



Innovative Medicines Initiative

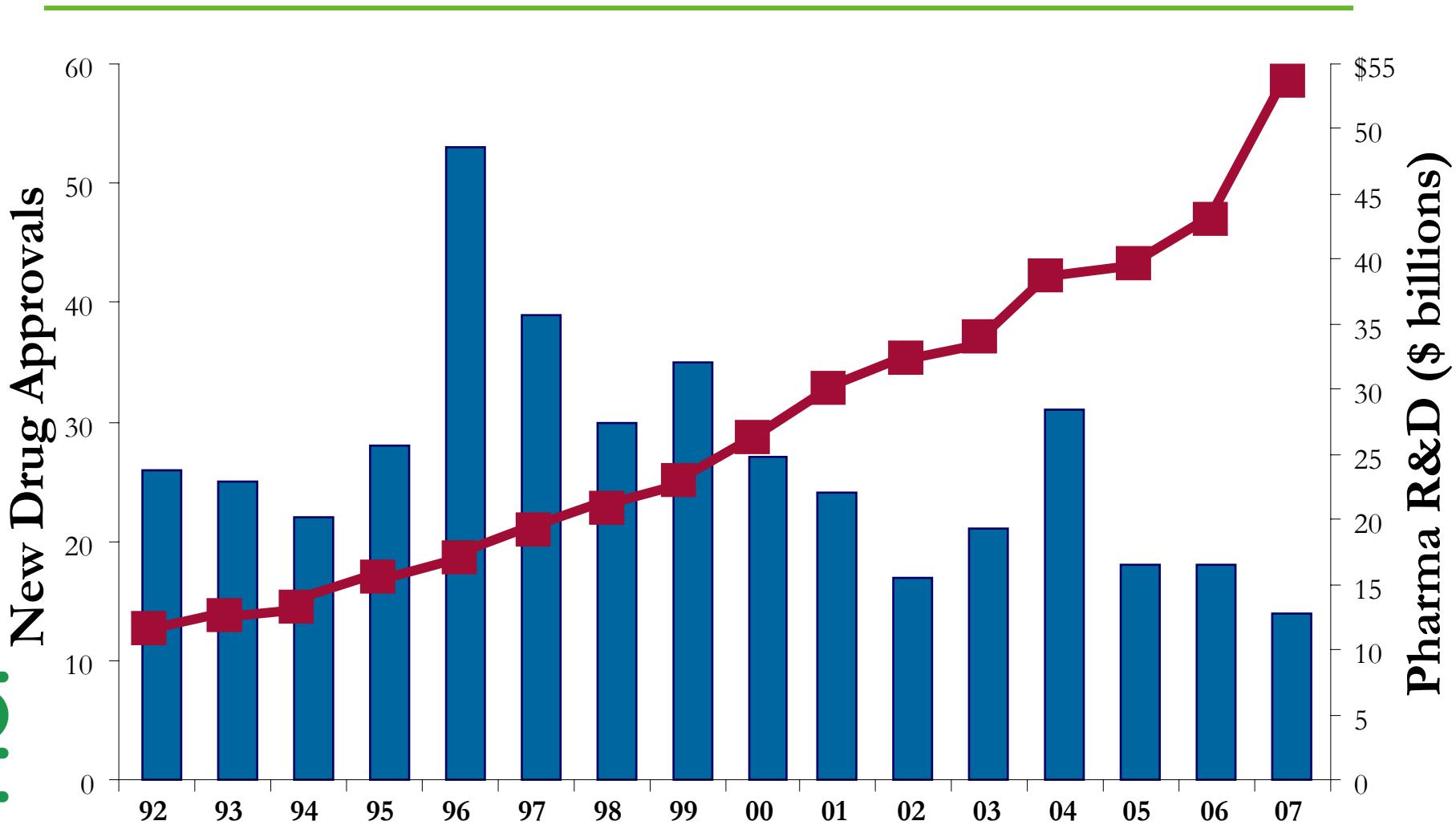
ddmore

Drug Disease Model Resources

Lutz Harnisch, Pfizer, UK
Mats Karlsson, Uppsala University, Sweden



The Productivity Gap in Pharma R&D



Source: Burrill & Company; US Food and Drug Administration.

Innovative Medicines Initiative: the Largest PPP in Life Sciences R&D

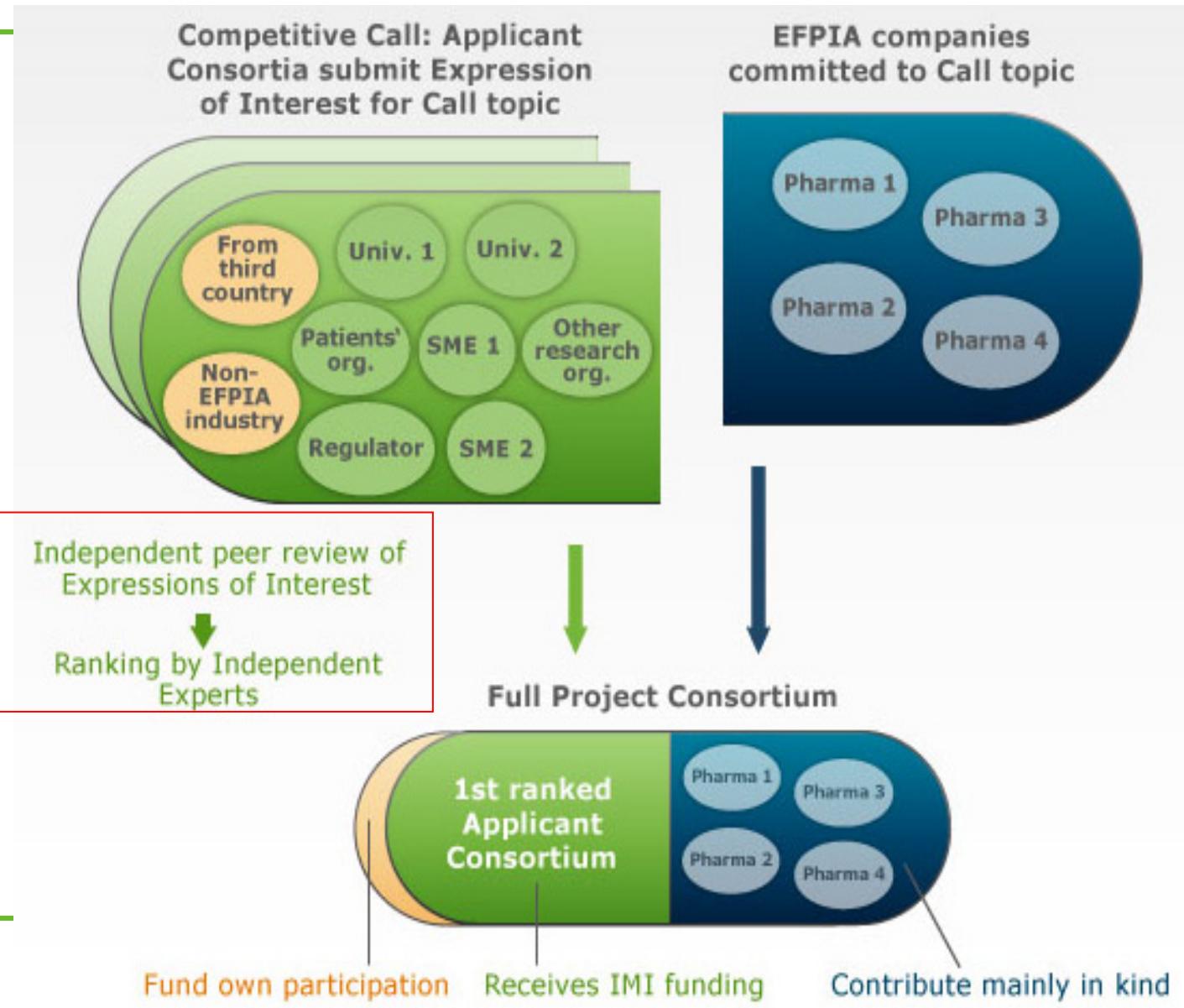


- Key concepts
 - Open innovation
 - Pre-competitive research

The Four Pillars of the Innovative Medicines Initiative



Building an IMI Consortium



EFPIA Member Companies

Participating companies (September 2010):



Bristol-Myers Squibb
Together we can prevail.

Johnson & Johnson

NOVARTIS

sanofi aventis
L'essentiel c'est la santé.

AMGEN

Chiesi

Lilly

novo nordisk®

SERVIER

AstraZeneca

ESTEVE
A lot to discover

Lundbeck

ORION

sigma-tau

Bayer

genzyme

MERCK SERONO

pfizer

Boehringer
Ingelheim

gsk
GlaxoSmithKline

MERCK SHARP & DOHME

Roche

ucb

DDMLF initiating companies

10 designed the Drug Disease Model Library & Framework Call text

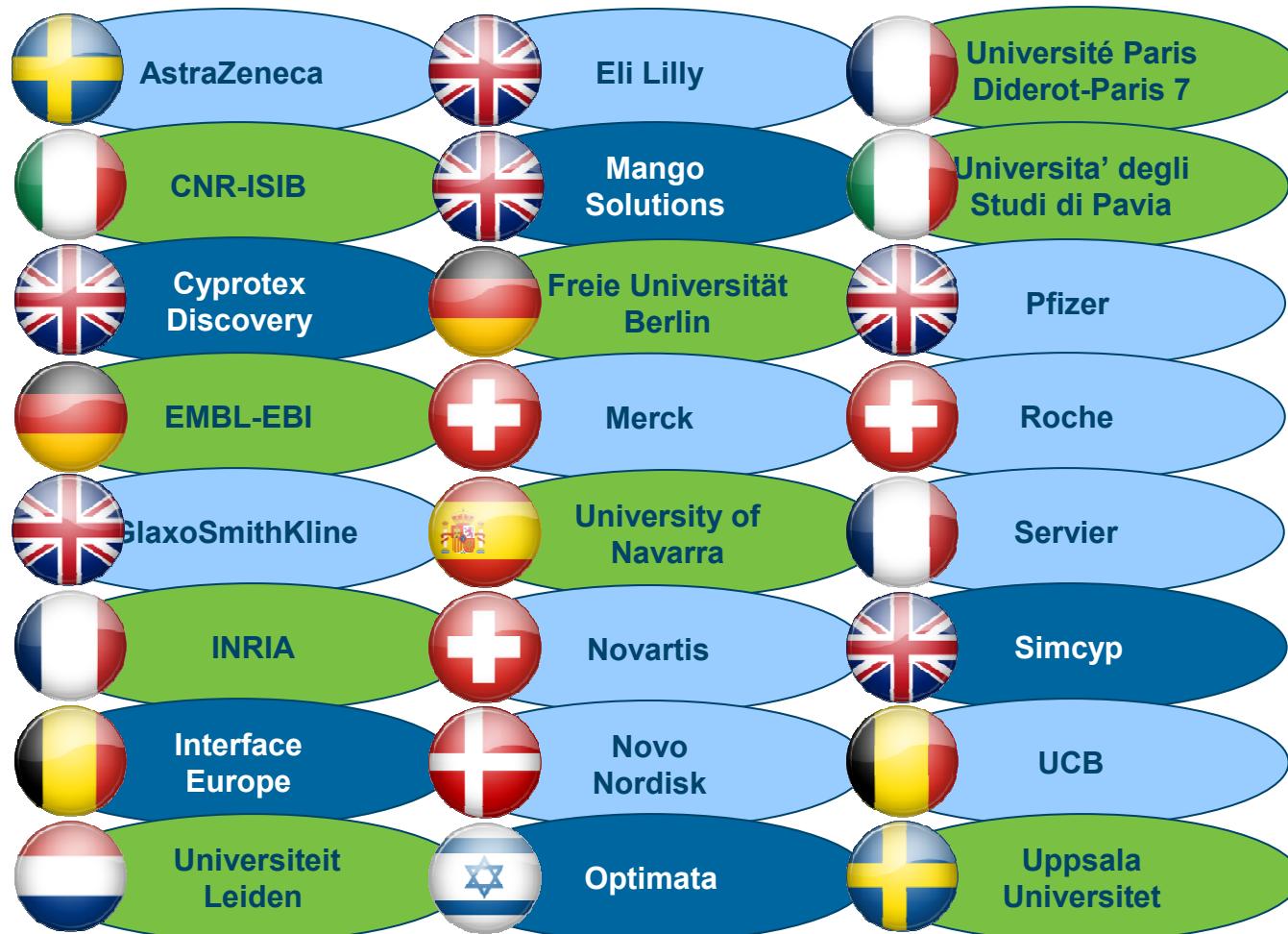


IMI Strategic Research Agenda led to DDMoRe's primary aims

The scientific and functional requirements for the KM Platform can be summarised as follows:

- **Data federation:** seamless search and navigation across heterogeneous data sources, both private and public;
- **Data integration:** the capacity to pool data from heterogeneous sources in a scientifically, semantically and mathematically consistent manner for further computation;
- **Shared services:** the development, sharing and integration of relevant and powerful data exploitation tools such as modelling and simulation.

Participants are a unique combination of model builders, model users, software developers and teachers



Time and money

- **Timing:**
 - **Starting Date:** 01/03/2011
 - **Duration:** 60 months
- **Financing:**
 - IMI funding: € 9.615.058
 - Other contributions: € 1.729.833
 - EFPIA in kind contribution: € 9.820.120
 - **Total Project Cost:** € 21.165.061

DDMoRe – The Vision

Major deliverables

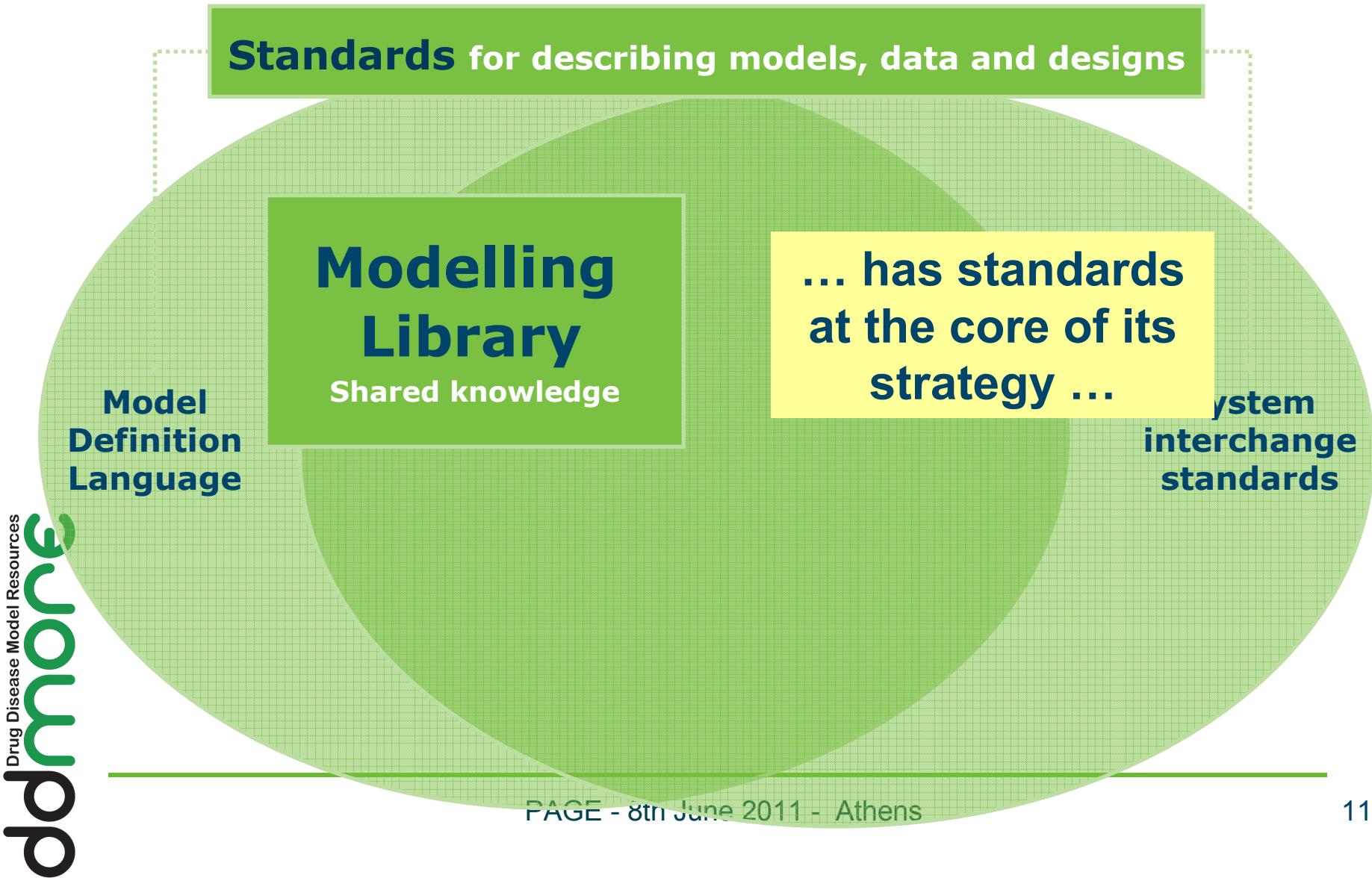
Modelling Library

Shared knowledge

- Data contains raw information, which is difficult to share
 - IP, CDISC
- Models
 - represent an interpretation, understanding of the data (given experimental conditions)
 - allow to predict the future with uncertainty
 - are an *intellectual container of the knowledge*

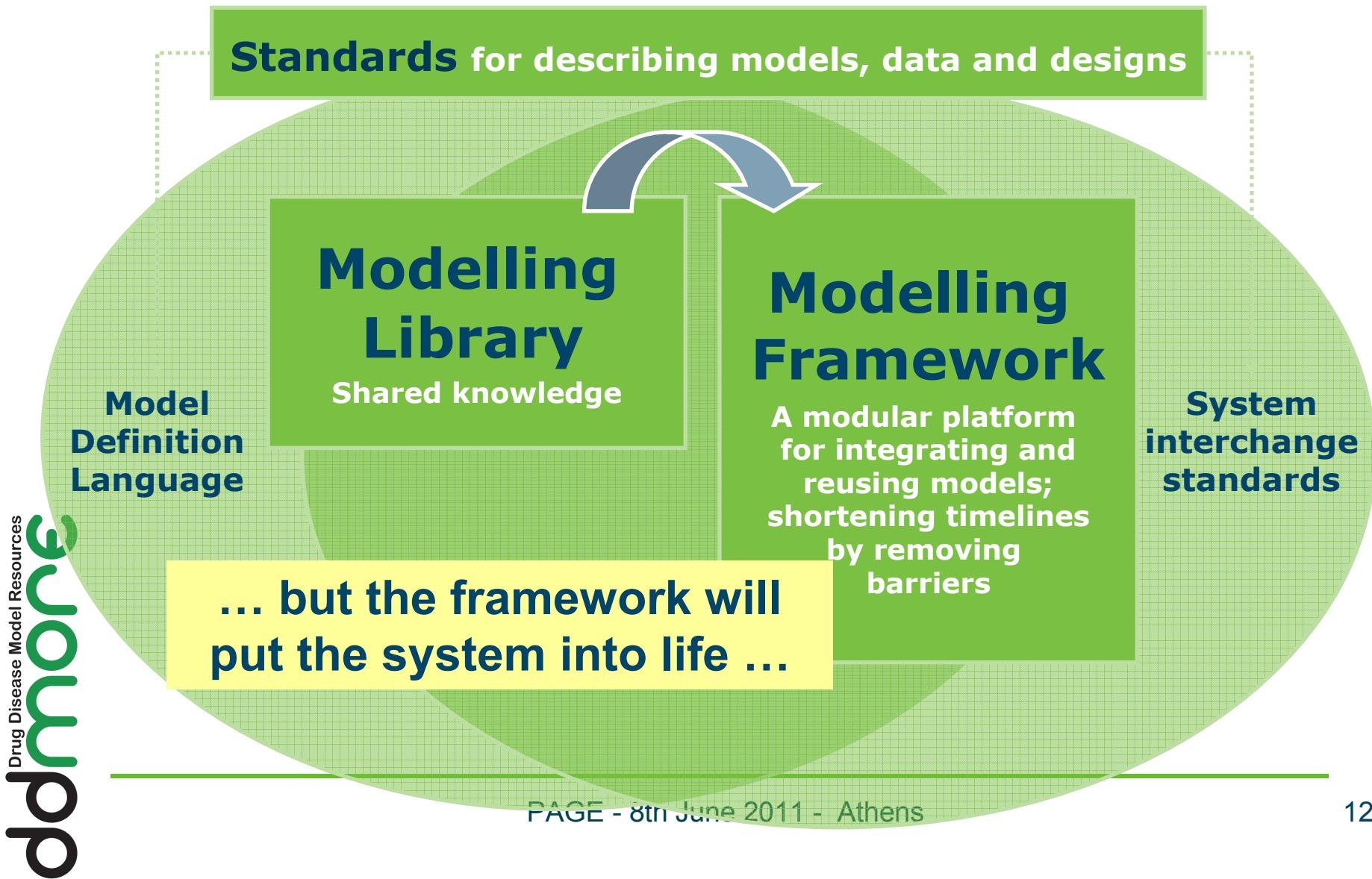
DDMoRe – The Vision

Major deliverables



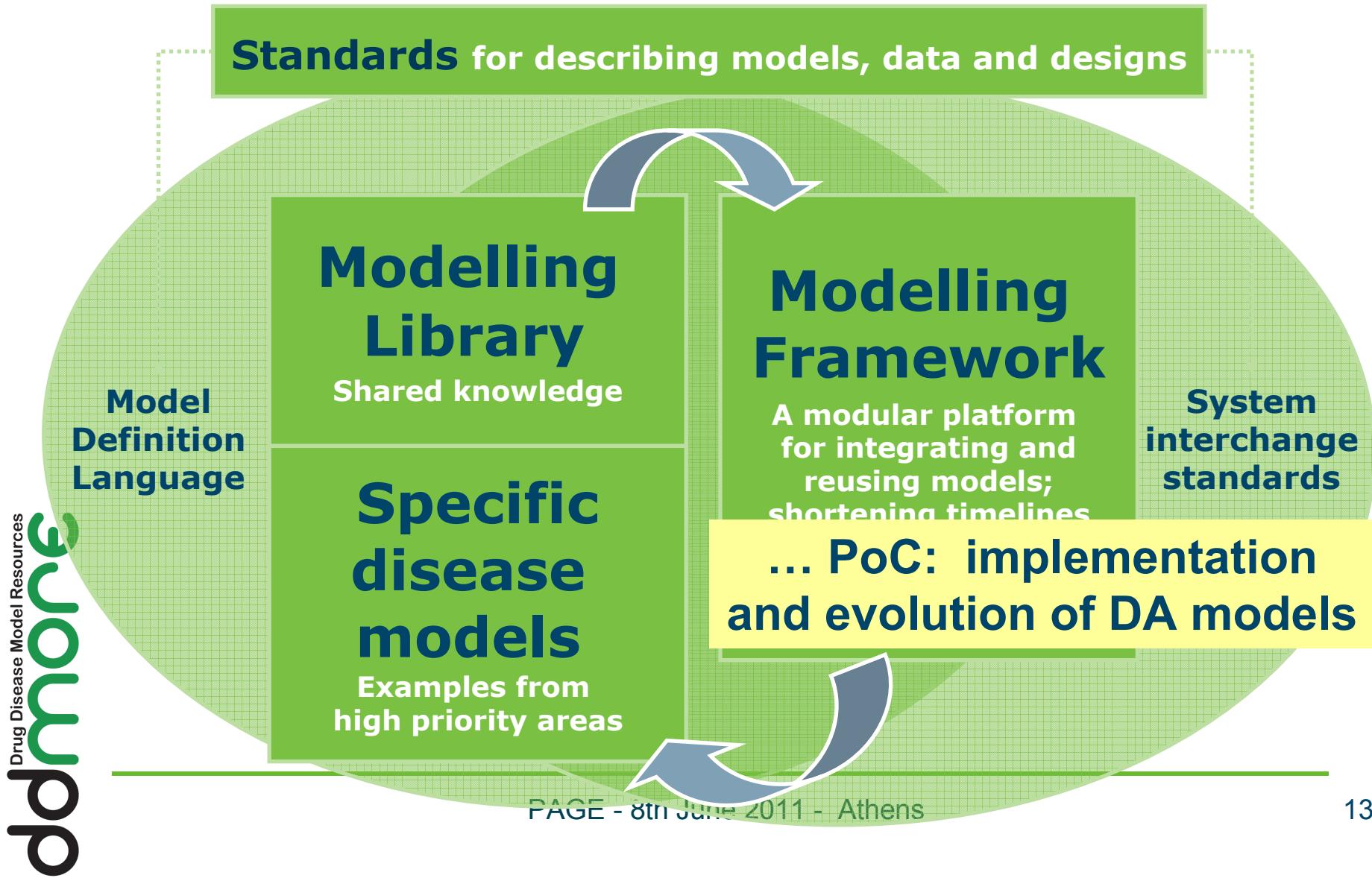
DDMoRe – The Vision

Major deliverables



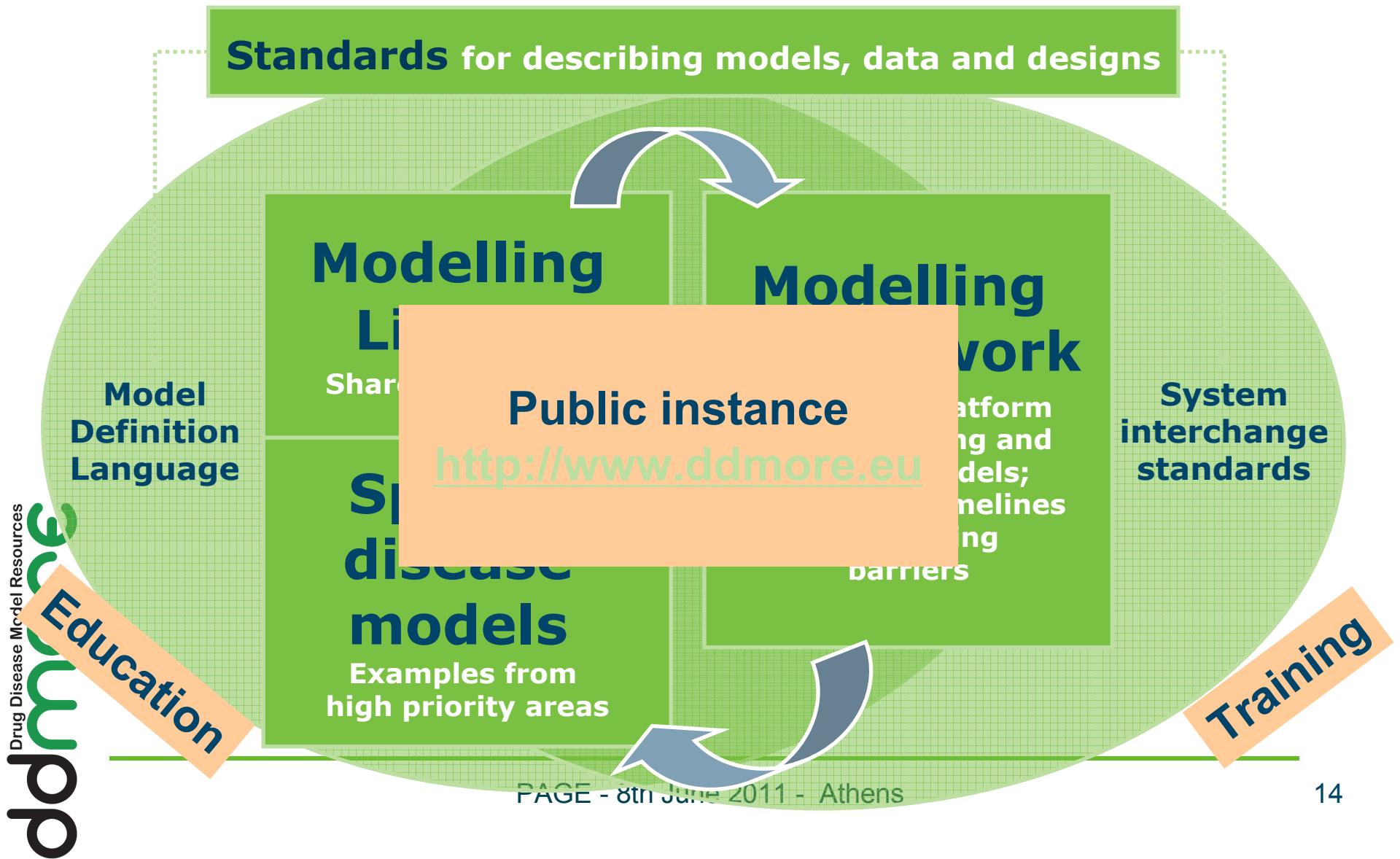
DDMoRe – The Vision

Major deliverables

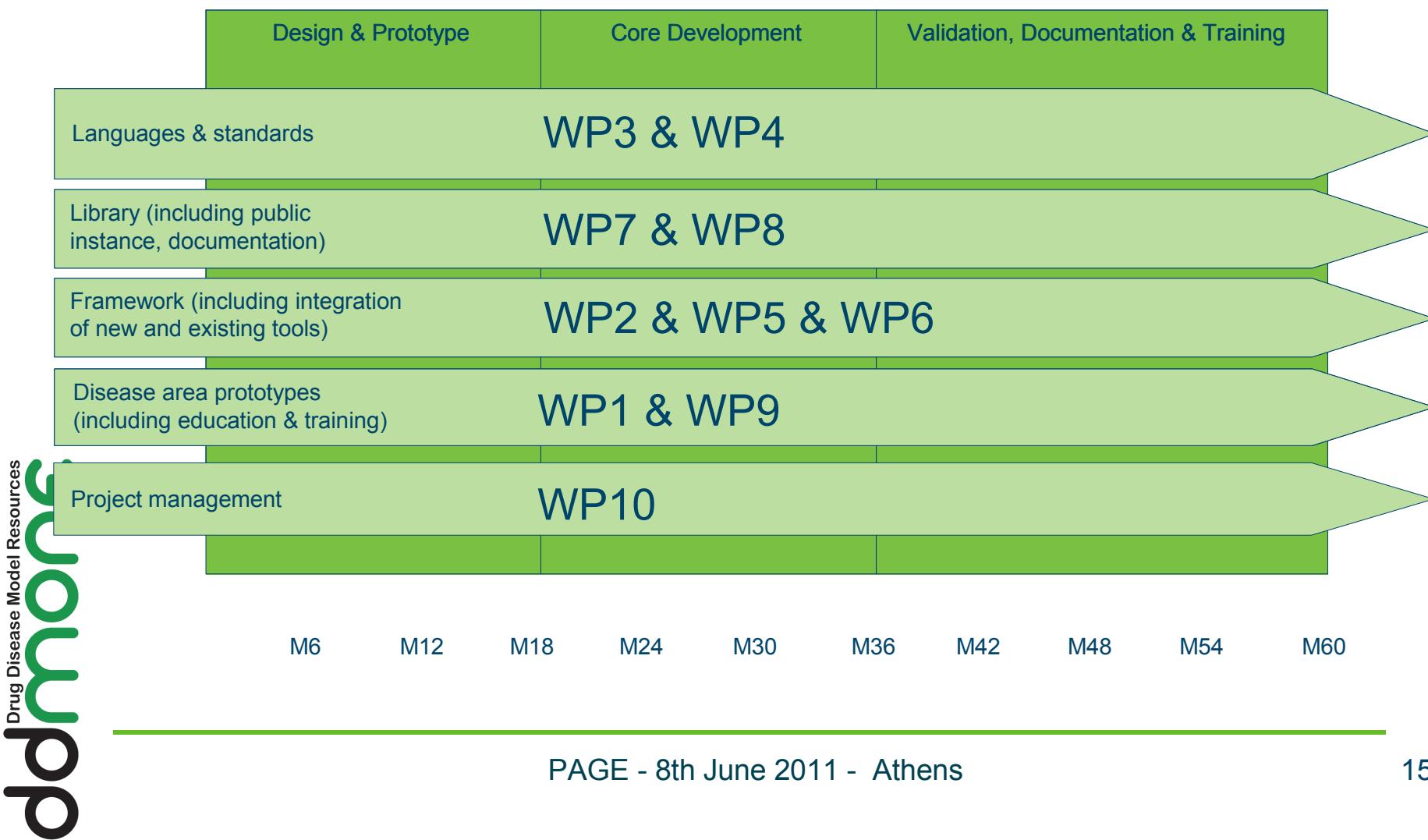


DDMoRe – The Vision

Major deliverables



The project is split into 10 work packages, covering all project activities



WP-leads

WP	Lead	Co-Lead
1 Disease Area Prototypes	Inaki Troconiz (UNAV)	Roeline Jochemsen (Servier)
1a Diabetes	Andrea Mari (CNR-ISIB)	Norman Mazor (Roche)
1b Oncology	Benjamin Ribba (INRIA)	Dinesh deAlwis (LLY)
1c Other DAs	Paolo Magni (UNIPV)	Miren Zamacona (UCB)
2 Framework	Bernard de Bono (EMBL-EBI)	Martin Spendiff (Novartis)
3 Model Description Language (MDL)	Nick Holford (UU)	Mike K Smith (Pfizer)
4 Model Markup Language (MML)	Nicolas Le Novere (EMBL-EBI)	Niels Rode Kristensen (NOVO)
5 Existing Software	Jim Ditchburn (Mango)	Hugo Maass (GSK)
6 New Software	Marc Lavielle (INRIA)	Joachim Grevel (AZ)
7 Infrastructure & Public instance	Andrew Hooker (UU)	Pascal Girard (ME)
8 Documentation	Wendy Aartsen (UL)	Alain Munafò (ME) - rotation
9 Education&Training	Charlotte Kloft (FUB)	Oscar della Pasqua (GSK)
10 PM	Lutz Harnisch (Pfizer)	Mats Karlsson (UU)

DDMoRe: Overall Benefits

- Improving the **environment** for modelling and simulation (M&S) activities related to **model based drug discovery and development** in a way that promotes **retention and sharing of knowledge** among all stakeholders (industry, academia, regulatory)
- Creation of a **common ontology** with the ability to describe all the components of pharmacometric and mechanistic (biologically-based) modelling - including data, models, code, metadata, analysis results and inferences
- Development of a **public and freely available library** for pharmacometric, statistical and systems biology models, and a software interoperability **framework** to enable efficient sharing of information (data and models), as well as current and future methods and applications in this area
- unique endeavour, collaboration between **24 partners** from industry and academia in pursuit of common goals

Further information

Project Coordinator:

Dr. Lutz Harnisch
Senior Director, Pharmacometrics
Pfizer Ltd, UK
Email: Lutz.O.Harnisch@pfizer.com

Managing entity of IMI beneficiaries:

Prof. Dr. Mats Karlsson
Professor of Pharmacometrics
Uppsala University, Sweden
Email: Mats.Karlsson@farmbio.uu.se

Project website:

<http://www.ddmore.eu>

www.imi.europa.eu