European Federation of Pharmaceutical Industries and Associations

Call 4 – Themes, topics, process

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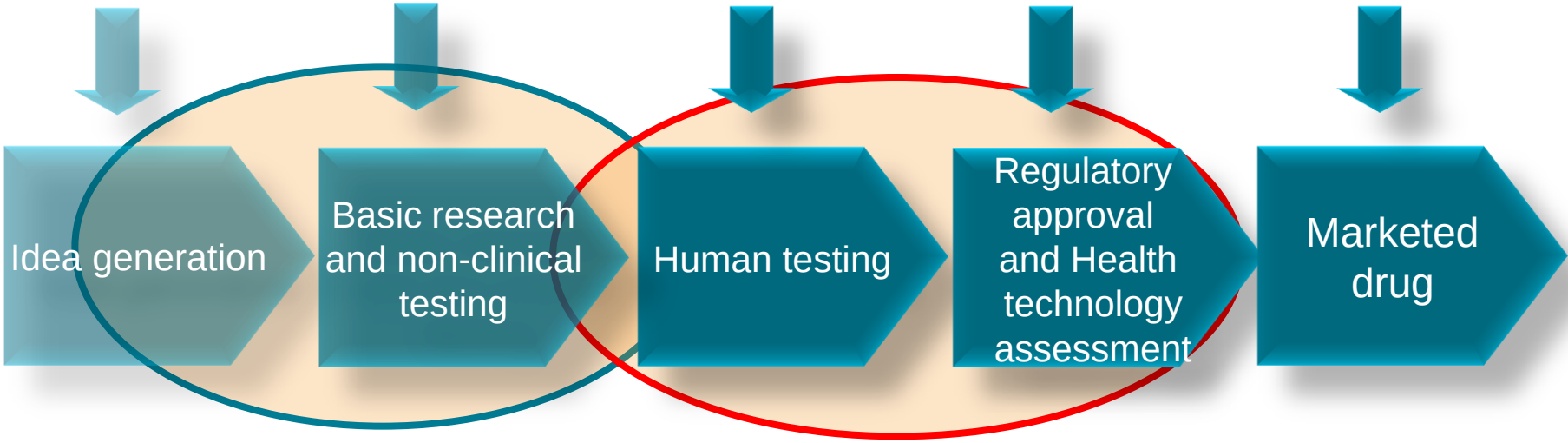
IMI Vision

Make Drug R&D processes in Europe more efficient and effective and enhance Europe's competitiveness



Focus of IMI Calls 1 - 3

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Thematic clusters

EU Medical Information System

Chemistry, Manufacturing and Control

Technology and molecular disease understanding

Taxonomy

Regulatory and Health Technology Assessment

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4th Call topic proposals

Cluster 1: EU Medical Information System
1. Building up a European Medical Information Framework to improve healthcare and facilitate research
2. ETIKS: European Translational Research Infrastructure & Knowledge Management Services
Cluster 2: Chemistry, Manufacturing and Control
3. Delivery and Targeting Mechanisms for Biological Macromolecules
4. In vivo predictive biopharmaceutics tools for oral drug delivery
5. Sustainable Chemistry – Delivering Medicines for the 21st Century
Cluster 3: Technology and Molecular Disease Understanding
6. Human Induced Pluripotent Stem (hiPS) Cells for Drug Discovery and Safety Assessment
7. Understanding and Optimising Binding Kinetics in Drug Discovery

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European Medical Information Framework (EMIF)

Challenge:

- Fragmentation of existing patient health information in different systems and locations inhibits ready and efficient access to the type of patient level data required to facilitate research where access to large data sets are required

Deliverables:

- Sustainable and scalable infrastructure / Knowledge Management Service providing access to patient level required to support innovative research
- Two initial case studies as proof of concept
  - Metabolic complications of obesity
  - Protective and precipitating markers for the development of Alzheimer's Disease and other dementias

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European Translational Infrastructure & KM Services (ETIKS)

Challenge:

- Lack of infrastructure and information support for Translational Research (TR) activities (across IMI projects, and other EU medical and bioinformatic translational collaborations)

Deliverables:

- Sustainable, interoperable, collaborative TR platform, based on open, agreed standards
- Development of an active TR analytics & informatics community

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Delivery and Targeting Mechanisms for Biological Macromolecules

Challenge:

- Addressing bottlenecks associated with the development and delivery of novel innovative biological macromolecules (e.g. proteins/peptides, oligonucleotides)
- Gain a greater understanding of potential exploitable transport and target systems to aid the delivery of large biological molecules, in relevant quantities, to specific tissues, cells and intracellular targets

Deliverables

- Detailed elucidation of cellular uptake mechanisms
- Understanding of variables which determine distribution of biological macromolecules
- Organ and tissue specific nanotechnology-based delivery methods for biological macromolecules
- Delivery strategies for biological macromolecules via local (e.g. inhalation and oral uptake) and injectable application routes

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In vivo predictive biopharmaceutics tools for oral drug delivery

Challenge:

- Addressing formulation bottlenecks to better define the critical (physicochemical, formulation and physiological) factors that determine dosage form effects after oral administration
- Improve the accuracy and predictivity of research methods: e.g. in vivo studies, computer modeling, biosimulation
- Improve biopharmaceutics “developability” assessment in compound selection and improve formulation development to attain target drug absorption properties

Deliverables

- Physicochemical tools
- In-vitro tools (e.g. Dissolution/Permeability/Intestinal stability)
- In-vivo tools / understanding
- Integration of different models (including complex in-silico tools)

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Sustainable Chemistry – Delivering Medicines for the 21st Century

Challenge:

- The discovery of new synthetic methodologies for the development and manufacture of small molecule medicines which are demonstrably more sustainable than existing methods

Deliverables

- Identify synthetic approaches addressing the most significant sustainability challenges for medicine development and manufacture post 2020
- Develop recommendations for graduate training and education programs
- Reduce cost and deliver more sustainably produced medicines

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Human iPS cells for Drug Discovery and Safety Assessment

Challenge

- Increase understanding of the research potential of induced pluripotent stem (iPS) cells and their cellular derivatives for drug development and safety assessment
- Increase access to sufficient quantities of well characterized, genetically diverse iPS-derived cell types for research use by industry and academia throughout Europe

Deliverables

- Establish standardized biological assays addressing disease biology and responses to treatment
- Establish regulatory framework for iPS cell use for research purposes
- Establish an iPS biobank for iPS cell lines (including quality control) and provision of a centralised test facility (accessibility of iPS cell lines from different ethnicities and patients with defined genotypes / phenotypes)

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Understanding and Optimising Binding Kinetics in Drug Discovery

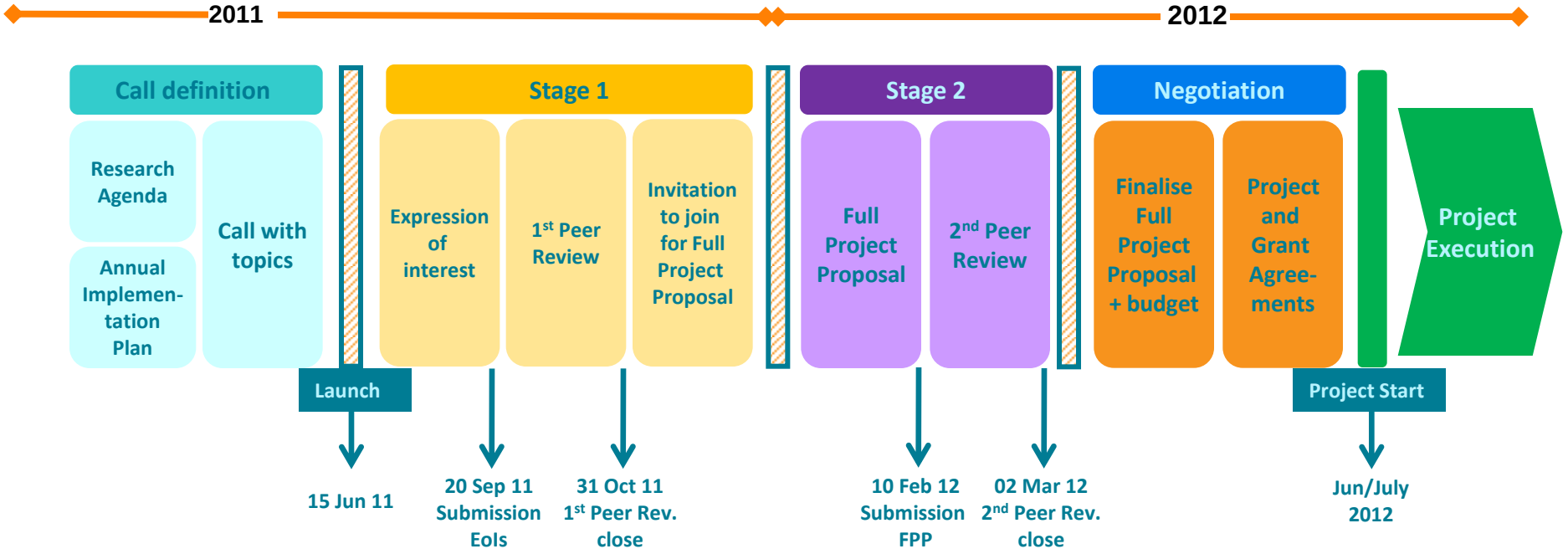
Challenge

- Understanding binding kinetics at a molecular level to determine the factors responsible for changes in kinetic behavior
- Improve predictivity of assays and take advantage of emerging technologies

Deliverables

- Guidelines for understanding the molecular phenomena that allow manipulation of kinetics by small molecule design
- Technology evaluation using agreed benchmark tool compounds and molecular systems
- Improved methods and recommendations for obtaining high(er) throughput kinetic measurements
- Development of robust, predictive PK/PD modeling paradigms that will improve understanding of how *in vitro* kinetic effects translate into *in vivo* efficacy and duration of action
- Enhanced data-sharing within the framework of drug binding and kinetics

4th Call Time Schedule (preliminary)



2011

- **June 15:** Launch
- **Sept 30:** Submission EoIs
- **Oct 31:** Peer review close

2012

- **Feb 10:** Submission FPP
- **March 2:** Peer review close, Negotiation starts
- **June/July:** Start of projects

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Summary

- Across the whole value chain
- Big themes: focussed on areas that will improve efficiency across R&D rather than a specific therapeutic area
- Joining forces in essential public private collaboration
- Launch of the Call – mid June; deadline for submission of Expression of Interest – mid October