ad collaboration, resulting in a new era of European medical R&D. It is expected that this also contribute to a long-term cultural shift within the European S&T community, including a new way of thinking and different approaches to R&D among researchers, technology developers, decision-makers and others. Furthermore, the involvement of authorities during the Preparatory Action and the flagship is also a relevant impact on research efforts in the EU.

Creation of EU-added value and enhancing outcomes of research programmes

EU-added value will be created through the long-lasting collaborations that will be established between the various aforementioned actors. Their involvement in the Preparatory Action will support the development of the S&T roadmap taking, taking into consideration all perspectives in a quasi-quadruple helix approach. Regional and national authorities play a particularly important role as they will define their own priorities and make available complementary funding. By engaging with authorities, the action will be better positioned ensure a greater coherence between the initiative's priorities and those at regional and national level. Value will also be brought to the EU and the initiative through a partnering mechanism, facilitating the implementation of Partnering Projects funded by regional and national authorities, and with objectives aligned with those of the Flagship initiative. The initiative will also contribute to enhancing the value of these Partnering Projects and the programmes that funded them by providing specific platforms and benefits that will increase their international visibility.

In summary…

The challenge behind the proposed action is vital for the future of Europe's healthcare and the wellbeing of its population. The concerted efforts of these areas, the multidisciplinary nature of the envisioned work, and the involvement of hundreds of stakeholders from different areas will be possible under the framework of the FET Flagship instrument. The underlying societal challenge is massive and crucial for the future of healthcare and wellbeing of the population, and this is the right moment to take advantage of the unique position of Europe to launch such great endeavour. The focused efforts of all those areas, its multidisciplinarity and interdisciplinarity, make this challenge only possible to be tackled with the catalytic framework of the FET-Flagship instrument of the European Commission.

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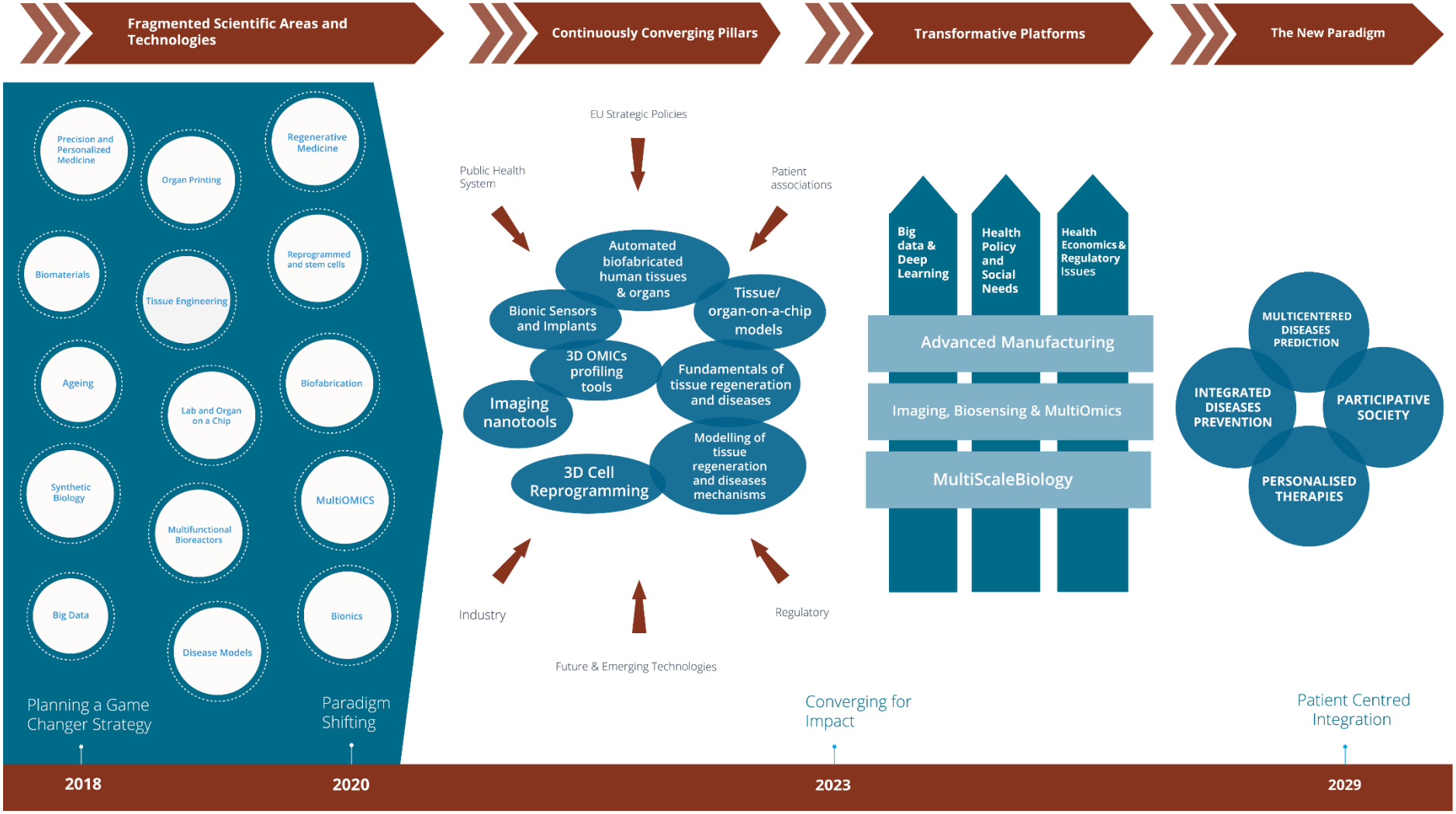

Figure 1. Long-term scientific and technological roadmap

STEERING COMMITTEE

A FET Flagship on Personalised and Patient Centred Healthcare

Name	Institutional Affiliation	Position	Country
Luigi Ambrosio	Consiglio Nazionale delle Ricerche	Director	Italy
Gerjo van Osch	Erasmus MC	Head Connective Tissue Cells and Repair Group	The Netherlands
Elisabeth Engel	IBEC Barcelona	Group Leader	Spain
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Name	Country
ACCIÓ - Catalan Innovation Agency	Spain
Andalusian Initiative for Advanced Therapies	Spain
Axencia Galega de Innovación (GAIN)	Spain
Council for Competitiveness	Czech Republic
Emilia Romagna Regional Government - Department of Health	Italy
Executive Agency for Higher Education, Research, Development and Innovation Funding	Romania
Foundation for Science and Technology	Portugal
German Federal Self-Help Association for Osteoporosis - BfO	Germany
Greek Ministry of Research	Greece
Health Institute of Turkey	Turkey
Liverpool City Region Local Enterprise Partnership	UK
Malta Medicines Authority	Malta
Ministry of Education and Sciences	Bulgaria
Ministry of Education, Science and Culture	Iceland
Ministry of Education, Science and Sport	Slovenia
Ministry of Health	Italy
Ministry of Health	Portugal
Ministry of Science, Education and Culture	Germany
Ministry of Science, Technology and Higher Education	Portugal
National Centre for Research and Development (NCBR)	Poland
North Regional Development and Coordination Commission (CCDR-N)	Portugal
Region of Crete	Greece
Region of Western Greece	Greece
Science Foundation Ireland	Ireland
State Development Corporation of Thuringia - LEG	Germany
Strategic Research and Innovation Partnership Health-Medicine	Slovenia
The Dutch Top Sector Life Sciences and Health (LSH)	The Netherlands
The Icelandic Center for Research	Iceland

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[8] The full and updated list of Associated Partners and Supporters from Academia and Health Institutes is available on the project website: http://web.spi.pt/fetflagship-personalisedhealthcare/supporters/

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[9] The full and updated list of Associated Partners and Supporters from Research Institutes is available on the project website: http://web.spi.pt/fetflagship-personalisedhealthcare/supporters/

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[10] The full and updated list of Associated Partners and Supporters from Industry is available on the project website: http://web.spi.pt/fetflagship-personalisedhealthcare/supporters/

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