



A joint undertaking between Academia & Industry



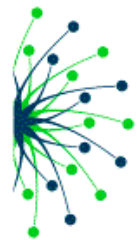
Innovative Medicines Initiative

Overview of the EHR4CR project

Electronic Health Record for Clinical Research

Pierre-Yves Lastic, Sanofi

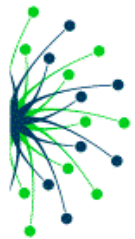
(on behalf of the EHR4CR consortium)



Overview



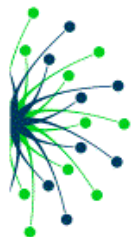
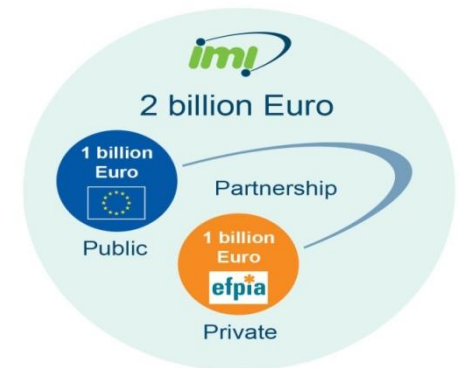
- Innovative Medicine Initiative (IMI)
- Project Objectives
- Organization
- Work Packages
- Current Status



About IMI



- A Public-Private Partnership between EU and EFPIA focused in research on needs common to the Pharmaceutical Industry and Patients at European level (2007-2017)
- Aims to removing major bottlenecks in drug development, where pre-competitive research is the key, and to re-invigorate the European bio-pharmaceutical sector
- IMI projects offers industry an opportunity to build new business models based on collaboration and transparency
- Coordinated research efforts with shared funding (EFPIA contributes with in-kind resources). Research focuses on fields of high industrial and policy relevance
- The IMI 2009 Call for proposal has 9 topics proceeding to stage 2 (final stage to become a project) addressing the two strategic pillars:
 - Predictivity of Efficacy Evaluation and
 - Knowledge Management (call topics 7,8 and 9).



Overall Structure of Research Projects

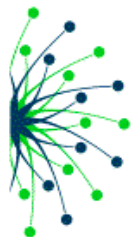
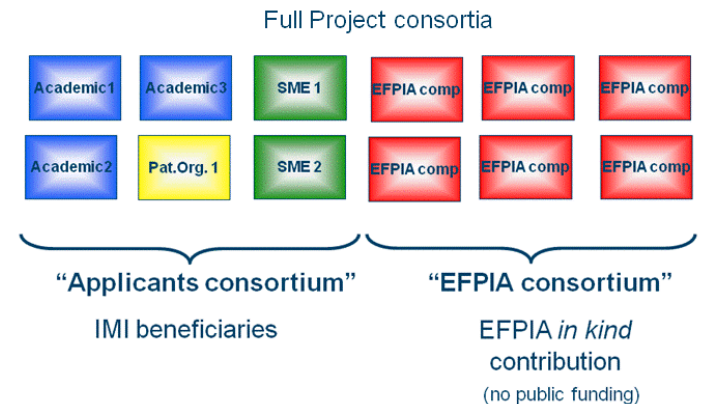


IMI Call topics for proposals are conducted through a 2-stage process

The first stage of the call process is addressing 'Applicant Consortia' (e.g. collaborations between academia, SMEs, patient organisations, non EFPIA industry, etc), to submit to the IMI JU an Expression of Interest in response to a call

- The second stage, following the first stage peer review, the 'Applicant Consortium' of the best Expression of Interest, and the 'EFPIA consortium' that already are associated to the topic, will be invited to form a full 'Project Consortium'
- The full project proposals will be evaluated based on consistency with the original Expression of Interest, on scientific excellence, the quality of the implementation plan and the potential impact
- Only full project proposals that have been favorably reviewed in the evaluation process can be selected for funding and will be invited to conclude a Grant Agreement governing the relationship between the selected project consortium and the IMI JU.

The IMI project principles are to ensure shared leadership roles (research) but to be coordinated by EFPIA

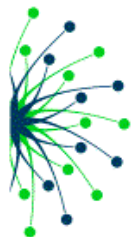


Project objective & outputs

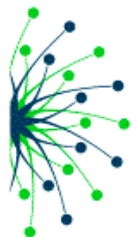
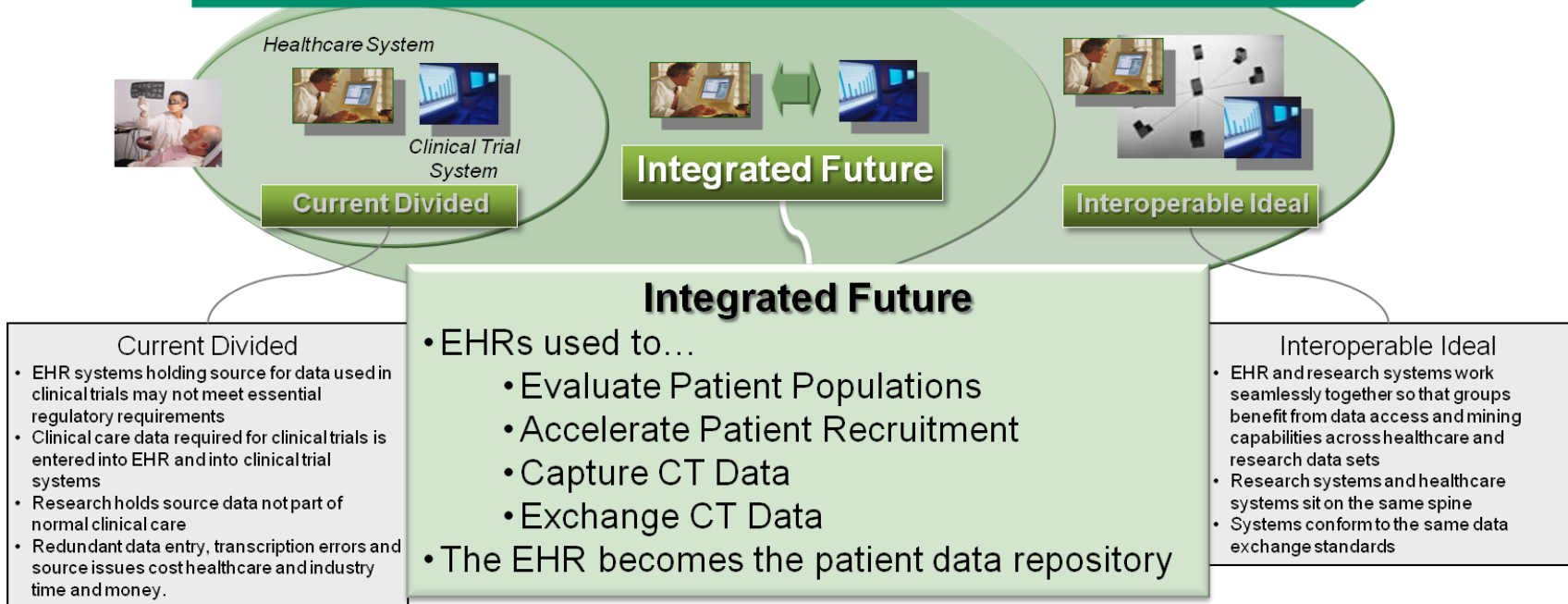
The EHR4CR project will develop a platform and business model for re-using EHR data for supporting medical research.

Output:

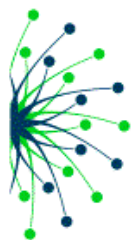
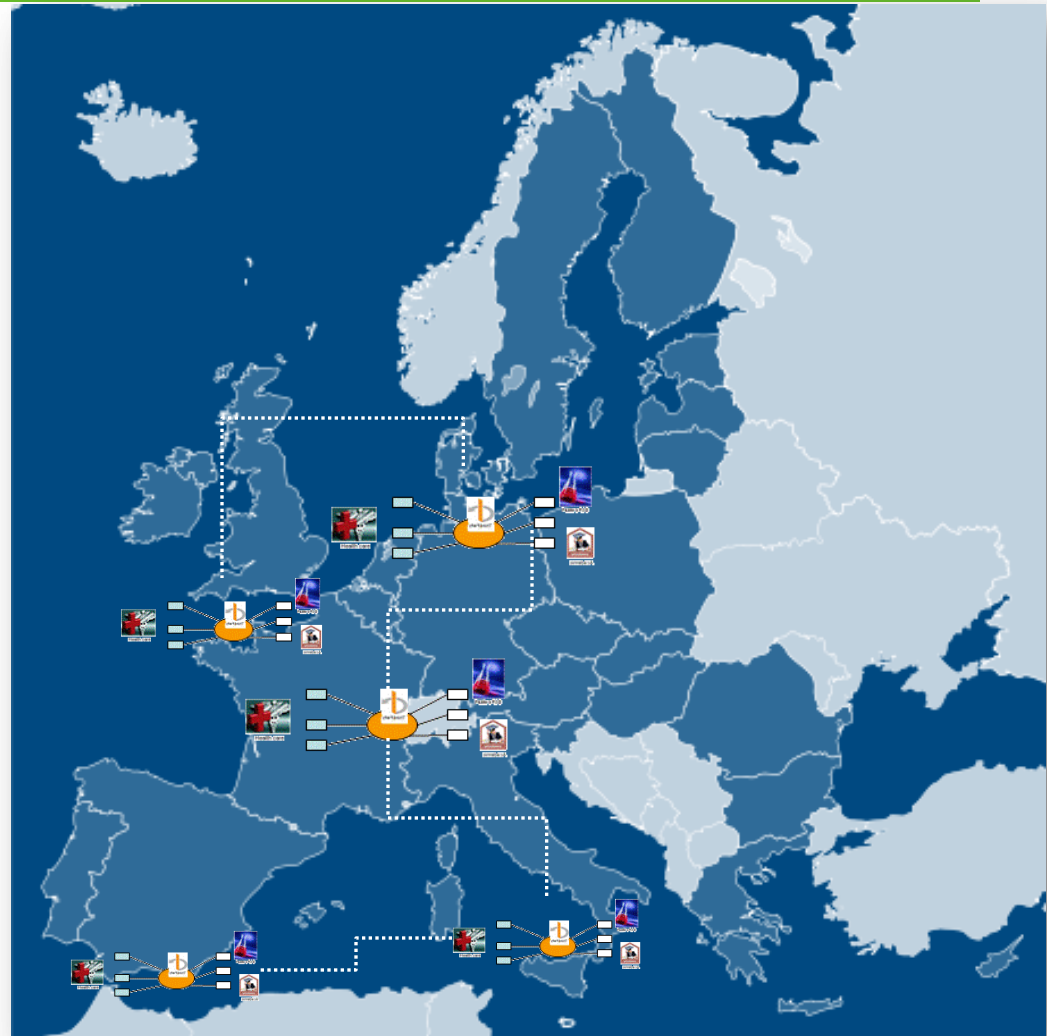
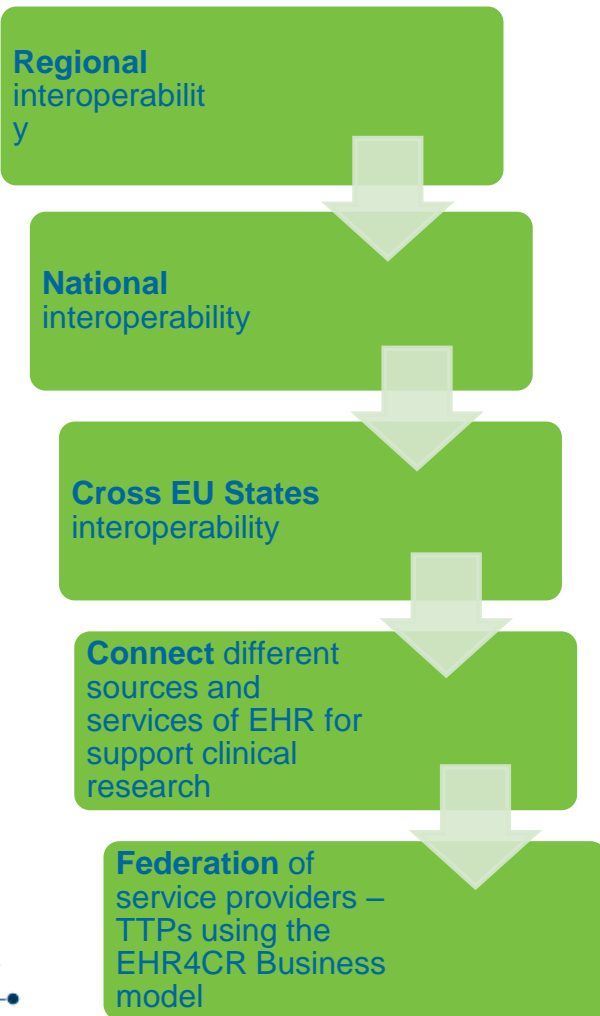
- **Requirements Specification and Business Model**
- **Technical Platform (a set of tools and services)**
- **Different Pilots for validating the solutions:**
 - ✓ for different scenarios (e.g. patient recruitment);
 - ✓ across different therapeutic areas (e.g. oncology);
 - ✓ across several countries (under different legal frameworks).



Emerging and Future EHR-Research Connectivity and Complexity

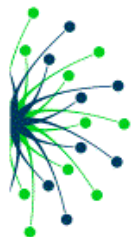


Vision: Scalable Organisational Model for EHR re-use



Benefits

- Accreditation and certification will enable research and clinical trials to be delivered more cost effectively. Both vendors of certified products and hospitals (source data) that will be accredited will have a competitive advantage.
- A new business model for re-using EHR data in research will aim at offering benefits for “**all**” stakeholders and strengthen the collaboration amongst “**all**” the partners in Research... !



Benefits (cont.)

Patients and health care perspective:

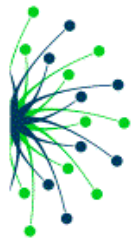
- Closer co-ordination between care providers and patients, resulting in safer and more evidence-based diagnosis and treatment
- Significantly facilitate re-use of EHR data to allow more efficient management of public health issues

Academic perspective

- Provide tools and services to better plan and conduct academic trials (investigator-initiated trials)
- Facilitate comparative effectiveness research, e.g. paediatric trials, trials on rare diseases, trials with biotherapy)

Pharmaceutical perspective:

- Improve speed and quality of clinical patient recruitment process and study design by accurate understanding of real patient populations
- Support to conduct observational and outcomes research studies in real-world settings

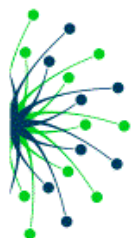
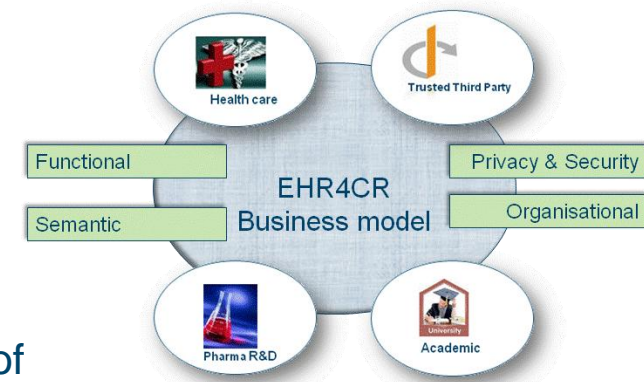


EHR4CR Business model



EHR4CR business model will:

- Specify in detail the product and service offering;
- Include analyses and an impact analysis on multiple stakeholders;
- Deliver a self-sustaining economic model including sensitivity analysis;
- Define appropriate governance arrangements for the platform services and for pan-European EHR4CR networks;
- Define operating procedures and trusted third party service requirements;
- Identify the value proposition and incentives for each of the key players and stakeholders impacted by EHR4CR;
- Define accreditation and certification plans for EHR systems capable of interfacing with the platform;
- Provide a framework to define public and private sector roles in reusing EHRs for clinical research;
- Define a roadmap for pan-European adoption and for funding future developments.

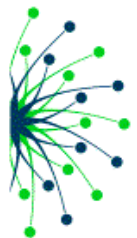
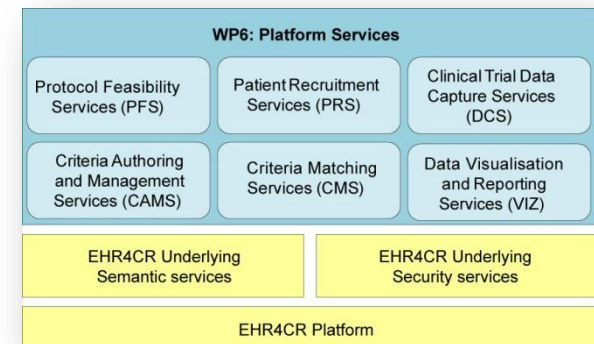


EHR4CR Technical Platform



EHR4CR platform will:

- Support the feasibility, exploration, design and execution of clinical studies and long-term surveillance of patient populations;
- Enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate confidentially participation requests via the patients' authorised clinicians;
- Provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and integration with existing clinical trials infrastructure products (e.g. EDC systems);
- Facilitate improvements of data quality to enable routine clinical data to contribute to clinical trials, and importantly vice versa, thereby reducing redundant data capture.



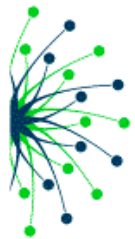
The partners



- **11* Pharmaceutical Companies (members of EFPIA)**
- **22 Public Partners (Academia, Hospitals and SMEs)**
- **5 Subcontractors (Advisory Board).**

EHR4CR

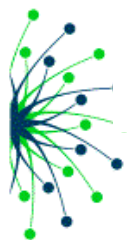
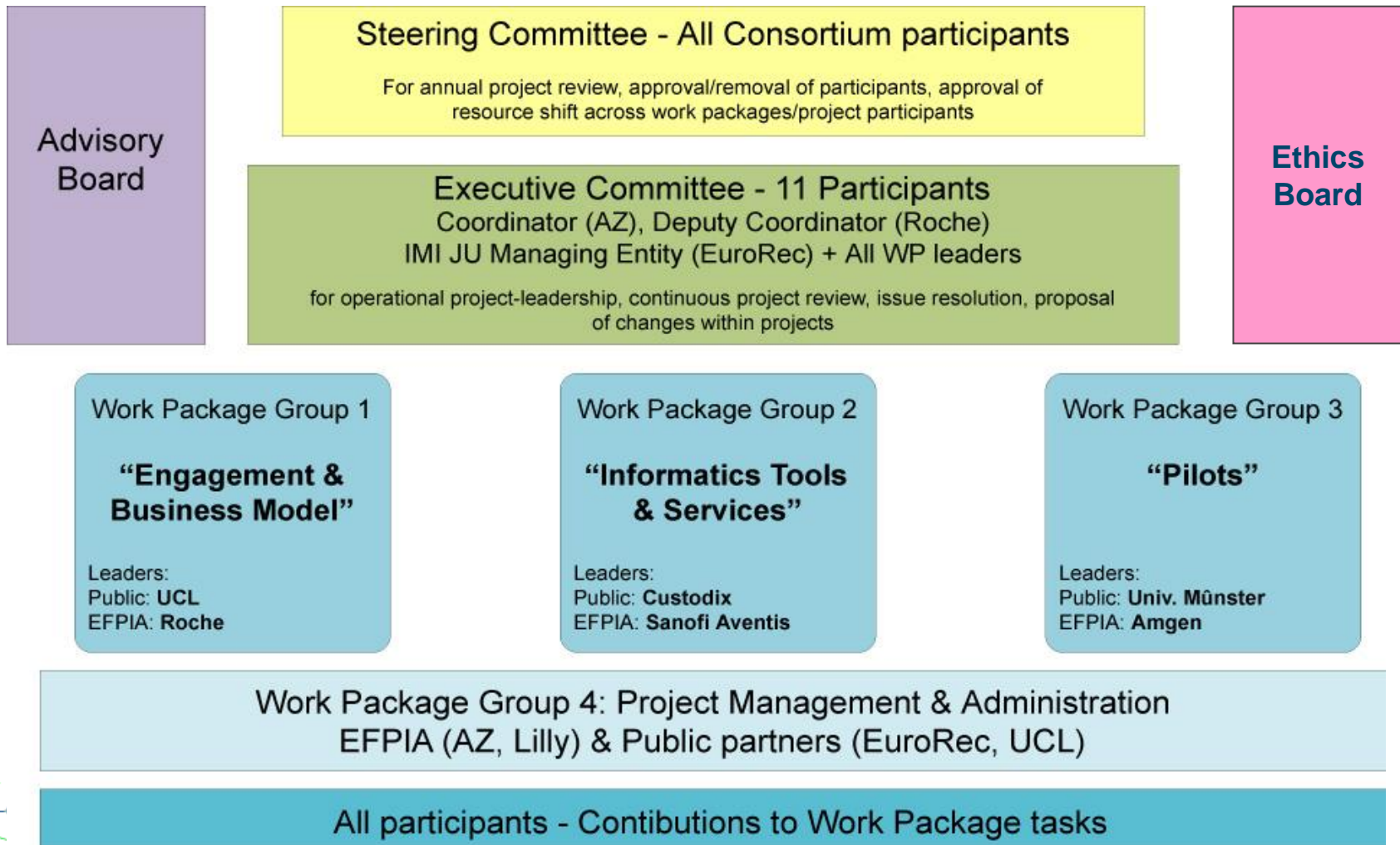
** (Amgen, AZ, Bayer, Eli Lilly, Merck KgA, MSD, Janssen/J&J, Novartis, Roche, Sanofi-Aventis and MSD Europe)*



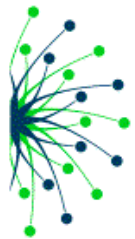
The partners



Governance structure



Overview of Work Package Groups



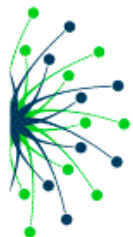
Work Package Group 1

Engagement & Business Model



Objectives

- **WP 1 (Specification & Evaluation)**
 - Review the ethical, legal and regulatory landscape in Europe
 - Define the use case scenarios applicable to the EHR4CR platform and business model.
- **WP 2 (Business model & Strategic road map)**
 - Develop a roadmap specifically for the EHR4CR platform, focusing on benefits, investments and adaptations needed
 - Develop a comprehensive business model to establish a durable European service to include specialized products requiring key partnerships for services to be provided
- **Example of tasks**
 - Governance Success Factors (e.g. identify the regulations and cross-border legislative issues that EHR4CR must address and comply with)
 - Evaluation of the Pilots
 - Develop a Business model including product and service offering, governance arrangements, operating procedures, third party service requirements and proposals, accreditation and certification plans



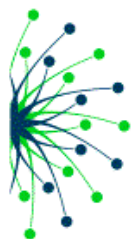
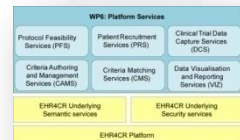
Work Package Group 2

Technology Platform & Tools



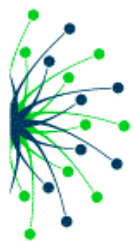
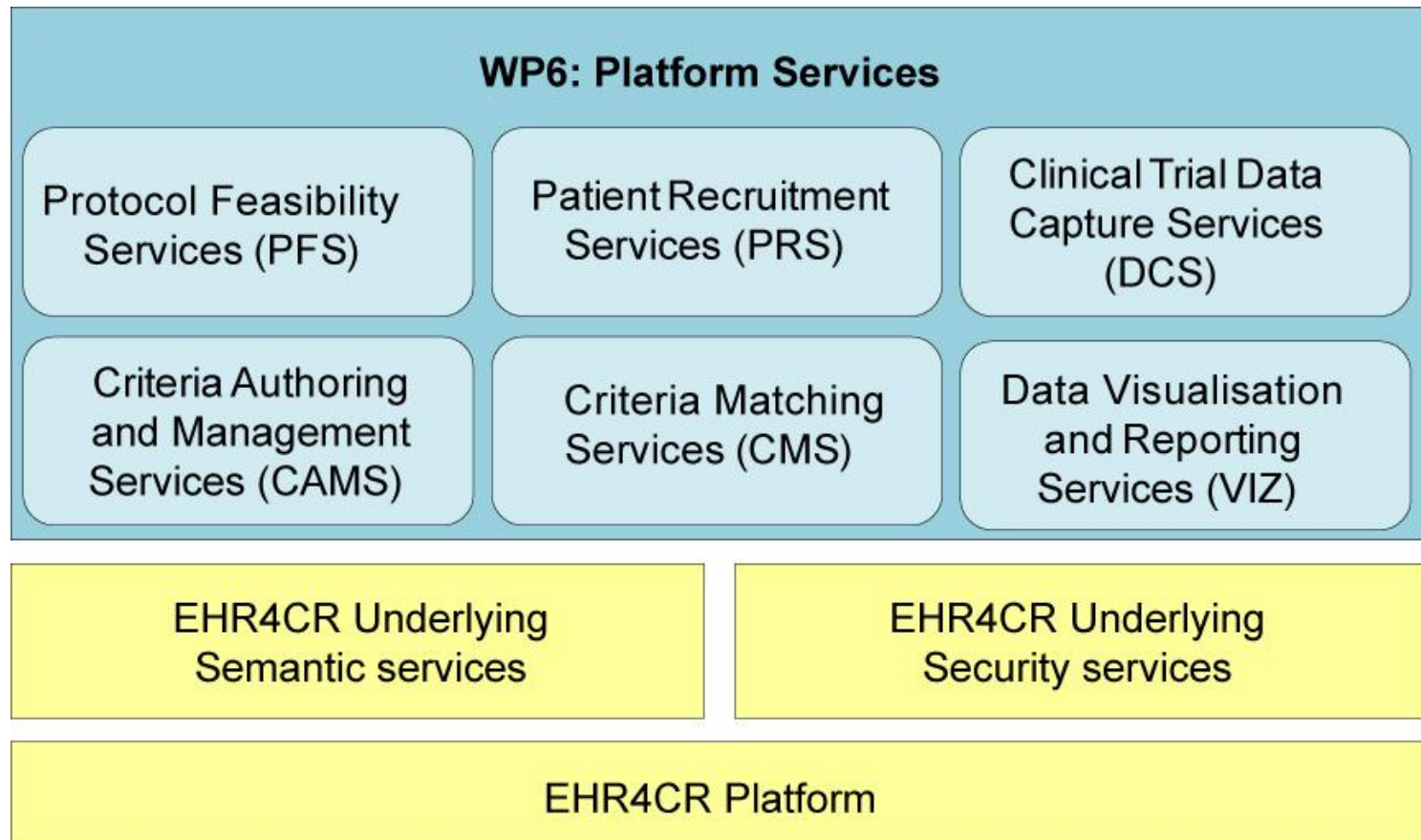
Objectives

- **WP3 (Architecture and Integration)**
 - Define the architecture of the EHR4CR platform, provide a reference implementation and oversee the overall EHR4CR platform integration and operation.
- **WP 4 (Semantic Interoperability)**
 - Provide tools and services to ensure semantic interoperability between varying and disparate data sources (EHRs and CDMS), allowing for consistent interpretation of data
- **WP5 (Data protection, Privacy & Security)**
 - Provide the core security services for the EHR4CR platform and ensure that data and process flows are optimised for data protection and compliance
- **WP 6 (Platform Services)**
 - Design and implement end-to-end solutions (tools and services) that address the requirements of the different EHR4CR scenarios (e.g. clinical trial protocol feasibility)
- **Example of tasks**
 - Inventory of re-useable and available relevant solutions and components
 - Knowledge Models Mapping and Management Services and Tools
 - Core Security Services (AAA - Authentication, Authorisation, Audit)
 - Clinical Trial Protocol Feasibility Services (PFS)

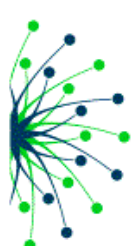
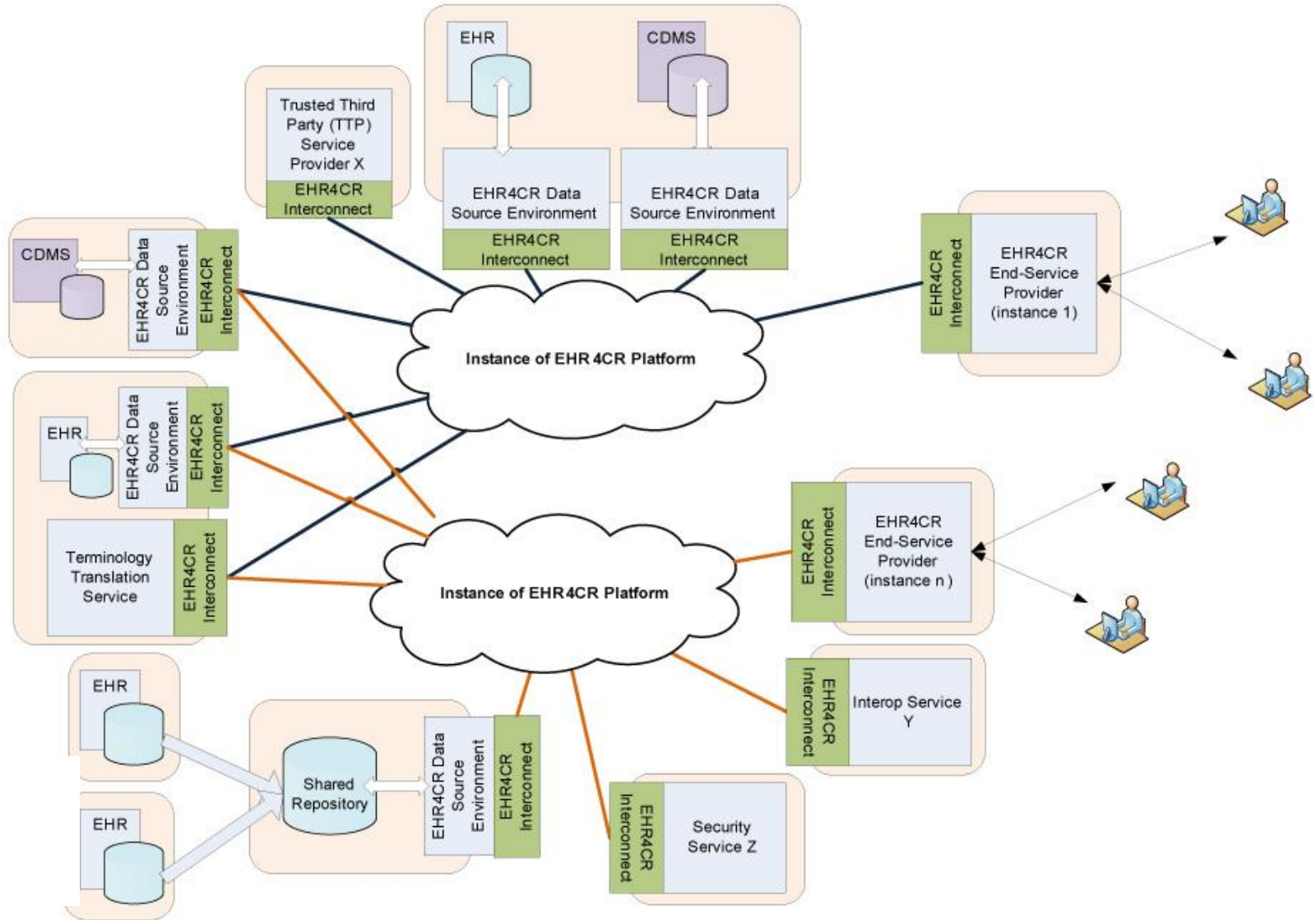


A joint undertaking between Academia & Industry

Overview of Platform services



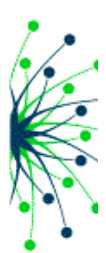
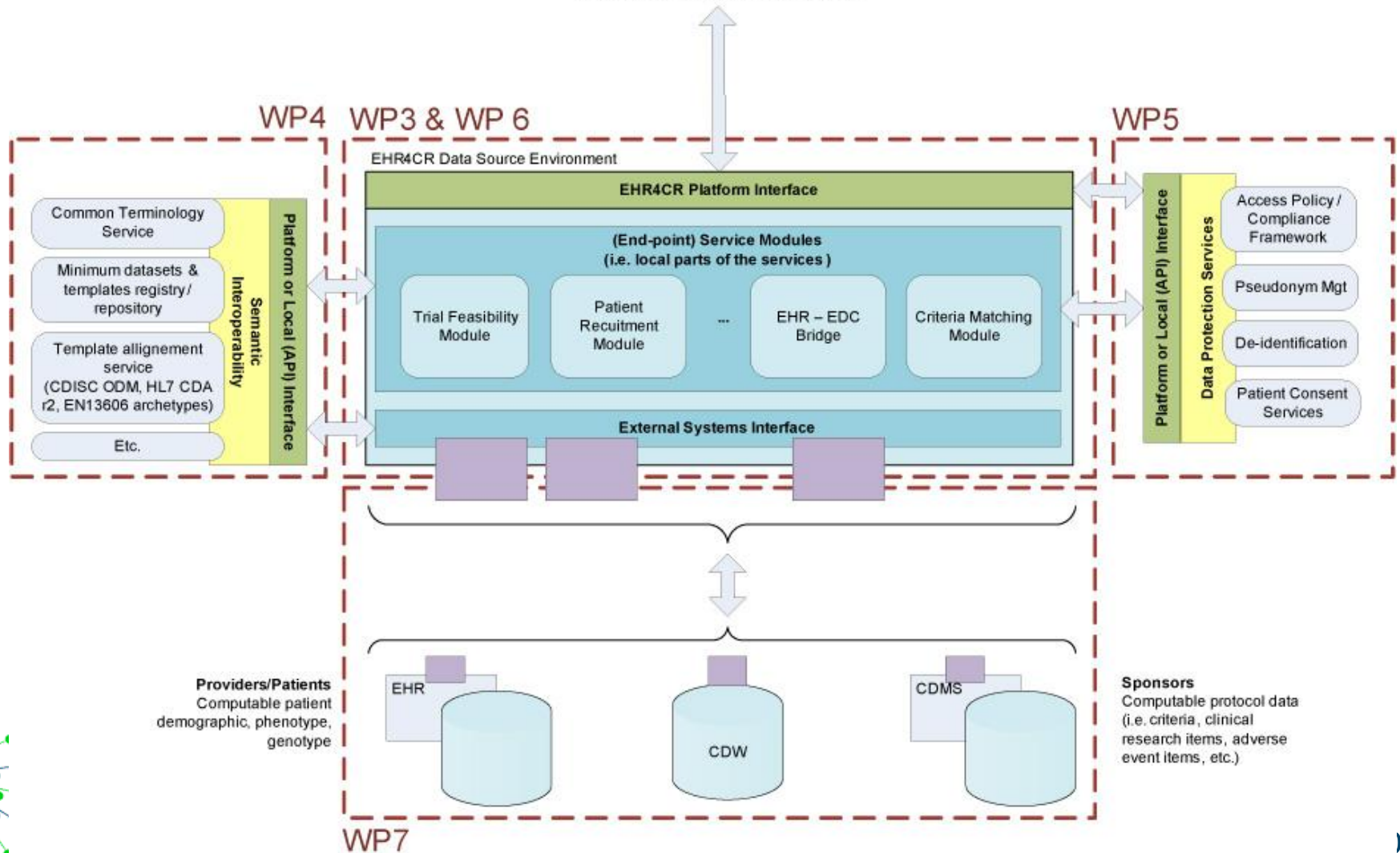
EHR4CR concept overview



EHR4CR data source flow



EHR4CR Service Platform



Objectives

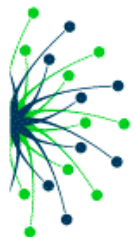
▪ WP7 (Pilots)

- Demonstrate the functionality of the tools and services provided by Work Packages 3-6 and to evaluate the EHR4CR platform in terms of clinical study design and execution with a specific focus towards a set of mutually acceptable medical domains agreed between the pilot sites and the EFPIA partners
- Pilots evaluations will occur at several large academic hospitals, interfacing with EHR systems, with a specific focus towards a set of mutually agreed medical domains between the pilot sites and EFPIA partners (e.g. Diabetes, Oncology).



▪ Example of tasks

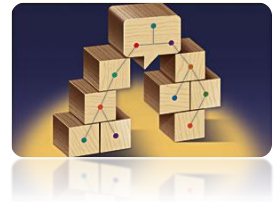
- Develop Interfaces between local EHR/CDW and CDMS systems and the uniform access layer
- Execute pilots on
 - Protocol Feasibility, Patient Recruitment, Clinical Trial Execution, Drug Safety Monitoring)
- of the inventory of local data sources and the matching of EFPIA clinical studies with suitable clinical data providers



Objectives

▪ WP 8 (Training & Communication)

- Support the communication and training between all EHR4CR Work Package Groups and Work Packages and promote EHR4CR services to prepare for EHR4CR platform exploitation
- Widely disseminate the EHR4CR outcomes and communicate with other EC FP or IMI projects in Europe and globally



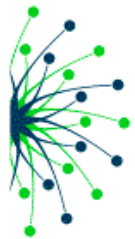
▪ WP 9 (Management)

- Coordinate the work of the EHR4CR project, administer day-to-day operations, manage the collaborative efforts of the Work Packages
- Ensure that the scientific work being conducted is delivered on time and on budgets through optimal project management, including quality monitoring, planning, reporting and financial control

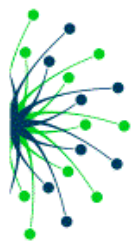
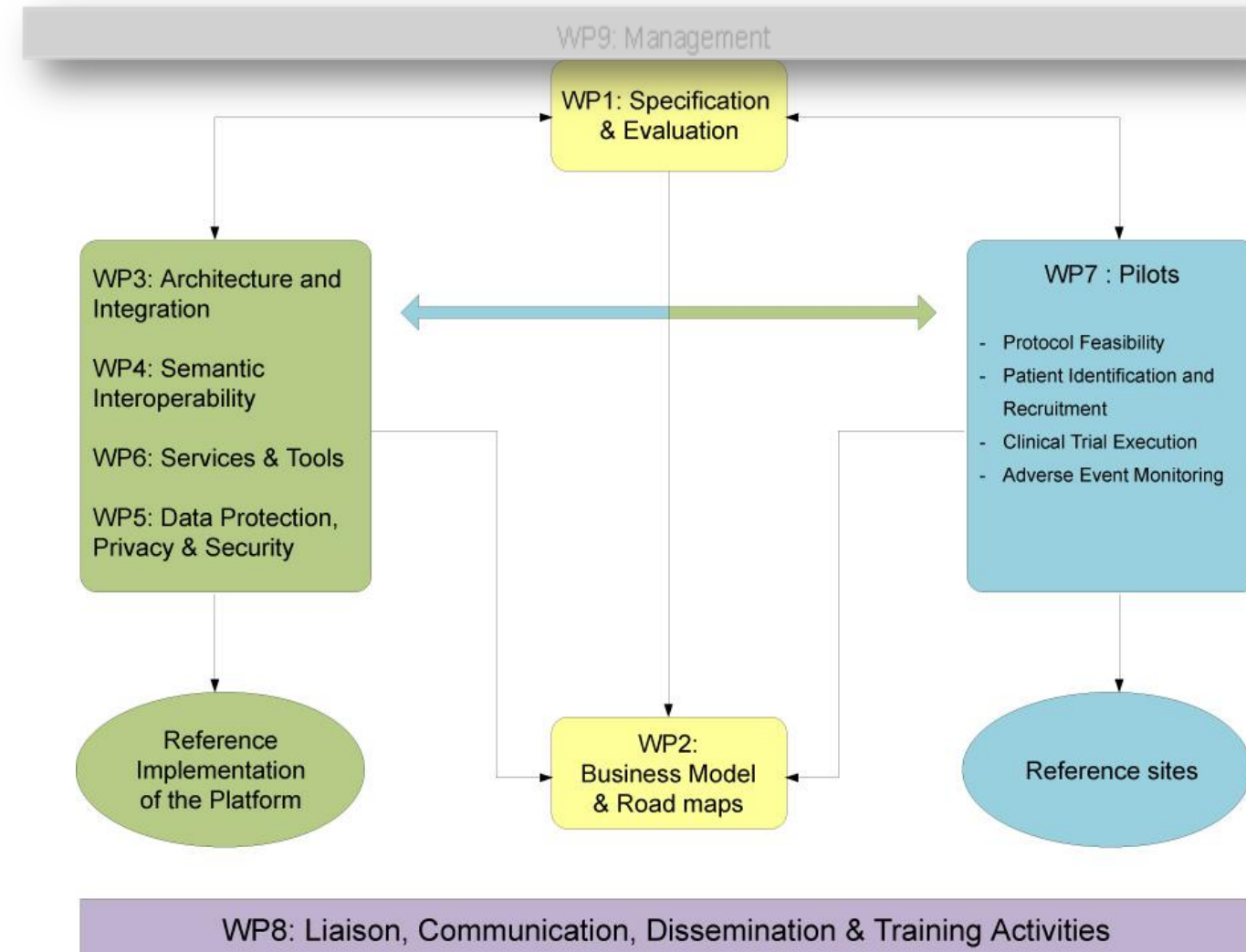


▪ Example of tasks

- Project Website development and maintenance, Project collaboration space
- Dissemination and liaison activities in EU
- Coordination and managing of IMI JU funding, Project management office
- Total quality management
- Computer systems validation

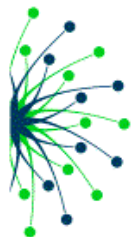


Project plan overview



Consortium status

- Background
 - Forming one EHR4CR consortia of 34 private and public partners to develop a full project proposal for 2009 IMI call topic 9, including finalizing stage 2 (March-September)
 - The project is coordinated by AZ and EuroRec acts as managing entity for public partners. Roche acts as deputy coordinator and Eli Lilly to cover Project Management
- Project Agreement and Grant Agreement finalised March 15th
 - Professional Service Agreement finalised between Efpia and Data Mining International, March 15th
- Establishing chairman's for the Advisory Board and Ethical boards, February 15th



Status & Progress 2011



Project start March 1st 2011

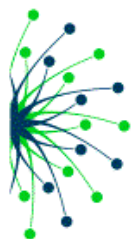
- Kick-off meeting
3 & 4 March, AstraZeneca, Göteborg, Sweden

Work Package Group 1: **Engagement & Business Model**

- Task 1.2 Kick-Off Workshop,
5 & 6 April 2011, Novartis, Basel, Switzerland

Work Package Group 2: **Technology Platform & Tools**

- Kick-Off Meeting,
4-6 May 2011, Sanofi-aventis, Paris, France



Work Package Group 3: **Pilots**

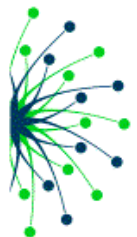
- Kick-Off Meeting June 23-24, 2011 at Novartis in Basel

Work Package Group 4: **Management**

- Launching a new collaboration space for partners (EuroRec) April 28th
- Forming a Project Management Office (Eli Lilly, MSD Europe, EuroRec and AZ)
- Workshop for developing a integrated project plan for the first 18th months, May 16th (Finalised on June 7th)

Project Alignment

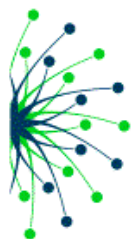
- Meeting of the Steering Committee, Ethics and all Work Packages on October 18-21, 2011, hosted by Sanofi in Frankfurt, Germany



Summary



- **EHR4CR** will move beyond the current state-of-the-art by combining previously isolated informatics progress
 - E.g. semantic interoperability, privacy enhancing techniques, and standards) with an entirely new approach to reusing EHR data for supporting medical research, underpinned by a comprehensive business model for governance, acceptance, adoption and sustainability.
- The project will demonstrate the viability and scalability of the **EHR4CR business model** through pilots
 - E.g. platform services designed for protocol feasibility, patient recruitment, and clinical trial data capture.
- The IMI EHR4CR project will run over 4 years with a budget of €16 million and involve 34 recognised European academic and industrial partners.
- The EHR4CR will be the largest public-private partnership to date with the goal to tie interoperability aspects together to provide adaptable, reusable and scalable solutions and be the first step to a pan-EU capability for clinical research with integrated interoperability for clinics across countries in Europe.



Q & A

