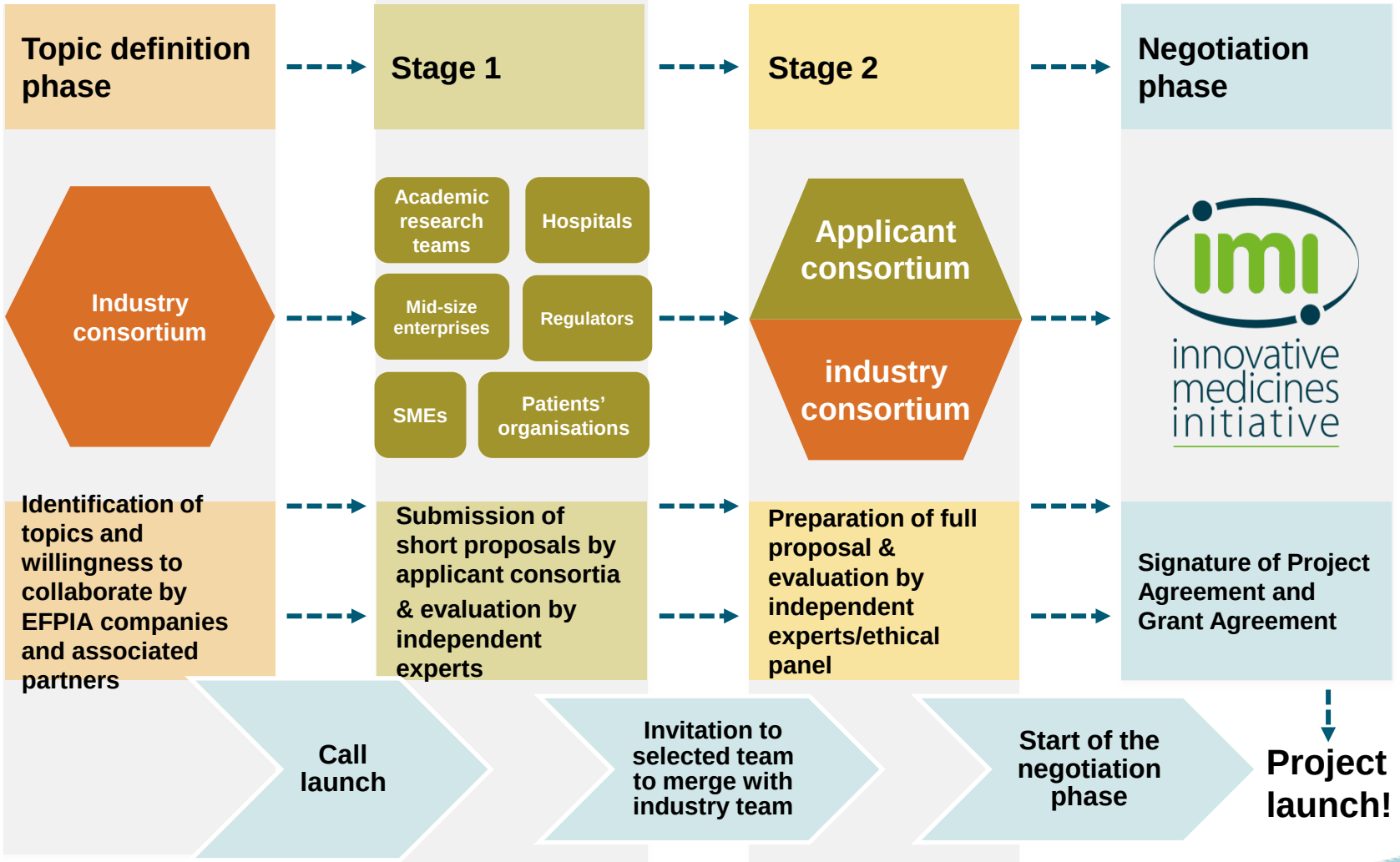
New Opportunities in IMI2

Hugh Laverty

13.01.2015 • IMI2 Info Day for Spanish industry• Barcelona

Typical IMI project life cycle



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An international, cross-sector community

Over 7 000 researchers

59 public-private consortia

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Making a difference

Implementation of project results inside industry

Project	Area	Results description
IMIDIA	**diabetes**	The human beta cell line EndoC BetaH1 has been validated by Endocells and 3 pharma partners confirming their initial insulin secretion capacity. These cells have been **successfully transferred as a research tool for drug discovery to industrial partners.**
DDMORE	**knowledge management**	Several drug/disease models identified by DDMORE are **adopted or further developed inside the industry.**
eTRIKS	**knowledge management**	Adoption of the eTRIKS results, **TransMART system deployments in 5 pharmaceutical companies.**
EUROPAIN	**Chronic pain**	Preclinical model of spontaneous pain in rodents has been developed, standardized, validated, and is already **used for internal decision making in the drug development process**. The ultraviolet B (UVB) pain model has also started to be **used for in house R&D**.

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Impact on regulatory framework

Project	Area	Results description
PROactive	**COPD**	**Qualification Advice completed** at the EMA
EU-AIMS	**autism**	Started EMA formal scientific advice procedure for **qualification of 5 biomarkers in ASD**
eTOX	**drug safety**	Provided an update on the eTOX database and the prediction system to the CHMP Safety Working Party (SWP) at EMA. **Scientific Advice Procedure was initiated**.
MARCAR	**cancer**	Has developed new biomarkers, technologies, and alternative test systems that help explain or predict animal and/or human carcinogenic pathways and mechanisms for non-genotoxic carcinogenesis. This will provide enhanced scientific rationale for Carcinogenicity Assessment Document (CAD) submissions, with **potential impact for ICH S1 carcinogenicity testing guideline revisions**.
Safe-T	**drug safety**	Developed and now **progressed towards an aligned EMA/FDA qualification** a set of novel safety biomarkers for drug-induced kidney, liver, and vascular injury.
DDMORE	**knowledge management**	In May 2012 an advisory meeting with EMA and FDA representatives was held. Through a Modelling Review Group , DDMoRe is in regular contact with both the EMA and FDA regarding the qualification of the content of the project's Model Library.

SME success stories

FIRALIS
BRIDGING SCIENCE TO CLINICS

Thanks to IMI the company went from **6 to 50 employees.** Now they are ready to further expand.

ENDOCELLS

"1st product released to the market in 2013 – **IMI was instrumental in validation of the first cell line product**, 2nd product release planned this year, 3rd diagnostic product in development.

In preparation: **a new patent filing** to protect technologies for the creation of third generation human beta cell lines.

Developing a blood panel for AD for diagnosis, stratification and companion diagnostics in AD. **The Panel was tested on 300 patients in IMI project.**

Chemotargets

Developed in silico models for predicting toxicity, which were validated by pharmas in eTOX. Now they have **signed a contract with one of the companies to use their models in house.**

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Promoting patient involvement

- ✓ IMI makes efforts to enhance **patient centric approach**
  - **Patient dedicated workshops**
  - Involving **patients at all levels**
  - Providing **forum for discussion**

- ✓ IMI best practice examples:

EUPATI

U-BIOPRED

PROactive

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Collaboration

Key collaborative activity areas:
Diabetes, CNS disorders, Tuberculosis, Patient Reported Outcomes, Cancer, Preclinical Safety and Education & Training.

IMI projects have signed
14
MEMORANDA of UNDERSTANDING
with other international consortia

IMI signed horizontal agreements with:
Critical Path, **Juvenile Diabetes Research Foundation** as well as with **Clinical Data Interchange Standards Consortium**.

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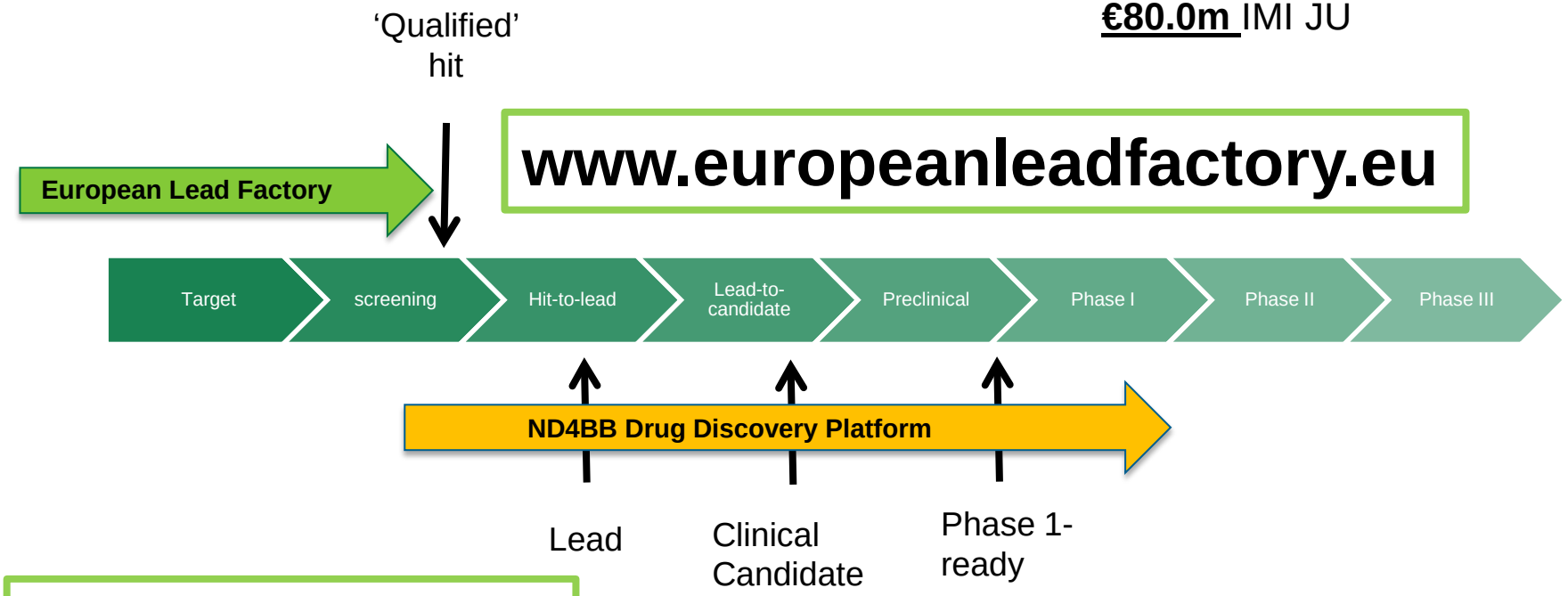
IMI's drug discovery platforms

European Lead Factory Focus: identification of new hits

ELF Budget:
€92.0m EFPIA in-kind
€80.0m IMI JU



nd4bb-enable.eu

ENABLE Focus: to move promising hits into early clinical development

ENABLE Budget:
€26.0m EFPIA in-kind
€58.9m IMI JU

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IMI2 – Calls

IMI2 - Call1

Launch date: **09 July 2014**

Translational approaches to disease modifying therapy of type 1 diabetes mellitus (T1DM)
Magda.Gunn@imi.europa.eu

Discovery and validation of novel endpoints in dry age-related macular degeneration and diabetic retinopathy
Nathalie.Seigneuret@imi.europa.eu

Submission date: **12 November 2014**

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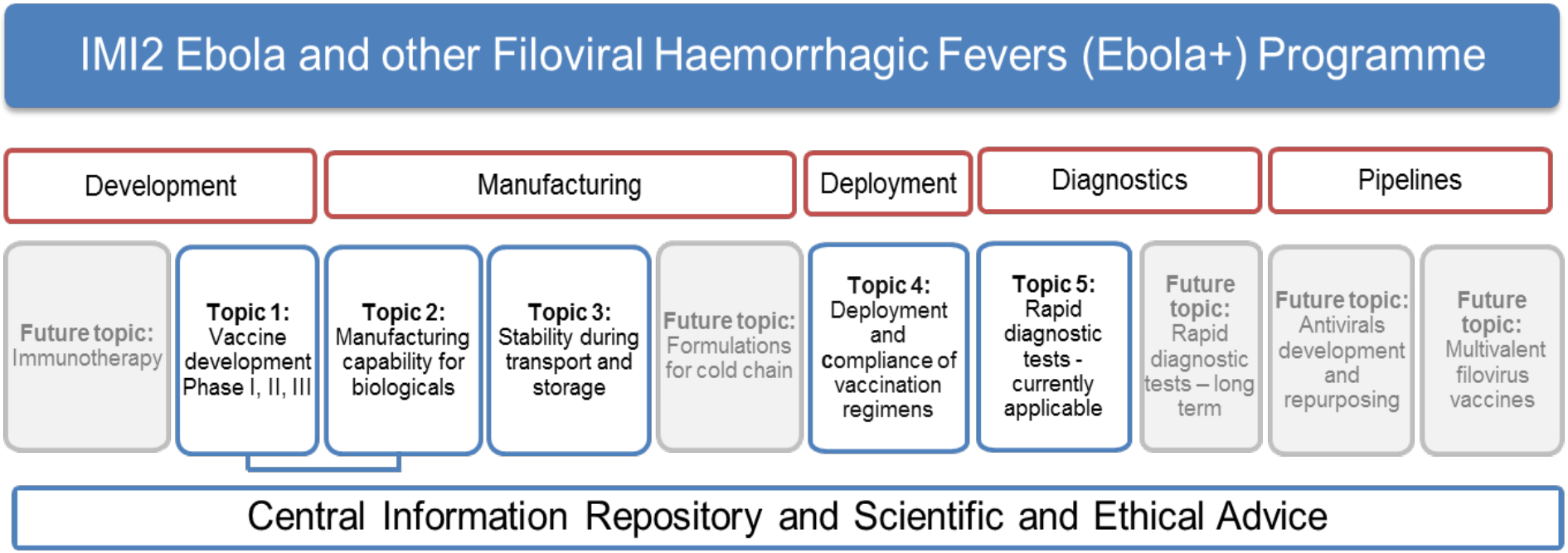
IMI2 – Call2

Ebola and other filoviral haemorrhagic fevers programme

Ebola+ programme overview

Launch date: **06 Nov 2014**



Submission date: **01 December 2014**

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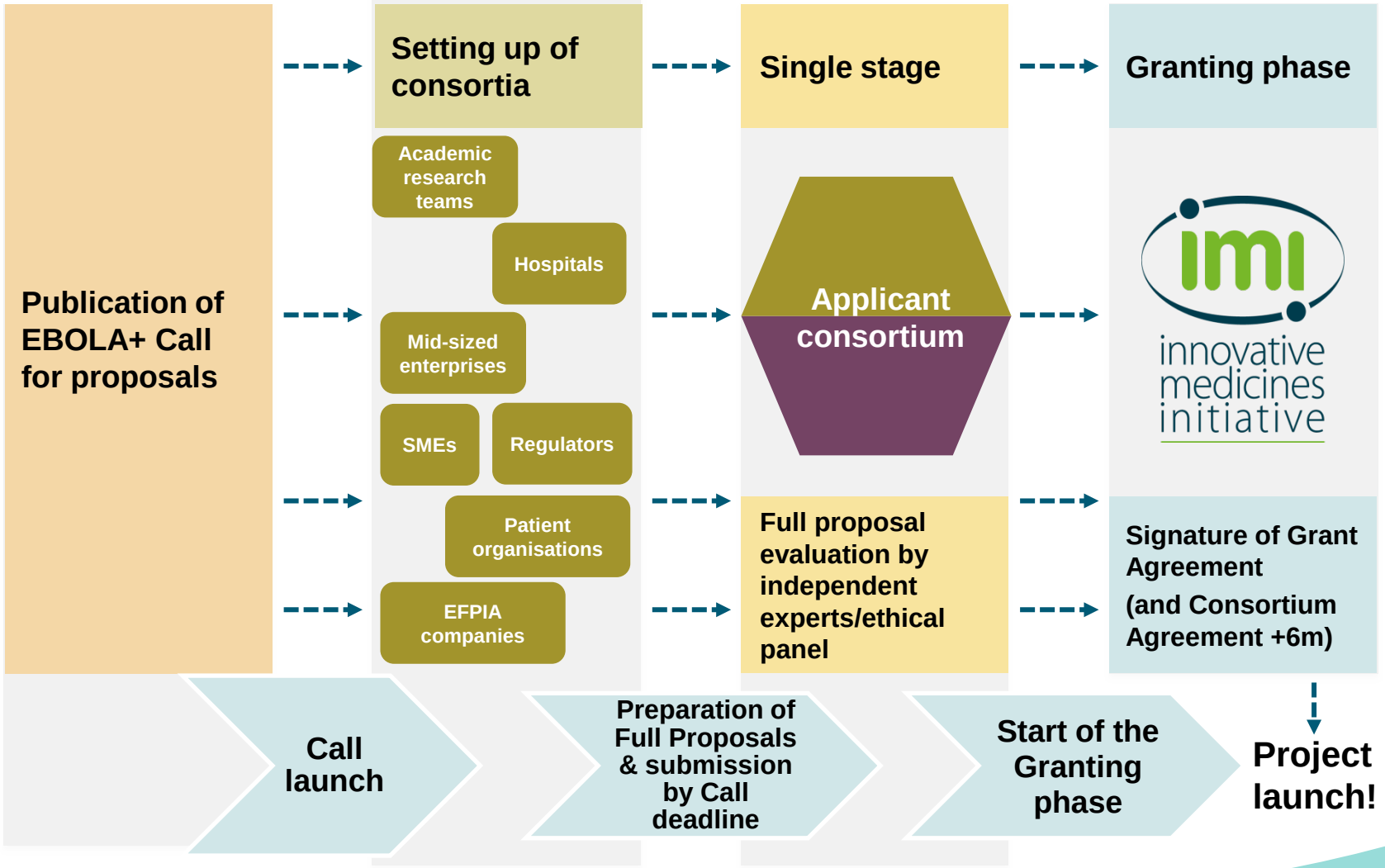
Single stage, fast-track process



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IMI 2 – Call 3 & 4

IMI 2 – Calls 3 & 4

Research and innovation topics (Call 3)

- Remote assessment of disease & relapse (RADAR): CNS
- Assessing risk & progression of prediabetes & type 2 diabetes
  Linking clinical neuropsychiatry & quantitative neurobiology
- Quality control in vaccine manufacture
- Pertussis vaccination research
- Knowledge repository for patient focused medicine development

Submission deadline: **24 March 2015**

Coordination and Support Action (Call 4)

- Enabling platform on medicines adaptive pathway to patients

Submission deadline: **11 February 2015**

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Remote Assessment of Diseases And Relapse (RADAR) Programme

OVERALL AIM: to **Improve patient outcomes through remote assessment.**

BY

- **Develop and validate the science** of using **bio-signatures to characterise disease** and predict changes in disease state **through observational studies** *(basic clinical research)*

- Encourage innovation and development of **novel biosensors** and the associated **knowledge management** technology *(basic technological research)*

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2. Assess risk & progression of prediabetes and T2D for disease modification– Objectives

- Prioritise and/or validate a panel of human biomarkers or assays of pancreatic beta cell function, stress, mass, and death.
- Prioritise and/or validate a panel of human biomarkers or assays of hepatic, skeletal muscle, and/or adipose cellular dysfunction derived from or contributing to progression of insulin resistance.
- Develop innovative potential regulatory approaches: adaptive clinical trial designs, enabling feasible and robust benefit/risk assessments in clinical trials for therapeutic intervention.
- Model short- and long-term economic and public health morbidity and mortality benefit/risk assessments of the therapeutic intervention.

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3. Linking clinical neuropsychiatry and quantitative neurobiology – Objectives

- To explore the same set of quantifiable biological parameters across selected symptom constellations common to distinctly classified syndromes by classical taxonomy including neuropsychiatric issues in neurodegenerative diseases

- These studies would be driven from clinical quantitative biology back through appropriate translation to the measurement of homologous pre-clinical quantitative biological indices.

4. The Consistency Approach to Quality Control in vaccine manufacture - Objectives

- To develop a new paradigm for improved quality control of established human and veterinary vaccines, *The Consistency Approach (CA)*, by generating a "fingerprint" of the physico-chemical and immunochemical properties instead of reading out end points in animals to demonstrate safety and efficacy of each batch release testing. This will require:
  - Technology and methodology innovation in analytics
  - In vitro models demonstrating functionality of immune responses
  - Bioinformatics
  - Translation into a set of consistency tests that will allow improved monitoring of vaccine quality during production and final formulation
- Facilitation of regulatory acceptance and implementation

5. Pertussis vaccination research - Objectives

- To increase the scientific understanding of the immunity to pertussis in humans, in particular to identify biomarkers of pertussis protective immunity

- To progress our understanding of pertussis vaccine-induced immune responses, differences between whole cell and acellular vaccines, role of maternal antibody

- To generate technological tools and infrastructure that enable the development of novel pertussis vaccines

→ Refinement of current vaccination schedules ?

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6. Knowledge repository to enable patient-focused medicine development - Objectives

- Set up of a Patient Inspired Knowledge Hub (PIKH) that enables sharing non-competitive information with and by users from patient groups, regulators, health authorities, academia and industry.

- The project is a response to the lack of a uniform process to engage patients in the drug development process.

- The PIKH will facilitate and enable the incorporation of patient input into the drug development processes, used broadly by stakeholders in a uniform (standardized) way among a range of stakeholder organizations.

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Call 4 - Two Stage-Coordination and Support Action (CSA)

Enabling Platform on Medicines Adaptive Pathways to Patients

Scope:
Establishment of an enabling platform with relevant stakeholders for the coordination of Medicines Adaptive Pathways to Patients (MAPPs) related activities within IMI2.

This forum will enable a gap analysis, informing new research activities in IMI2 and creating a comprehensive repository of knowledge of activities including non IMI activities relevant to MAPPs and opportunities for coordination.

Submission deadline: **11 February 2015**

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- Join our LinkedIn group – bit.ly/LinkedInIMI

Questions?

- E-mail us: infodesk@imi.europa.eu

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Thank you

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IMI-2 Call 3 - December 2014

Call 3 - Two Stage-Research and Innovation Action (RIA)

1. Remote Assessment of Disease and Relapse – CNS
2. Assessing risk and progression of prediabetes and type 2 diabetes to enable disease modification
3. Linking clinical neuropsychiatry and quantitative neurobiology
4. The consistency approach to quality control in vaccine manufacture
5. Pertussis vaccination research
6. Knowledge repository to enable patient-focused medicine development

- **Submission deadline: 24 March 2015**

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Remote Assessment of Diseases And Relapse (RADAR) Programme

OVERALL AIM: to **Improve patient outcomes through remote assessment.**

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- Encourage innovation and development of **novel biosensors** and the associated **knowledge management** technology *(basic technological research)*

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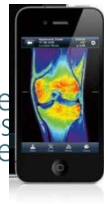
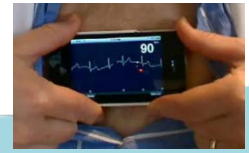
Challenges in Managing Chronic Disease Today

- Physician visits are **time-limited evaluations** based on **subjective observations** of both the patient and the physician or psychiatrist

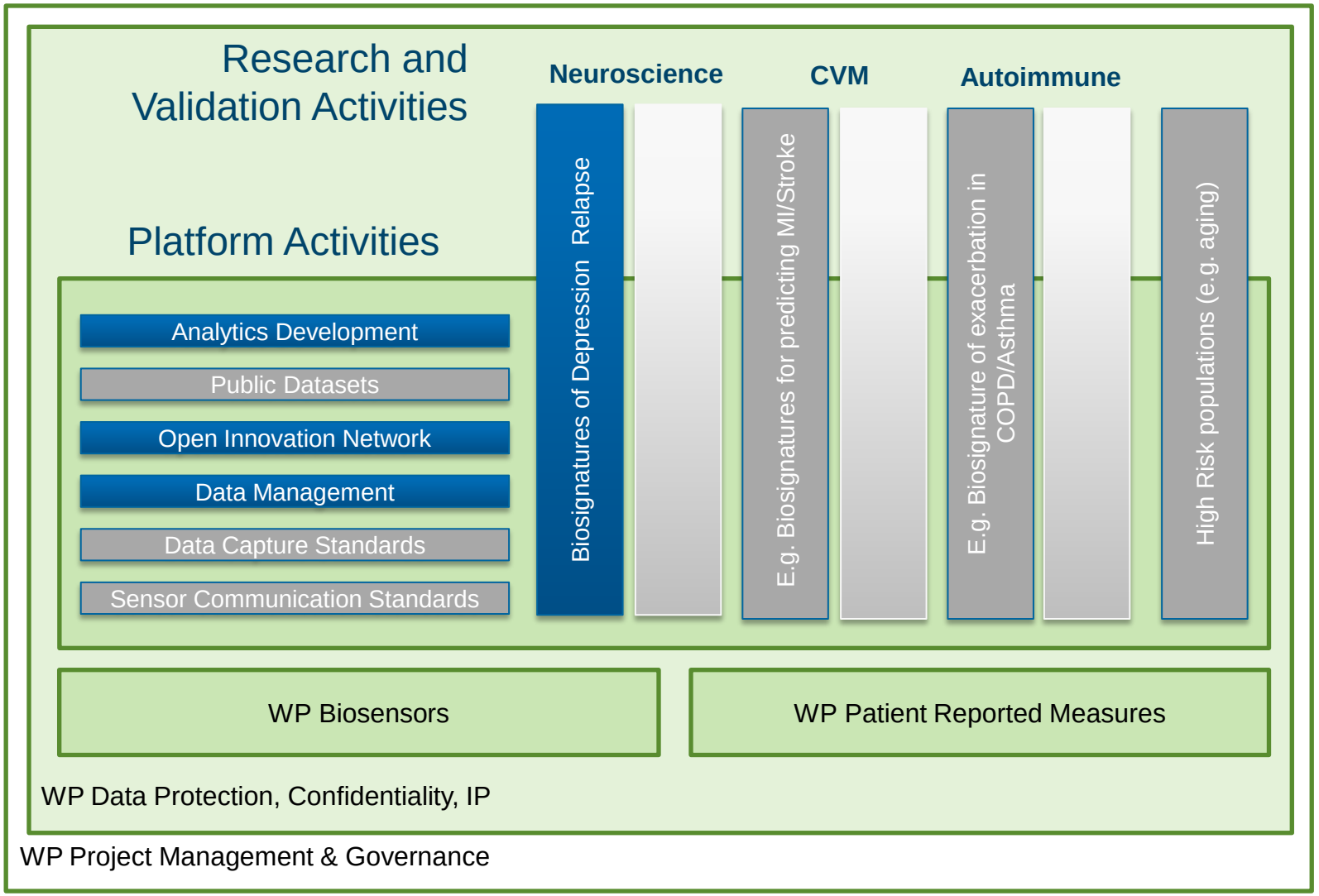
- **Changes in disease state** for each of these diseases can occur on timescales **much shorter than the interval between physician visits**

- Through technological advances over the last decade it is now possible to **objectively, remotely, and continuously** measure aspects of patient **physiology, behavior and symptoms**





RADAR – Vision



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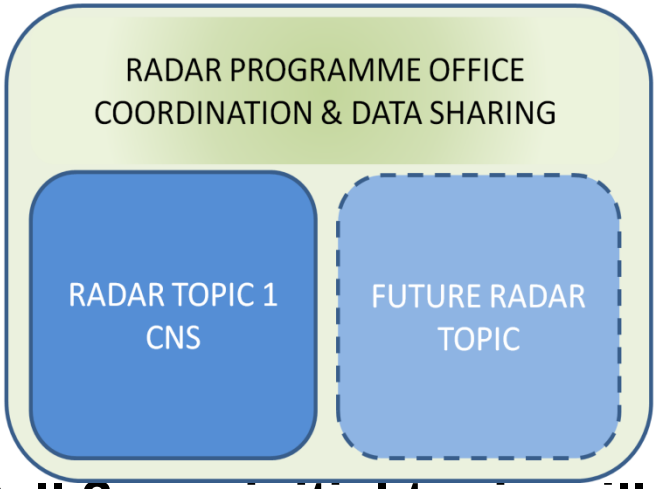
RADAR Programme architecture

The full RADAR programme will consist of several topics that are resourced and managed independently but will share key features such as data, technological approach and overall coordination.



Under IMI2 Call 3,one initial topic will be launched in CNS.

A key element of the RADAR Programme is coordination across all RADAR topics. This will require applicants to 1) reserve some resource to support the coordination across different topics and 2) to conclude collaboration agreements to coordinate their work under the different Grant Agreements.

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1. Remote Assessment of Diseases And Relapse (RADAR) – CNS Objectives

Focussing on the three diseases of **unipolar depression, multiple sclerosis and epilepsy** a non-interventional/observational study of subjects is undertaken with three objectives:

- Characterisation of changes in disease state
- Characterisation of changes in disease state due to drug effects
- Prediction of change in disease state from remote sensing data
- Since depression has a high rate of co-morbidity with both MS and epilepsy, it is the intention to recruit a population that has overlapping morbidity between depression, MS and epilepsy such that we have patients representing each disease as a primary indication, as well as patients who are co-morbid with more than one disease.

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Remote Assessment of Diseases And Relapse (RADAR) – CNS Expectations (1)

- Candidate bio-signatures that predict relapse and track disease state changes in MS, Depression and Epilepsy using at least a common minimal set of metrics: **sleep architecture, physical activity, speech, cognition, social connectivity, memory.**

- Development of algorithms and analytic infrastructure suitable for collecting and analysing data from RADAR-CNS studies.

- Proposal of actionable privacy and usability parameters that would drive eventual uptake of, and adherence to, remote assessment solutions in CNS diseases.

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Remote Assessment of Diseases And Relapse (RADAR) – CNS Expectations (2)

- Delineation of putative regulatory pathways necessary for approval of remote sensing solutions in real-world patients. *This deliverable will be developed in consultation with regulators.*

- Delineation of putative clinical care pathways and use cases of remote-sensing solutions and how they impact and interface with stake-holders such as patients, care-givers, case-managers, physicians etc. *This deliverable will be developed in consultation with relevant external stake-holder groups*

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Remote Assessment of Diseases And Relapse (RADAR) –CNS Applicant Consortium

- Device and sensor companies - latest remote assessment technologies to be further developed or modified for use as intended in CNS diseases;
- Academic, clinical and disease area experts - design the clinical study (end-points, inclusion criteria) and interpret results for clinical significance;
- IT/ analytics - develop data management architecture, state-of-the-art algorithms to derive bio-signatures of symptoms and relapse from collected streaming data;
- Regulatory and health-care systems experts - define regulatory and clinical-care pathways for the remote assessment solutions.

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Remote Assessment of Diseases And Relapse (RADAR) – CNS Facts

- **Industry Consortium:** Janssen, Lundbeck, BiogenIdec, UCB, Merck: expertise in CNS clinical study design execution and regulatory approval pathways, Clinical data, expertise in data capture/ data management/ analytics/ data mining, devices to measure relevant parameters.
- **Budget**: IMI JU 11 M EUR; EFPIA 11 M EUR
- **Duration:** 5 years
- **Contact IMI Scientific Officer:** Colm Carroll Colm.Carroll@imi.europa.eu

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2. Assess risk & progression of prediabetes and T2D for disease modification– Objectives

- Prioritise and/or validate a panel of human biomarkers or assays of pancreatic beta cell function, stress, mass, and death.
- Prioritise and/or validate a panel of human biomarkers or assays of hepatic, skeletal muscle, and/or adipose cellular dysfunction derived from or contributing to progression of insulin resistance.
- Develop innovative potential regulatory approaches: adaptive clinical trial designs, enabling feasible and robust benefit/risk assessments in clinical trials for therapeutic intervention.
- Model short- and long-term economic and public health morbidity and mortality benefit/risk assessments of the therapeutic intervention.

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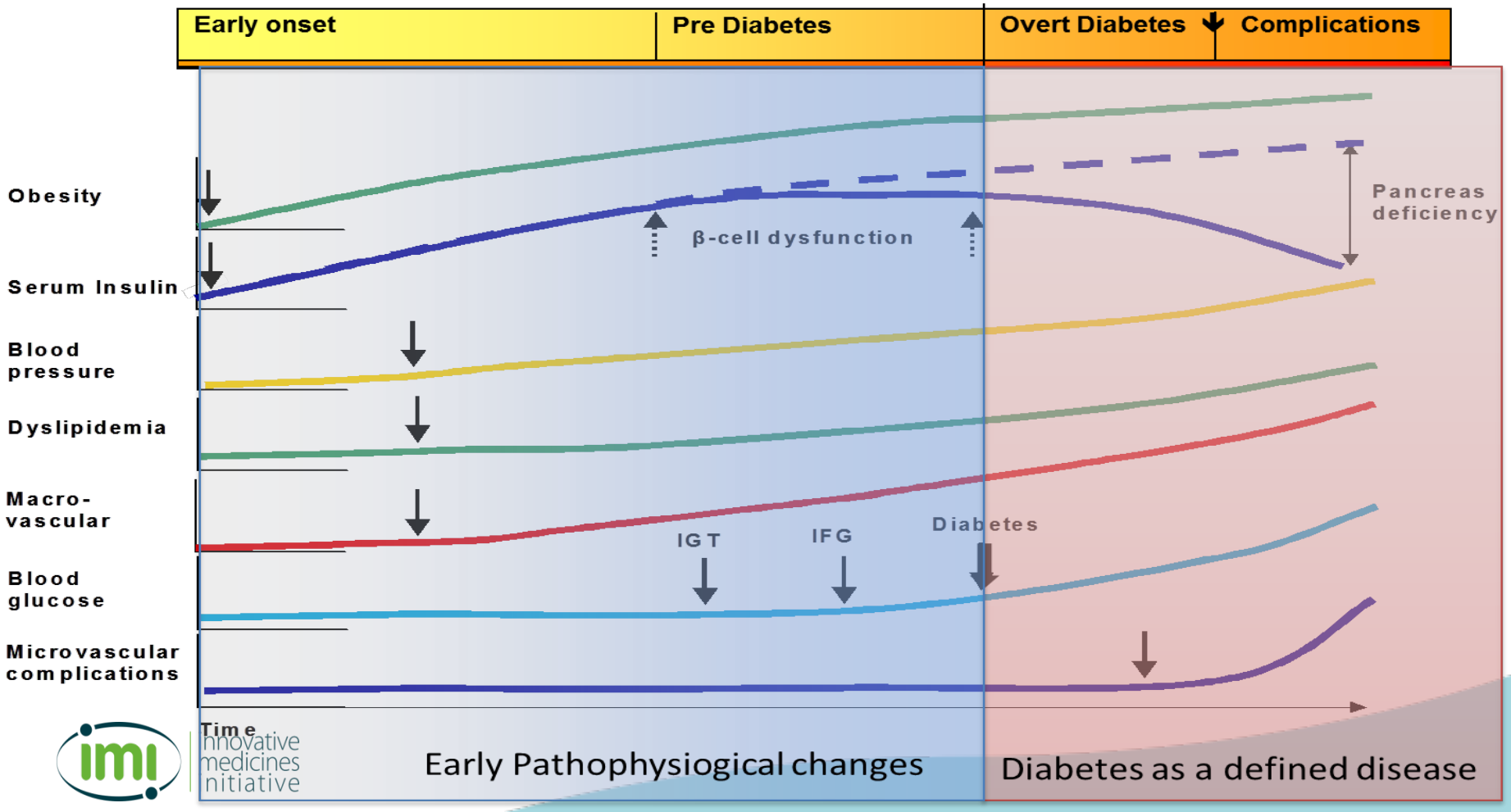
Diabetes defined late in the pathogenesis sequence

Biomarkers can be used to predict early changes in pathophysiology.

There is a need to identify biomarkers similar to HbA1c for pre-diabetes



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Assess risk & progression of prediabetes and T2D for disease modification-Expectations (1)

- Validation and/or discovery of human phenotypes and biomarker panels predictive of rapid declines in pancreatic beta cell health and function for prospective identification of rapid progressors from prediabetes to type 2 diabetes and/or for accelerating type 2 diabetes disease progression for clinical trial recruitment.
- Validation and/or discovery of human phenotypes and biomarker panels predictive of rapid declines in insulin action-targeted hepatic, skeletal muscle, and/or adipose cellular functions.

Assess risk & progression of prediabetes and T2D for disease modification-Expectations (2)

- Prioritisation and selection of robust phenotypes and biomarker panels for prospective patient segmentation/selection, clinical trial design and regulatory paths of new therapeutic options for prevention of progression from prediabetes to type 2 diabetes and acceleration of T2D progression
- Development of new regulatory approaches or standards enabling innovative and feasible clinical trial designs for disease modification in patients with prediabetes or type 2 diabetes
- Models for public health benefit and economic impact of therapeutic intervention to prevent or delay progression from prediabetes to type 2 diabetes

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Assess risk & progression of prediabetes and T2D for disease modification-Applicant Consortium

- **Experience & Capabilities**
- Academic basic, translational, clinical research
- Biomarker discovery and clinical assay implementation across relevant technologies
- Human pancreatic beta cell, hepatic, muscle, and adipose biology
- Clinical phenotyping of pre- and T2D patients
- Regulatory expertise
- Economic or public health modelling
- Project management

- **Assets**
- Relevant existing datasets and existing clinical studies
- Relevant longitudinal clinical cohorts and registries
- Relevant biobanks and bio-samples
- Involvement of patient organizations and appropriate ethical considerations

Assess risk & progression of prediabetes and T2D for disease modification-Facts

- **Industry Consortium:**
  Lilly, Servier, Janssen, Novo Nordisk, Sanofi

- **Budget: IMI JU 8.1 M EUR; EFPIA 8.1 M EUR**

- **Duration**: 4 years

- **Contact IMI Scientific Officer:** Magda Gunn
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3. Linking clinical neuropsychiatry and quantitative neurobiology – Objectives

- To explore the same set of quantifiable biological parameters across selected symptom constellations common to distinctly classified syndromes by classical taxonomy including neuropsychiatric issues in neurodegenerative diseases

- These studies would be driven from clinical quantitative biology back through appropriate translation to the measurement of homologous pre-clinical quantitative biological indices.

Linking clinical neuropsychiatry and quantitative neurobiology – Expectations (1)

- Select two or three symptom constellations, or domains that should be present across disorders, neuropsychiatric and degenerative, and identify a set of quantitative biological parameters/markers, to allow comparison both between symptom domains and across diseases, for each symptom constellation.

- Analyse the wide range of parameters measured in this experimental context towards selection and validation of a pragmatic subset useful in everyday diagnosis and to allow stratification of patients to facilitate more effective treatment and design of clinical trials, including the standardisation of measurement across sites.

Linking clinical neuropsychiatry and quantitative neurobiology – Expectations (2)

- Establish a network of clinical research sites for high quality observational studies in neuropsychiatric syndromes beyond the established classification systems.
- Establish a network of pre-clinical research sites for high quality translatable studies to explore the substrates identified as causal in the clinical studies. The tools validated in the study would also then transferable to general use beyond the initial network.
- Identify new hypotheses for therapeutic intervention for specific symptom constellations.
- Interact with regulators and prepare the regulatory path for acceptance of new metrics and approaches

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Linking clinical neuropsychiatry and quantitative neurobiology – Applicant Consortium

Experience & Capabilities

- Range of clinical Imaging and Biomarker platforms
- Statistics and study design
- Clinical study support
- IT – Data communication and data basing
- Pre-clinical imaging and biomarkers
- Pre-clinical technologies
- Regulatory expertise
- Project management

Assets

- Relevant existing datasets and existing clinical studies
- Relevant Clinical cohorts and registries
- Relevant bio-banks and bio-samples
- Involvement of patient organizations
- and its ethical considerations

Linking clinical neuropsychiatry and quantitative neurobiology – Facts

- **Industry Consortium**- Lilly, Boehringer-Ingelheim, Lundbeck, Pfizer, Novartis, Roche and Takeda (Pharmaceuticals, Medical imaging and electrophysiology, Experimental medicine providers, Statistics and data mining)

- **Budget: IMI JU 8.08 M EUR; EFPIA 8.08 M EUR**

- **Duration**- 3 years

- **Contact IMI Scientific Officer:** Elisabetta Vaudano

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4. The Consistency Approach to Quality Control in vaccine manufacture - Objectives

- To develop a new paradigm for improved quality control of established human and veterinary vaccines, *The Consistency Approach (CA)*, by generating a "fingerprint" of the physico-chemical and immunochemical properties instead of reading out end points in animals to demonstrate safety and efficacy of each batch release testing. This will require:
  - Technology and methodology innovation in analytics
  - In vitro models demonstrating functionality of immune responses
  - Bioinformatics
  - Translation into a set of consistency tests that will allow improved monitoring of vaccine quality during production and final formulation
- Facilitation of regulatory acceptance and implementation

The Consistency Approach to Quality Control in vaccine manufacture – Expectations (1)

- Demonstration of **proof-of-concept** for use of non-animal assays and techniques/key process parameters for integrated end to end quality and safety monitoring programme during vaccine lot production for a number of model vaccines:
  - safety tests for toxoid products
  - potency tests for viral vaccines
  - A set of non-animal methods (e.g. antigen assays, adjuvant assays and other consistency measures) for which proof-of-concept has been demonstrated for model vaccines to be optimised and evaluated to be used for other vaccines

The Consistency Approach to Quality Control in vaccine manufacture – Expectations (2)

- Development, optimisation and evaluation of techniques for demonstrating vaccine consistency and assuring release of potent and safe products:
  - Physicochemical techniques,
  - Immunochemical methods,
  - In vitro functional methods,
  - Genomics and proteomics assays.

- Global dissemination of knowledge and training for stakeholders

- Input into development/improvements of regulatory guidance to facilitate consistency approach to vaccine release testing.

The Consistency Approach to Quality Control in vaccine manufacture – Applicant Consortium

Experience & Capabilities

- Physicochemical techniques for conformational fingerprinting of antigens
- Pre-clinical (safety, CMC, assay development) and clinical expertise
- Proteolytic susceptibility of antigens to mimic APC action
- Immunochemical assay development
- Manufacturing processes and production consistency
- Antigen-adjuvant interactions
- *In vitro* cell models of immune responses
- Genomic and proteomic profiling
- Regulatory expertise
- Understanding of GLP, QA
- Animal models and laboratory animal science

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The Consistency Approach to Quality Control in vaccine manufacture– Facts

- **Industry Consortium**- Boehringer-Ingelheim, GlaxoSmithKline, Merck/MSD Animal Health, Merial, Novartis Vaccines, Sanofi-Pasteur, Zoetis

- **Budget: IMI JU 7.85 M EUR; EFPIA 7.85 M EUR**

- **Duration**: 5 years

- **Contact IMI Scientific Officer:** Angela Wittelsberger

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5. Pertussis vaccination research - Objectives

- To increase the scientific understanding of the immunity to pertussis in humans, in particular to identify biomarkers of pertussis protective immunity
- To progress our understanding of pertussis vaccine-induced immune responses, differences between whole cell and acellular vaccines, role of maternal antibody
- To generate technological tools and infrastructure that enable the development of novel pertussis vaccines

Refinement of current vaccination schedules ?

Pertussis vaccination research – Expectations (1)

- Immunological biomarkers that could reliably be used to streamline vaccine clinical trials
- An understanding of the difference in immune response profiles generated by natural pertussis infection and whole-cell vaccine (wP), and the acellular vaccine (aP) vaccines in selected population cohorts (children, adolescents, younger adults, older adults):
  - molecular dissection of the immune response,
  - effect of vaccination colonisation, carriage and transmission
- Generation of technological tools and infrastructure that enable the development of novel pertussis vaccines

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Pertussis vaccination research – Expectations (2)

- A European laboratory network and technological expertise to perform preclinical immunisation and B. pertussis challenge studies in predictive relevant pre-clinical disease models
- A molecular understanding of the progression of B. pertussis colonisation, infection and disease in the presence or absence of pre-existing immunity, by clinical studies:
  - in human cohorts naturally exposed to pertussis and/or
  - control challenge studies in human adult volunteers (a human challenge model that would need to be developed).

Pertussis vaccination research – Expectations (3)

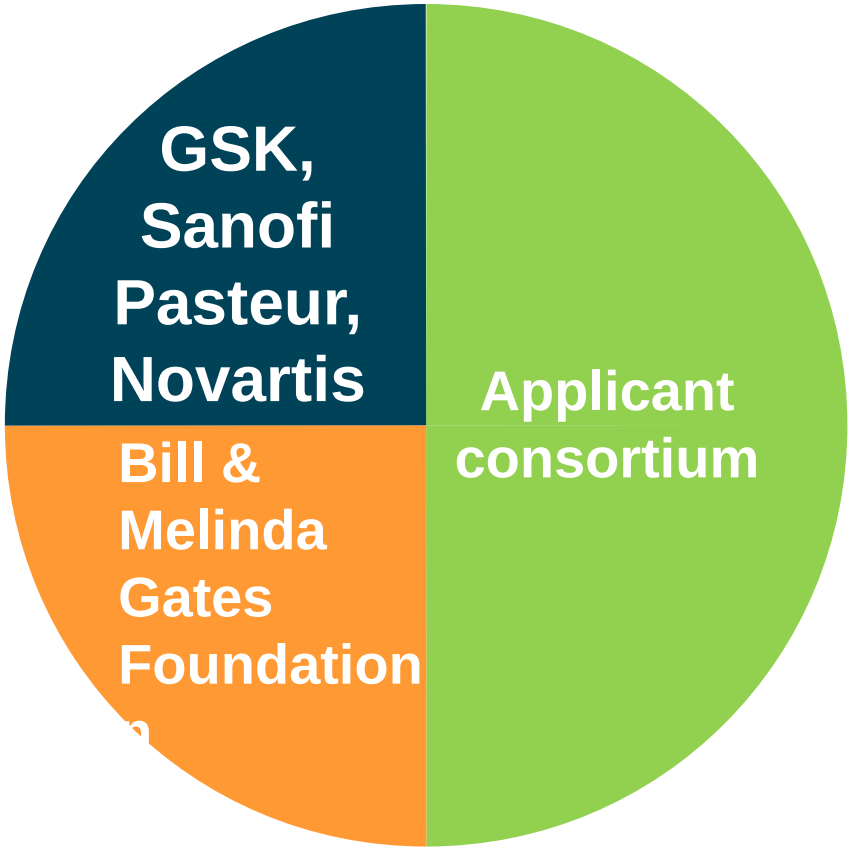
- Epidemiological studies that could cast light on the resurgence of pertussis (aP and wP vaccines countries)
- Assessment, acceptance and validation of the results of the project via collaboration and consultation with Regulatory Authorities and Public Health Institutions
- An understanding of the role of maternal antibody in modulating immune responses to pertussis vaccination in infants, so that recommendations could be made for adoption of maternal immunisation programs in low-income countries.

Pertussis vaccination research – Applicant Consortium

- In vitro, preclinical and clinical B. pertussis research or vaccination
- Bio- or immunoassays for pertussis infection and functional and memory immune responses to the vaccination
- Identification of biomarkers of infectious disease progression, immunological memory and/or vaccine efficacy
- Molecular epidemiology and in silico tools to investigate pathogen biodiversity and epidemiology of infectious disease
- Infrastructure for preclinical disease models, including in non-human primates
- Infrastructure for prospective clinical studies with licensed pertussis vaccines, access to relevant vaccination cohorts
- Control bacterial/respiratory pathogen challenge studies in human volunteers
- Access to epidemiological data on pertussis disease and vaccination
- Banking and Documenting clinical isolates of B. pertussis or biological samples from infected or vaccinated individuals

Associated Partners and other industries: a new dimension of opportunities

IMI2 Call 3: Pertussis vaccination research



Pertussis vaccination research – Facts

- **Industry and Associated Partners Consortium**: Sanofi Pasteur, GSK, Bill & Melinda Gates Foundation and Novartis
  (pertussis vaccine for prospective clinical studies, Know-how on clinical development of vaccines, expertise in *in vitro*, preclinical and clinical *B. pertussis* research, pertussis vaccination and pertussis epidemiology, identification of human biomarkers of infectious disease progression, immunological memory and/or vaccine efficacy, molecular epidemiology and use of *in silico* tools to investigate pathogen biodiversity, epidemiological data on pertussis disease and effectiveness of pertussis vaccination)

- **Budget: IMI JU 14 M EUR; EFPIA+ Associated Partners 14 M EUR**

- **Duration**- 5 years

- **Contact IMI Scientific Officer:** Angela Wittelsberger
  Angela.Wittelsberger@imi.europa.eu

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6. Knowledge repository to enable patient-focused medicine development - Objectives

- Set up of a Patient Inspired Knowledge Hub (PIKH) that enables sharing non-competitive information with and by users from patient groups, regulators, health authorities, academia and industry.
- The project is a response to the lack of a uniform process to engage patients in the drug development process.
- The PIKH will facilitate and enable the incorporation of patient input into the drug development processes, used broadly by stakeholders in a uniform (standardized) way among a range of stakeholder organizations.

Knowledge repository to enable patient-focused medicine development – Expectations (1)

- Identify appropriate points in time to interact with patients for development of medicine,
  - risks and benefits of interactions,
  - required capabilities,
  - anticipated enabling changes in regulatory affairs
- Standardize a framework to be used for patient engagement in medicine development
- Provide the ecosystem and mechanisms for stakeholders, for example pharmaceutical companies and patient advocacy groups, regulators, to discuss and share frameworks, methods and knowledge.

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Knowledge repository to enable patient-focused medicine development – Expectations (2)

- A risk assessment and evaluation report of conflict of interest in such a cooperation between industry and patients.

- Provide a sustainable service to identify possibilities of interaction/collaboration.

- Provide data and knowledge management services to enable:
  - - Making the framework available for broad use
  - - Populating the framework
  - - Improving the framework through group learning

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Knowledge repository to enable patient-focused medicine development– Applicant Consortium

- Experience with Patient Advocacy
- Regulatory Expertise
- Health Services Research
- Clinical Informatics
- Infrastructure and Software
- Advanced Knowledge Management
- Point of Care Know-how and Integration
- Community Education and Learning
- Education Systems
- Learning and training Management
- Analysis and complex clinical workflow experience
- Drug Development Life Cycle
- Innovation
- Requirements Engineering
- Product Development

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Knowledge repository to enable patient-focused medicine development– Facts

- **Industry Consortium**: MSD, Pfizer, UCB, Bayer
- **Budget: IMI JU 7.37 M EUR; EFPIA 7.37 M EUR**
- **Duration**- 3 years
- **Contact IMI Scientific Officer:** Ann Martin
  Ann.Martin@imi.europa.eu

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IMI-2 Call 4 - December 2014

Call 4 - Two Stage-Coordination and Support Action (CSA)

Enabling Platform on Medicines Adaptive Pathways to Patients

Scope:

Establishment of an enabling platform with relevant stakeholders for the coordination of Medicines Adaptive Pathways to Patients (MAPPs) related activities within IMI2.

This forum will enable a gap analysis, informing new research activities in IMI2 and creating a comprehensive repository of knowledge of activities including non IMI activities relevant to MAPPs and opportunities for coordination.

Submission deadline: **11 February 2015**

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Enabling Platform on Medicines Adaptive Pathways to Patients – Applicant Consortium

- Knowledge and expertise in medicinal products' life cycle;
- Sound understanding of the R&D pathways and their challenges.
- Ability to develop outreach and communication strategies on the role and challenges of MAPPs to the stakeholders and public at large.
- Proven expertise for managing and coordinating major projects of this complexity and scale.

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Enabling Platform on Medicines Adaptive Pathways to Patients– Facts

- **Industry Consortium**: AstraZeneca,BMS ,Amgen, Astellas, Bayer, Boehringer-Ingelheim, Eli Lilly, GSK/GSK vaccines, Ipsen, Janssen, Lundbeck, Merck KGaA, MSD, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi R&D/Sanofi Pasteur, UCB, Lysogene and EFPIA office.

- **Budget: IMI JU 1.13 M EUR; EFPIA 1.13 M EUR**

- **Duration**: 30 months

- **Contact IMI Scientific Officer:** Nathalie Seigneuret

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Thank you