EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA support to and involvement in regulatory science

HCPWP workshop on the framework of collaboration with academia, 15 June 2016

Presented by Corinne de Vries on 15 June 2016
Head of Science & Innovation Support (ad interim)
Human Medicines Research & Development Support Division

Outline

- General trends
- Current opportunities for regulatory interaction
- Intelligence gathering for science and innovation support
- Collaboration with academia: an eye to the future

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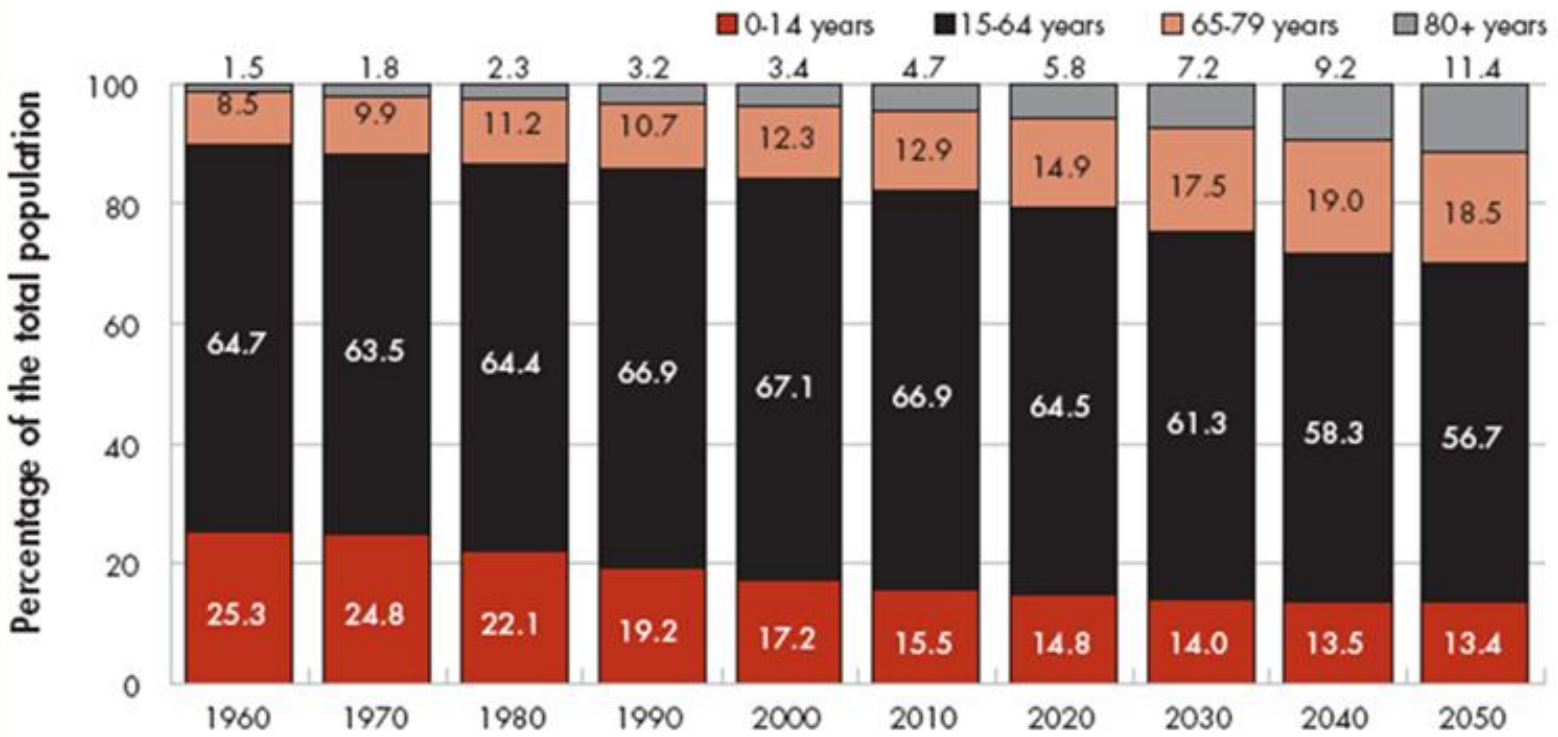
1

Population structure by major age groups, EU-25; 1960, 1970, ..., 2050



Sources: Eurostat – Demographic statistics (1960-2000) and 2004-based Eurostat population projections, trend scenario, baseline variant (2010-2050).


The European languages
ICELAND
Icelandic
Faroese
Norwegian
NORWAY
SWEDEN
Swedish
Sami / Lappish
Tornedalian Finnish*
FINLAND
Finnish
Karelian*
Nenets
Komi
Scottish Gaelic
Scot*
IRELAND
Irish Gaelic
Manx
UNITED KINGDOM
English
Welsh
Cornish
Northern-Frisian
DENMARK
Danish
Scanian*
Estonian
Votian
Ingrian
Vepsian
Livian
Latgalian*
Latvian
LATVIA
LITHUANIA
Lithuanian
Polish
Kashubian
RUSSIA
Russian
Mari
Chuvash
Mordovian
Frisian
Eastern-Frisian
Dutch
Flemish*
Walloon*
Luxembourgian*
BELGIUM
Low-German*
GERMANY
German
Sorabian
POLAND
Polish
Belorussian
BELARUS
UKRAINE
Ukrainian
Russian
Kalmouk
Breton
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Oil Languages*
FRANCE
Alsacian*
CZECH REP.
Czech
SLOVAKIA
Slovak*
Ruthenian*
MOLDAVIA
Russian
Moldovian*
SWITZERLAND
LIECHT.
AUSTRIA
Romanch
Ladin
HUNGARY
Hungarian
Romanian
Gagauz
ROMANIA
Tatar
Russian
Karaim*
Adygean
Karachay
Balkarian
Cherkess
Kabardian
Abkhaz
GEORGIA
Georgian
Ingush
Galician
Asturian*
Gascon*
Basque
Occitan
Francoprovencal
Lombardian*
Piedmontian*
Friulan
Venician
SLOVENIA
Slovene
CROATIA
Serbo-Croatian
Provencal*
Ligurian*
Gallo-Italic
Emilian*
BOSNIA-HERZEGOVINA
SERBIA
MONTENEGRO
MACEDONIA
BULGARIA
Bulgarian
Turkish
Pomak
Macedonian*
Albanian
Aroumanian
Greek
GREECE
Mirandesa*
PORTUGAL
Portuguese
SPAIN
Castilian
Aragonese
ANDORRA
Catalan
Valencian*
Andalous*
Corsican
Sard
Toscan
Italian
ITALY
Sicilian*
STATE
Languages in monolinguism situation
Languages in bilinguism situation
Discuted languages' variety*
Isolated languages
Speakers in the S tate
www.eurominority.org
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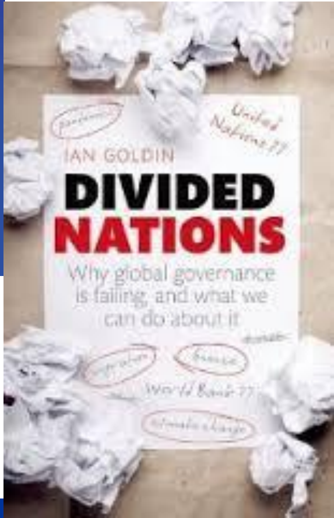
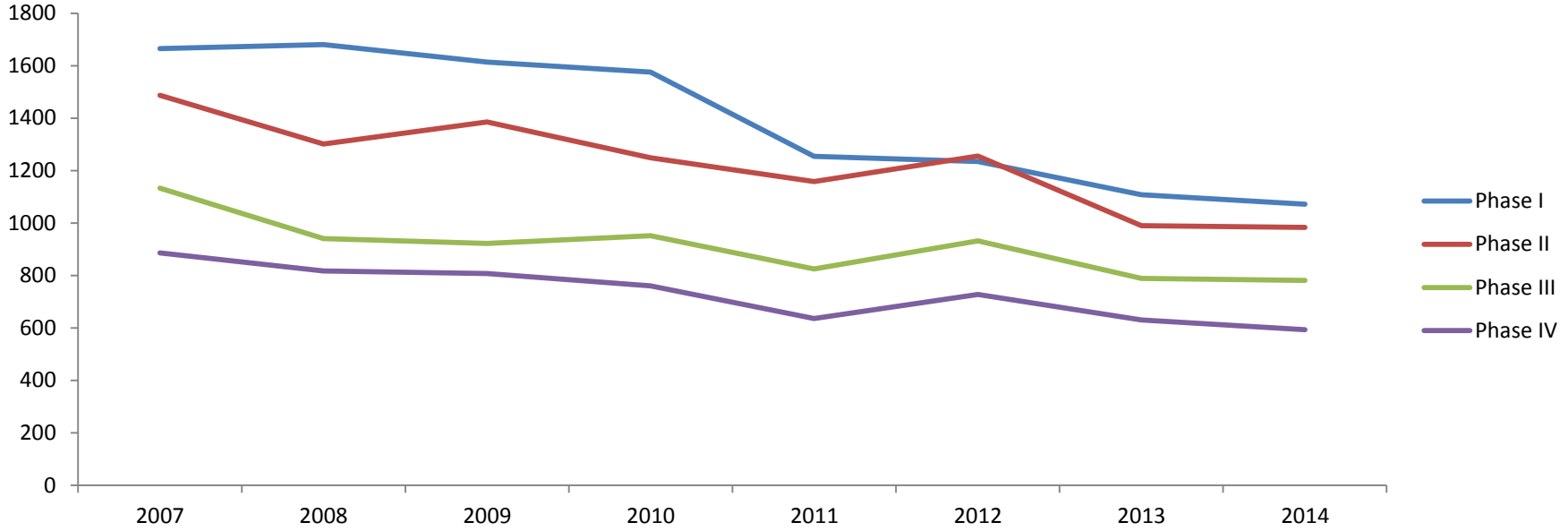
FACTS YOU SHOULD KNOW ✔
"The costs of many new medical products are becoming unsustainable for even the wealthiest countries in the world."
- Margaret Chan, World Health Organization
Global Medicine Spending
2005 $658 Billion
2014 $1 Trillion
1 in 3 Americans with a chronic disease
has difficulty paying for food, medications, or both
In India 115,000 women are diagnosed with breast cancer each year
The cost of medicine makes it out of reach for 3/4 of the population


United in diversity
9 May – Europe Day


IAN GOLDIN
DIVIDED NATIONS
Why global governance is failing, and what we can do about it

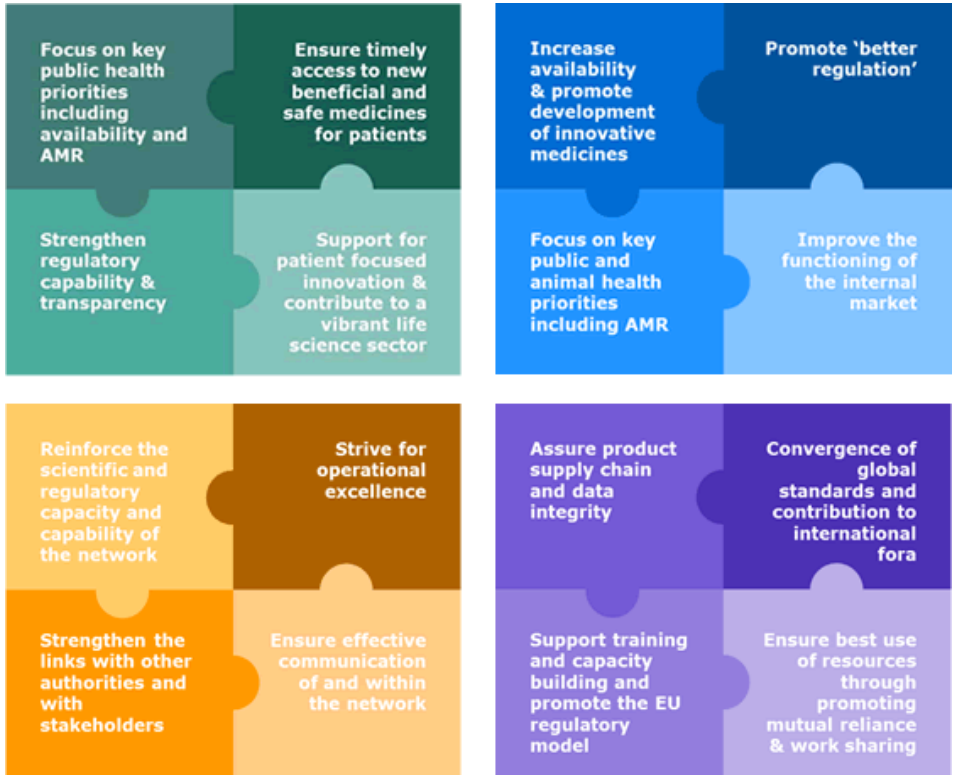
Clinical Trials in Europe



Global environmental changes / trends

- Costs for R&D are increasing
- Cost of innovative medicines are increasing
- Investments are moving away from Europe
- Ageing population will drive up consumption of medicines
- Number of expiring patents steadily decreasing
- Supply chain is increasingly complex, medicines shortages in some areas

EU Medicines Agencies Network Strategy to 2020



towards a system that

- is more agile
- more likely to deliver innovative medicine
- meets unmet medical needs
- fosters excellence, incl:
- effective use of resources available across the EU
- is patient focused
- promotes better regulation
- ensures effective communication
- …

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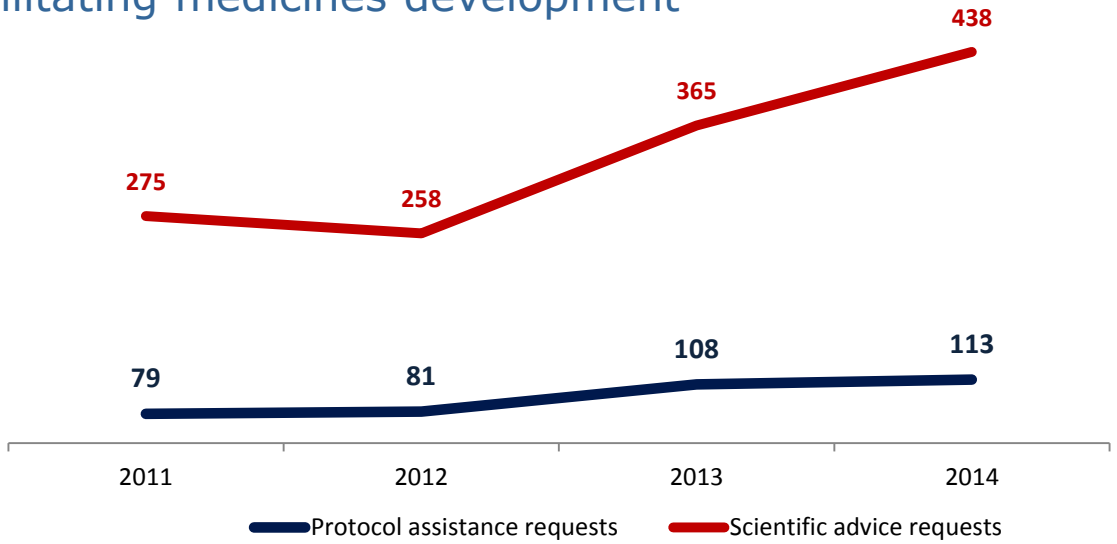
Opportunities for short / longer visiting arrangements

- National expert on secondment
- Visiting expert
- Traineeships

Scientific Advice

Facilitating medicines development



- Growth area
- 15 countries active
- Short cycle procedures (40 or 70 days)
- Strong integration in all Committee work

EMA-HTA Parallel Scientific Advice

Experience so far

- **73 parallel EMA – HTA SA procedures** with EU HTA bodies from UK, Italy, Germany, Sweden, France, Netherlands, Spain, Belgium, Austria, Poland, Norway, Hungary
- **Broad range of indications**:
  Lung cancer, Breast cancer, Pancreas cancer, Melanoma, Asthma, COPD, Diabetes, Heart Failure, Depression, Alzheimer's, Migraine, Infections, Rare diseases, Myasthenia Gravis

Home | Product Sector | Regulatory Region | Pre-marketing Regulation

MedTech | Pharmaceuticals | Diagnostics |

Scrip Regulatory Affairs

Demand Soars For Parallel EMA-HTA Advice

24 November 2015

Maureen Kenny

There has been a huge increase in use by drug companies of the scheme that enables them to get simultaneous feedback on their development plans for new medicines from the European Medicines Agency and national health technology assessment (HTA) bodies.

Almost 50% of the 62 procedures that have taken place since the scheme was launched as a pilot in 2010 have taken place this year. Twenty eight procedures have taken place in 2015 to date, well over twice the number – 11 – that took place in 2014. The EMA puts the increase down to the appreciation by applicants for the platform and its usefulness to them and to the fact that "applicants and regulators/HTA colleagues are now more experienced" in this kind of interaction with multiple stakeholders[1].

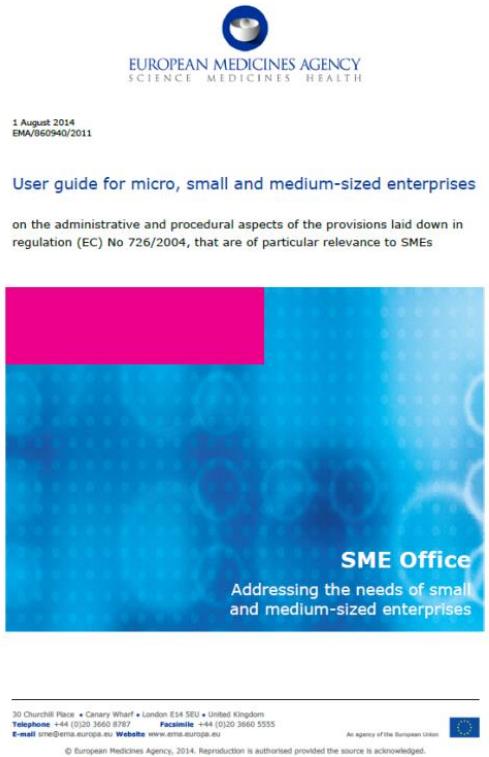
SME Office: tailoring assistance to SMEs

A strategic regulatory toolbox to promote innovation & development of new medicines by SMEs:

- A single interface, facilitate communication
- SME assignment, public SME register
- Fee incentives, regulatory assistance, translations
- News bulletins, SME user guide, workshops

In 2015,

- 1450 SME companies registered with EMA



http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004134.pdf

Innovation Task Force

- **Free of charge, early dialogue** on **scientific, legal and regulatory** issues
- **knowledge exchange** on innovative strategies involving **EU network**
- **address the impact of emerging therapies and technologies** on current regulatory system
- identify the **need for specialised expertise** at an early stage
- identify issue of particular interest to regulators in **preparing for formal procedures** (e.g. biomarkers qualifications, scientific advice)

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White spots in pharmaceutical pipelines–EMA identifies potential areas of unmet medical needs

Expert Rev. Clin. Pharmacol. Early online, 1–8 (2015)

Box 1. Oncology white spots (Medical Dictionary for Regulatory Activities terminology).

- Bone neoplasms malignant (excl. sarcomas)
- Epithelioid sarcomas
- Lymphangiosarcomas
- Mesenchymomas
- Pineal neoplasms
- Ocular neoplasms (excl. melanoma)
- Renal pelvis and ureter neoplasms
- Small intestinal neoplasms malignancy
- Germ cell neoplasms

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Box 2. Viral infections white spots (Medical Dictionary for Regulatory Activities terminology).

- Arenaviral infections
- Newcastle viral infections
- Parapox viral infections
- Paravaccinia viral infections
- Astroviral infections
- Echo viral infections
- Filoviral infections
- Hantaviral infections
- Phleboviral infections
- Prion-associated disorders

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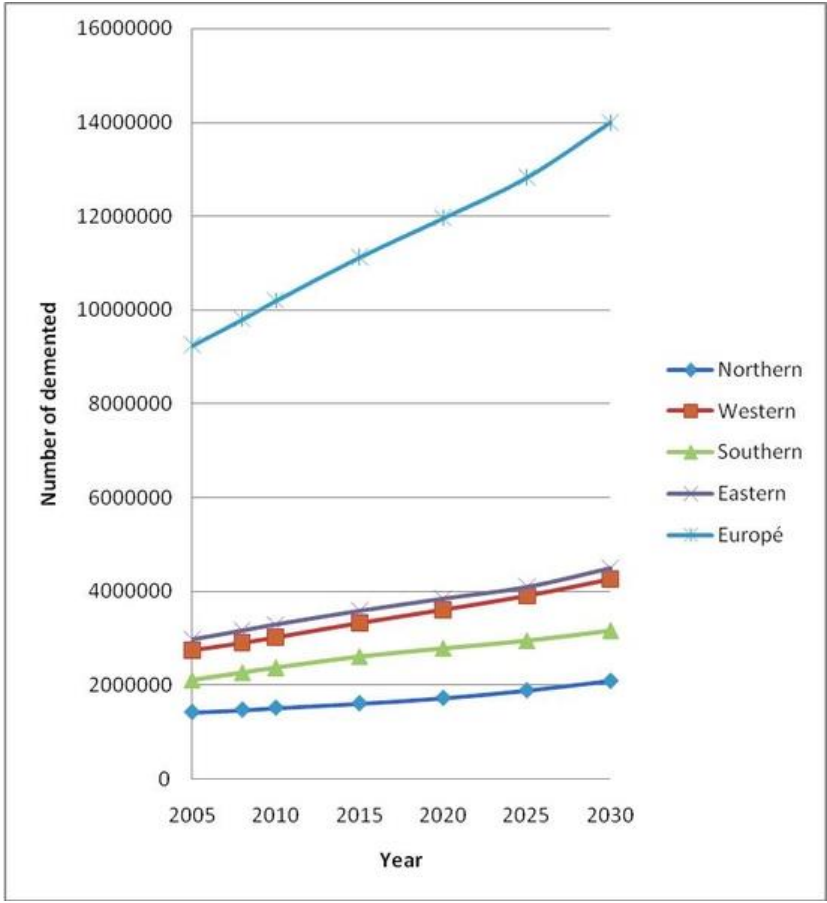
Box 3. Psychiatric disorders white spots (Medical Dictionary for Regulatory Activities terminology).

- Amnestic disorders
- Confusion and disorientation
- Delusional disorders
- Infancy, childhood and adolescent psychiatric disorders
- Gender Identity Disorders
- Parasomnias
- Personality disorder with eccentric behavior (Cluster A)
- Personality disorder with dramatic behavior (Cluster B)

SA: Alzheimer's Disease activity

- Unprecedented numbers of SA
- Unprecedented numbers of initial MAAs: **0**
- Data sharing initiative

what went wrong?



ITF recent trends analysis (2013-2015)

EUROPEAN MEDICINES AGENCY

- **Borderline products and Novel and technologies**
  - Cosmetic / Food → Def. MoA (MDEG / Helsinki)
  - Biomaterials
  - Demarcation towards cell, tissue and blood regulation
  - Combination products / principle MoA
  - Nanotechnology

- **Regulatory framework** for "really" **Personalised Medicines**
  - N=1 trials
  - treatment algorithms
  - Conditions vs. MoA
  - Modelling and Simulation / Extrapolation

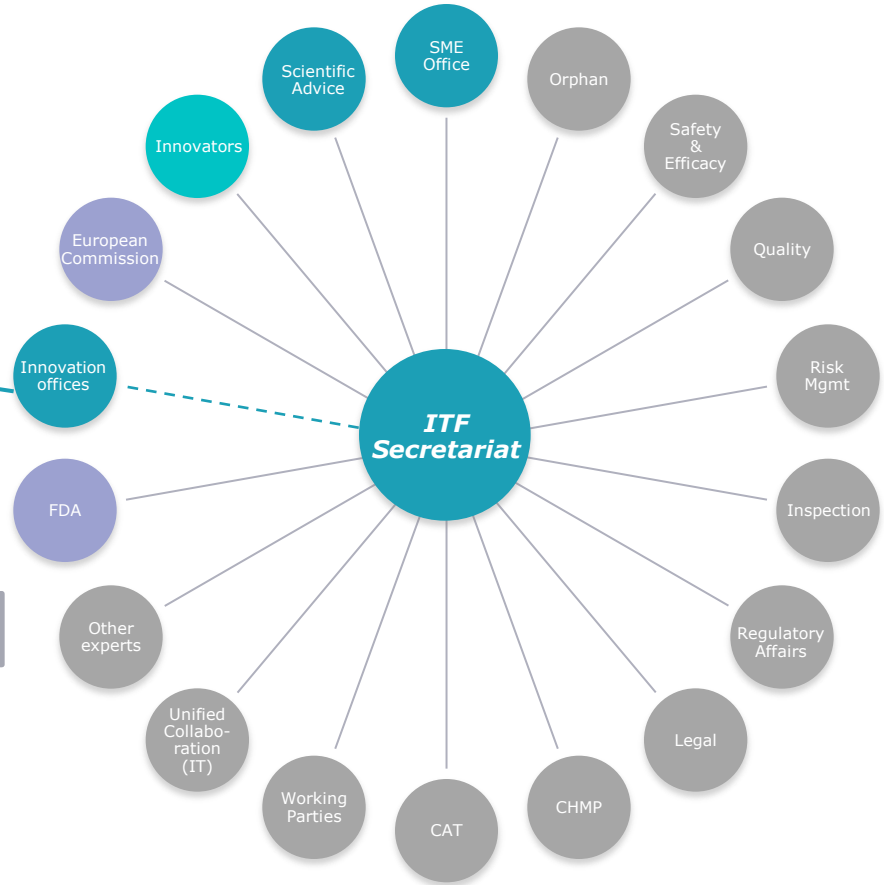
- **eHealth**
  - Health Apps,
  - electronic data collection / processing in CTs / e-consent

- **Bedside manufacturing**
  - bring the (individualised) product to the patient,
  - technical integration / cont. manufacturing / QbD

- **"Expertise" gap / bridge** for SA during drug development
  - NC → FiM CT → Phase II / III design (global FDA / PMDA)

EU Innovation Network

Multi-disciplinary/MSs network



IMI consortia we provide support to:

PROTECT

ADAPT-SMART

ADVANCE

WEB-RADR

Get Real

FLUCOP

Standardization and Development of Assays for Influenza Vaccine Correlates of Protection

Eu2P
EUROPEAN PROGRAMME IN PHARMACOVIGILANCE AND PHARMACOEPIDEMIOLOGY

PATIENT-SMART

In addition:

- Advisory board membership
- Dedicated liaison officer

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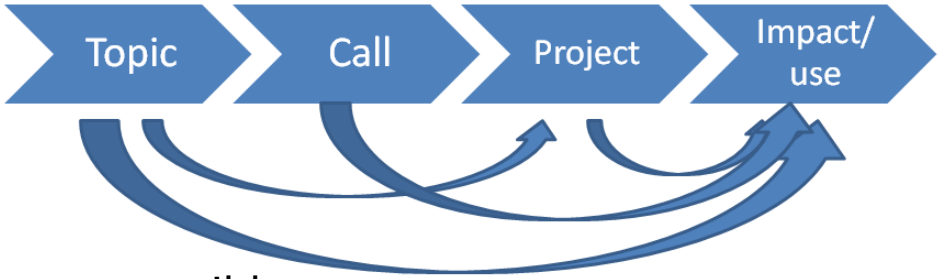
Regulatory science projects



Considerations: as strategic and effective as possible

- Resource implications
- Conflict of interest – perceived or real
- Alignment with Network Strategy 2020
- Impact on EU public health
- Existing opportunities for regulatory interaction
- Not at the bidding stage – no competitive (dis)advantage

Opportunities for short / longer visiting arrangements

- National expert on secondment
- Visiting expert
- Traineeships

Thank you for your attention

Further information

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