The Association for Predictive Medicine, making in silico clinical trials a reality

Barcelona, 5 June 2015

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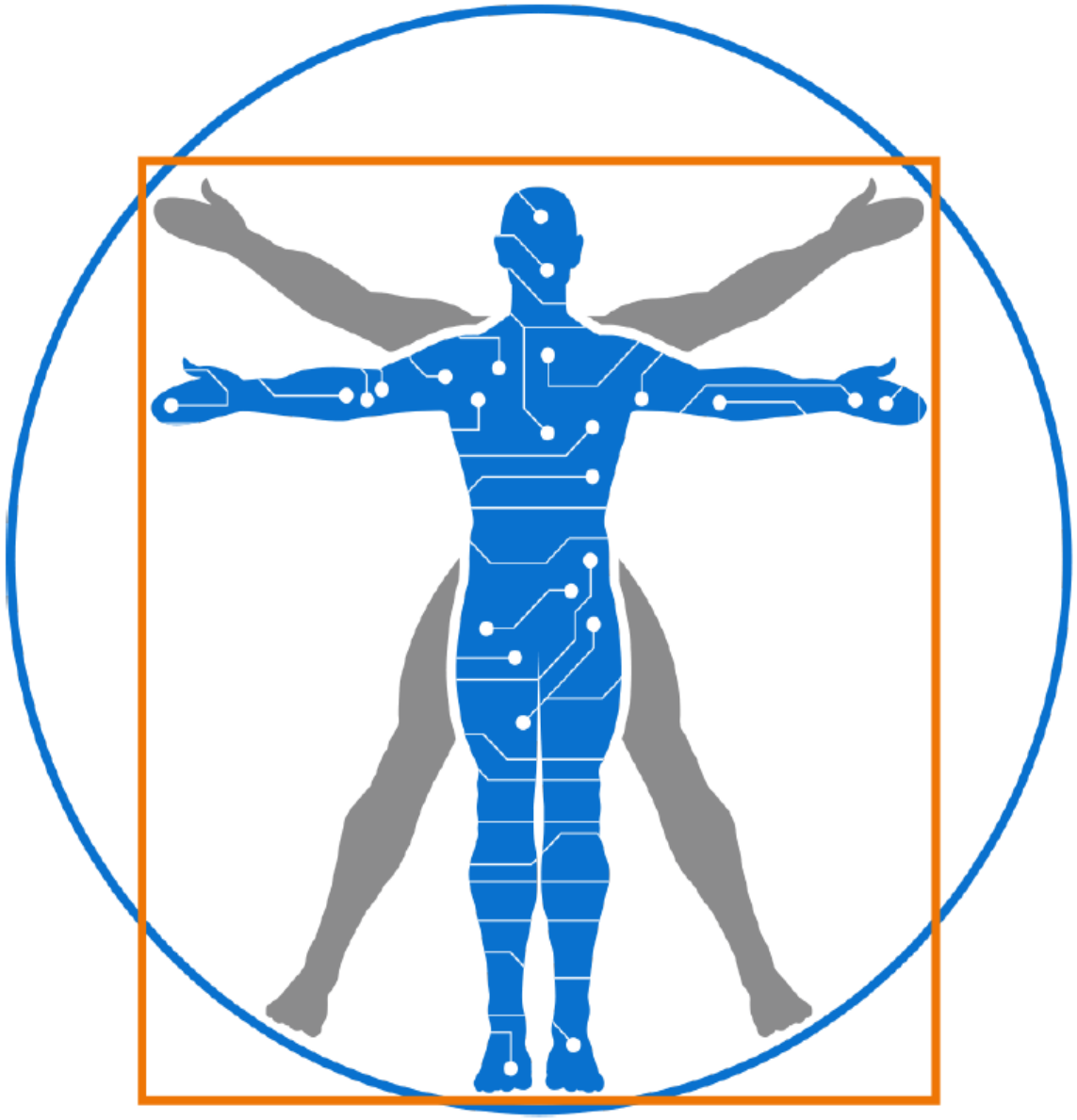
"And you, who want to demonstrate with words the form of man with all the aspects of his limbs, put aside such an idea, because the more minutely you describe it, the more you will confound the reader, and the further you will remove him from understanding of the thing described- therefore it is necessary both to depict and to describe"



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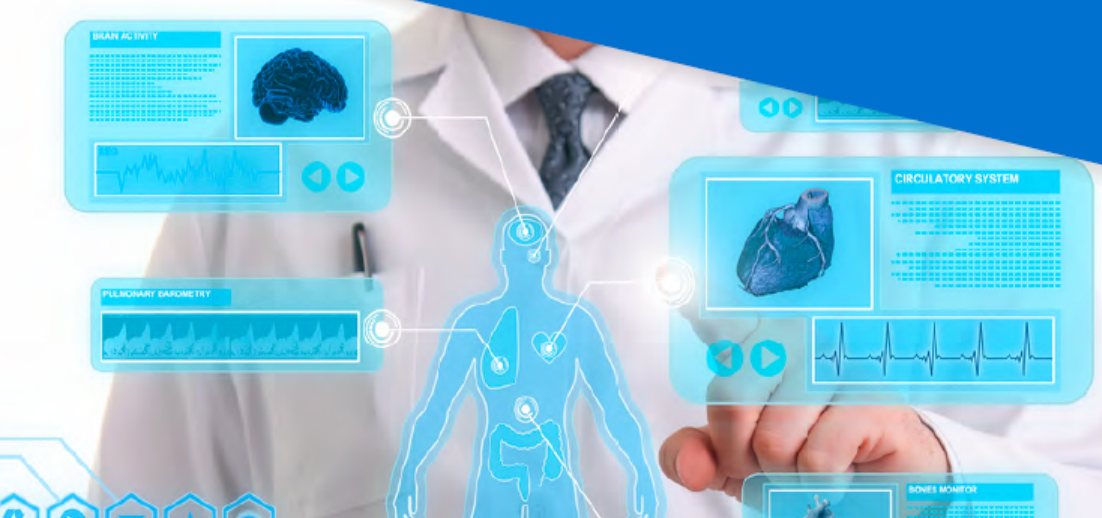

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What is predictive medicine?

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Predictive medicine or "in silico medicine" is the use of **computer modelling** and **simulation** in the diagnosis, treatment, or prevention of a disease.

It contributes to advancing **Personalized Medicine** though the use of Big Data, turning raw data into **actionable information** that informs our decisions about healthcare.

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Process / Examples

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1

Modelling and **simulation**, which is the core of predictive medicine, is already used to improve decision making in a range of other industries such as aviation, finance and weather forecasting.

2

In aviation design, the use of modelling and simulation can **reduce the need** to design and build **multiple prototypes**.

3

Engineers take all the **relevant data** and build a **computer model** to help them decide which aircraft would be the **fastest, safest** and **most efficient.**

4

This improves their decision making and **reduces the cost** of their research.

5

Let's **apply** the same principle to the design of a **clinical trial**.

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Process / Examples

- The use of **modelling and simulation for clinical trials** can have an impact across the full value chain.
- By testing these scenarios using **predictive medicine**, we avoid having to test these in a clinical setting and can find which **design trial** would be best suited **for the new treatment**.
- This greatly **reduces costs**, time to market and ensures the most robust trial possible.
- **Predictive not limited to trial design** but can be used to predict.

Making the right decision …

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Imagine you want to see how long a clinical trial should last to ensure proof of efficacy …

1

Huge quantities of data are processed into meaningful knowledge, essential to build a **computer model.**

2

This model turns the raw data into **useable information for the user.**

3

This model can be used to demonstrate for example, **efficacy of treatment** over time.

Most importantly, the model is used to answer **"what if questions".**

e.g.: what happens if I increase dosage?
Use more or less patients or run the trial over a longer period?

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Is the **current model** fit for purpose?

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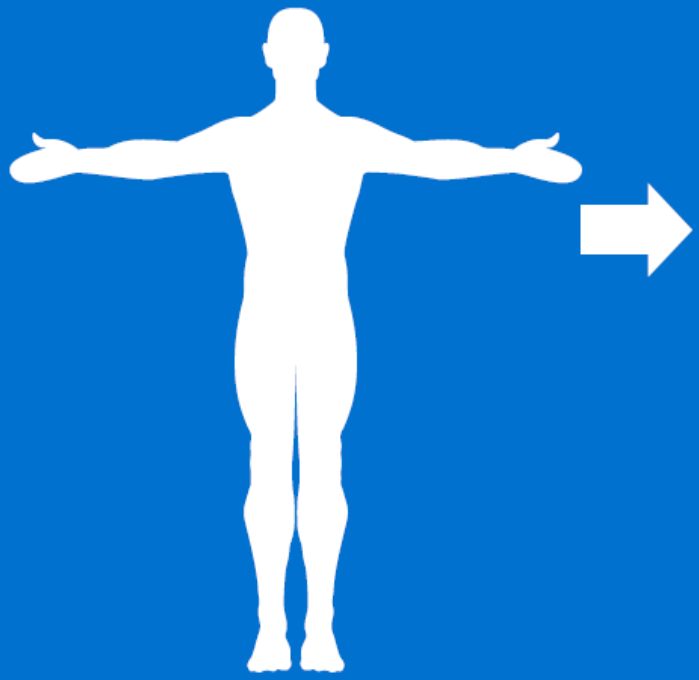
Disease-focused



"One size fits all drug"

But

- Cost of producing new compound estimated at **$1 Billion**, $4 billion if you take into account failure rate
- **Unpredictable adverse events** which take useful products out of the market
- Industry faces severe challenges due to a **declining pipeline**
- **Very long timeline for research** with no guarantee of success (2 in 10,000)

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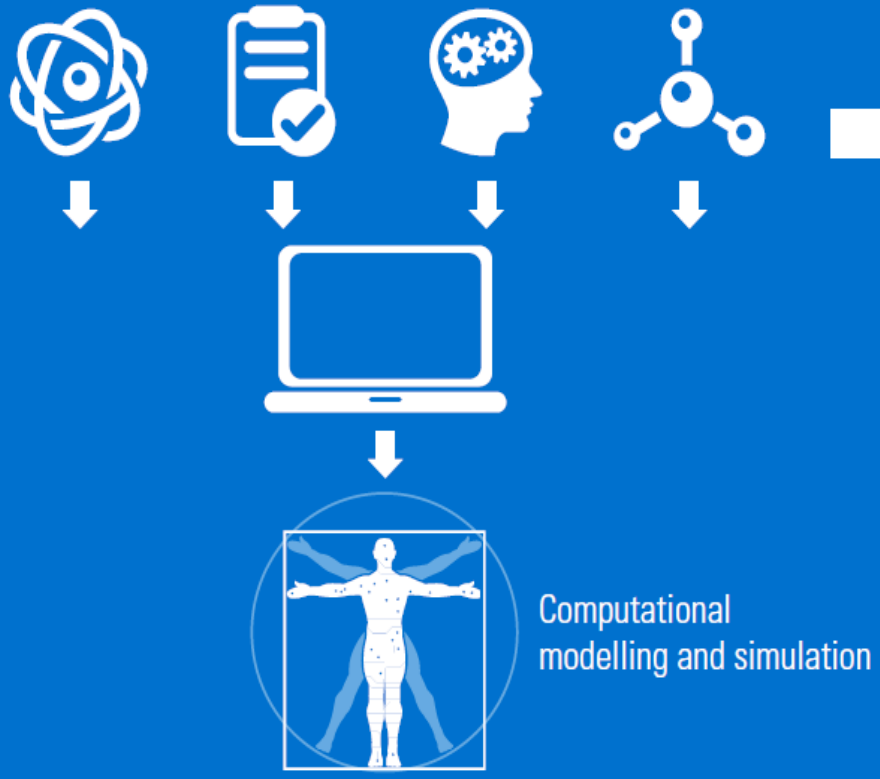
Represents a paradigm shift to a **new** model of developing medicinal products

Patient-focused

Trial results | Evidence | Patient data | Research results



Computational modelling and simulation

Tailored trials, diagnosis and treatment

- **Increased success** rate of medicinal products through better trial design
- **Correct identification of patients** can avoid adverse reactions and keep products on the market
- **Reduced cost** of research as is done on computers
- **Reduced animal testing,** which is costly

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How much data should be made available and what type? Raw data?/Summaries? Validate Phase 1 toxicology models?
Are phone apps for health medical devices? How do we regulate this and control data?
How do we use data for health? How to integrate petabytes of data? Appropriate use of it in diagnosis and drug development?
Symptoms
• Clinical Trials Regulation ✓
• Medical Devices Regulation ✓
• Data Protection Regulation ✓
• Healthcare Apps concept Paper ✓
• mHealth consultation ✓
• eHealth Action Plan ✓
Diagnosis
• New policies and regulation needed
What is medical software and what is software for medical purposes? How do we define it? Can modelling improve patient safety?
Are phone apps for health medical devices? How do we regulate this and control data?
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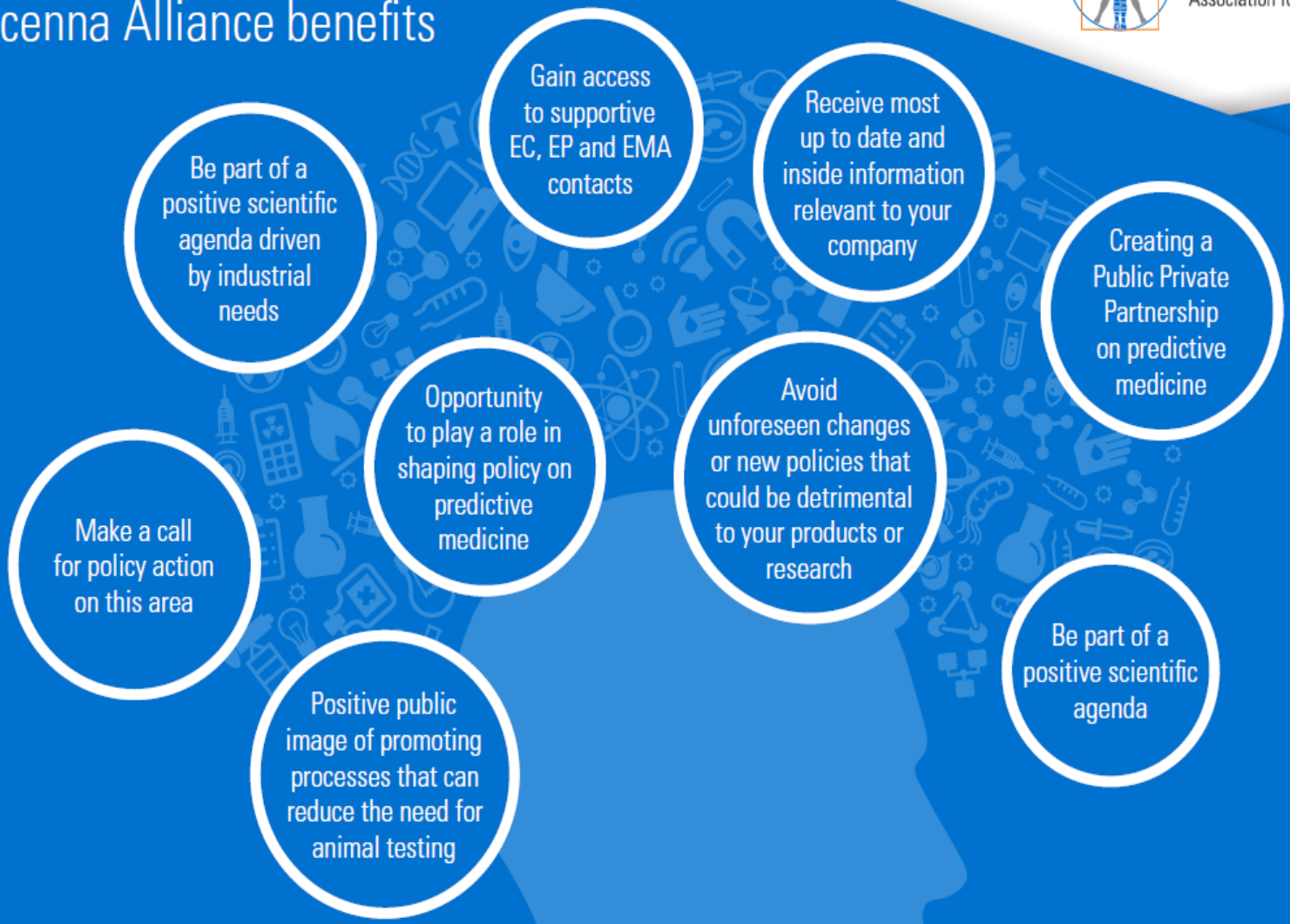

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Medical Devices Industry

- MDR has continued confusion on line between software and medical device;
- Growth of in silico market – modelling and simulation can help with implantables;
- Avoid the next metal on metal hip scandal;
- Stay informed on non-MDR policy that affects your market

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Software Industry

- Lack of validated models – lack of confidence
- Line between apps/software and programs for healthcare increasingly blurred – mHealth regulation
- Major issues on Data Protection
- Opportunity to influence already on going debate – avoid threats to your market

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Cosmetics Industry

- Complete ban on animal testing for cosmetics in force since 2013;
- Stop Vivisection campaign ongoing;
- Work on promotion of validation of in silico models for toxicology and animal testing;
- Avoid dubious alliances and work with a science-based platform.

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The Virtual Physiological Human will revolutionise the way health knowledge is produced, stored and managed as well as the way in which healthcare is currently delivered.

European Commission

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A voice of the in silico community at the EU level

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Rohde Public Policy

- Only consultancy in Brussels that works exclusively in healthcare policy
- Offices in Brussels, Paris, Berlin, London
- RPP to act as secretariat for the Association for Predictive Medicine.
- Membership of the Association means the direct support of RPP.

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Impact of Government Affairs

Directly on Legislation

- Needlestick Directive;
- Data Protection Regulation;
- Medical Devices Regulation;
- Reach Legislation

Expertise in developing political branding for products/topics through creative routes

- Hepatitis
- Pancreatic Cancer

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Impact of Government Affairs

EPP Group in the European Parliament

VPH Institute
Building the Virtual Physiological Human

S&D Group of the Progressive Alliance of Socialists & Democrats in the European Parliament

Towards personalised and in silico medicine: eHealth Action Plan and VPH

Co hosted by Seán Kelly MEP and Vittorio Prodi MEP

Wednesday 26 June 2013, 13:00 – 14:30

Stressed the need for research "champions" in times of austerity in research

Called for the Parliament to recognise VPH as an effective eHealth solution in the eHealth Action Plan 2012-2020

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EP Resolution on the eHealth Action Plan 2012-2020 (January 2014)

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- "Q. whereas successful eHealth initiatives and projects like epSOS or the Virtual Physiological Human initiative have demonstrated the great value of eHealth solutions"
- "36. Urges the Commission and the Member States to continue working through pilot projects, such as epSOS and 'Renewing health', and/or the Virtual Physiological Human initiative in order to develop pan-European interoperability, and to continue to support innovative solutions for person-centred care, including advanced modelling and simulations, needed to achieve the aims of predictive and personalised medicine"

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Parliamentary Question

Parliamentary questions

24 July 2014

Question for written answer
to the Commission
Rule 130
Seán Kelly (PPE) , James Nicholson (ECR) , Claudiu Ciprian Tănăsescu (S&D)

Subject: In silico medicine in Horizon 2020 Parliament's resolution of 14 January 2014 on the eHealth Action Plan 2012-2020 explicitly calls on the Commission to continue to support the 'Virtual Physiological Human initiative' pilot project.

What steps will DG Research and Innovation take to ensure that Parliament's request for a greater focus on in silico methods in the creation of predictive and personalised medicine will be adequately represented in the next Horizon 2020 Work Programme for Health, Demographic Change and Wellbeing?

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Contact with the European Commission

- Meeting on 26 August 2014 with EC Officials;
- 12 representatives, were present, including the Directors Paul Timmers and Mr. Peteris Zilgalvis

- **Topics covered:**
  - in silico medicine in Horizon 2020
  - Data Protection Regulation
  - Engagement with EMA on validation of in silico models

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Outcome of contact with EC

Jan 26, 2015

INTERVIEW WITH PETERIS ZILGAVIS

HEAD OF UNIT HEALTH AND WELLBEING IN EUROPEAN COMMISSION

What are the research priorities on eHealth in the Digital Agenda?

"We have an open call right now which emphasizes the virtual physiological human-the computer modelling of the organs-,mHealth and the empowerment of the patient. In the future we will be following further the directions of mHealth and virtual physiological human…"

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Current Status of in silico in Horizon 2020

1

1.5 Methods and data

PM 19 – 2017- In-silico clinical trials [CNECT]

2

PM 21 – 2017 - Personalised computer modelisation and in-silico systems for well-being [CNECT]

3

1.4 Active ageing and self-management of health

PM 13 – 2016 + 2017 - Support for eHealth related European SMEs stimulating innovation, investments and growth, including clinical validation of VPH solutions [CNECT- SME Instrument]

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Creating alliances with stakeholders

- European Society for Medical Oncology (ESMO)

Data Protection Regulation

- Centre for Alternatives to Animal Testing

Collaboration on EMA Regulation Amendments

- Centre for Alternatives to Animal Testing

Joint Position Paper on Stop-Vivisection Campaign

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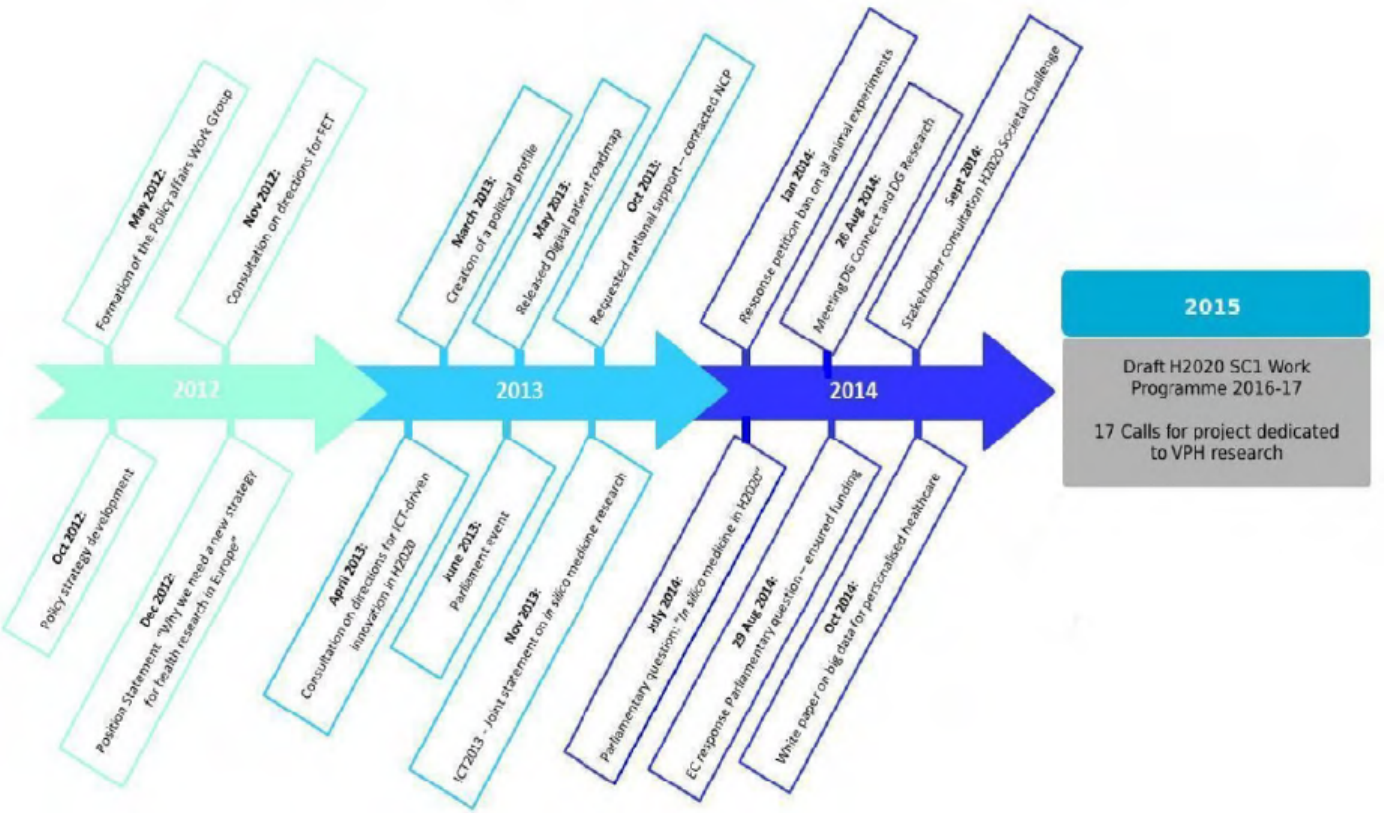

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What next for 2016?

- Heavy focus on the creation of policy & regulatory environment that is favourable to the uptake of in silico models used by members
- Ensure that EU health policy includes modelling and simulation, data driven medicine as an integral part of the strategy
- What issues to push in this context to be decided by Members
- Only Membership of APM can guarantee you too benefit from these policy initiatives

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