Barbara Haake, vfa

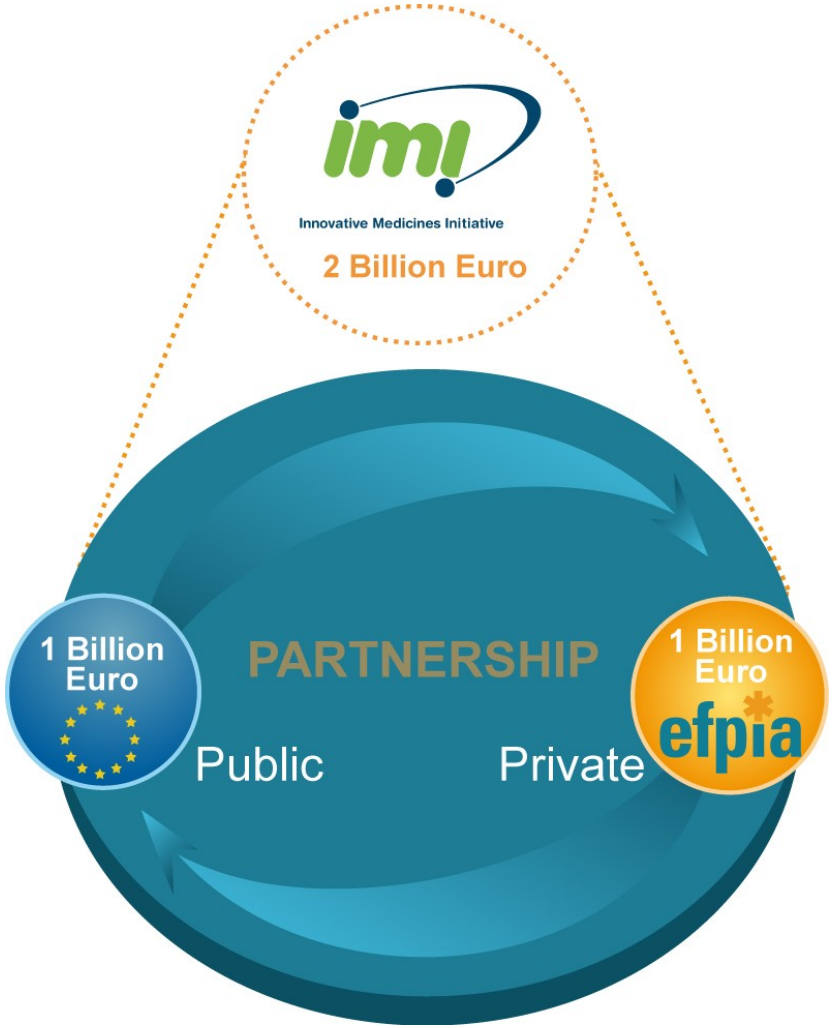
German Association of Research-Based Pharmaceutical Companies

industry-coordinator of EUPATI

V Conference of Technology Platforms in Biomedical Research
14.- February 2012

The EUPATI project receives support from the IMI JU

IMI: Vision



- **New model** for Public Private Partnership in Life Science
- Focus on
  Efficacy in 5 Disease Areas,
  Safety,
  Knowledge Management and Education & Training

IMI: Were we are today

- 1st Call launched April 30, 2008.
  Projects started from mid 2009 - early 2010 (15 projects).
  Total Project Budget 280 Mio €.
- 2nd Call launched November 27, 2009.
  8 projects launched in Feb/March 2011
  Total Project Budget 180 Mio €.
- 3rd Call launched October 20, 2010
  Projects are currently put together (7 projects).
  "**Fostering Patient Awareness On Pharmaceutical Innovation**"
  ➡ **EUPATI**
  Total estimated Project Budget in the range of 140 - 200 Mio €.
- 4th Call launched July 18 2011
  7 potential projects
- 5th Call and future Calls (2012 – 2013).

Unmet need of patient and public on information on therapeutic innovation

- **Drug development:** a highly regulated, costly, long and complex process, largely unknown to the public

- **Patients and patient advocates**
  - **seek up-to-date, correct, understandable and credible information** about innovation in treatments
  - are largely unaware about clinical trials, translational research, personalized medicine, pharmacoeconomics - **and their potential supportive roles in those areas**
  - **lack the education and training** required to participate as a partner in drug research and development (R&D) - from participation in clinical trials to advising on protocol design, informed consent and ethical review process, marketing authorization, value assessment and healthcare policy

- FP7-funded PatientPartner project demonstrated a **clear need and willingness of patient advocates to contribute** to pharmaceutical R&D

What is the European Patients Academy on Therapeutic Innovation?

The European Patients' Academy on Therapeutic Innovation is:

- **initiated and led by key European Patient Advocacy organisations**
- the key European initiative to develop and provide **objective, credible, correct and up-to-date public knowledge** about medical research
- a paradigm shift in **empowering patients and the public to understand medical research** and how to contribute to it
- a **strong multi-stakeholder consortium** of patient organisations, academia, NGOs and industry

EUPATI: European Patients' Academy on Therapeutic Innovation

- **develop and disseminate** accessible, well-structured and user-friendly information and education resources on therapeutic innovation
- **build competencies** among well informed patients and the public about pharmaceutical R&D
- **build expert capacity** in patient advocates
- **create the leading public library** on patient information in six most common languages
- **establish a widely used, sustainable infrastructure** for objective, credible, correct and up-to-date knowledge
- **facilitate patient involvement in R&D** to support industry, academia, authorities and ethics committees

EUPATI: Outreach to advocacy leaders and public at large

Topics addressed by EUPATI

Implementation by WP4 task forces

Needs Assessment	Content Sourcing	Content Development	Quality Control	Quality Assurance/ Validation	Delivery / Deployment

TF1: Medicines development process from research to approval

TF2: Personalized and predictive medicine.

TF 3: Drug safety and risk/benefit assessment of medicines

TF 4: Pharmaco-economics and health technology assessment.

TF 5: Design and objectives of clinical trials (& involved stakeholders)

TF 6: Patients roles & responsibilities in innovative medicines development

EUPATI – led by 4 key pan-European patient associations with broad outreach

- **European Patients Forum**
  - EUPATI Project coordination
  - 50 umbrella patient organisations. Through 'members of members', potential outreach to 150 million patients
- **European Genetic Alliance Network**
  - Linked with national and regional patient alliances in Germany, Eastern Europe, Italy, Netherlands, United Kingdom and Ireland, Sweden, Spain, Italy, Greece and Balkan countries
- **EURORDIS – Rare Diseases Europe**
  - Representing 479 rare disease organisations in 45 different countries (25 EU countries)
- **European AIDS Treatment Group**
  - More than 100 members in over 30 countries.

Academic & research excellence in the consortium

- **Strong academic impetus from key academic partners**, e.g. Universities of Manchester and Copenhagen, with unique expertise in core aspects of the project
- Some organisations of consortium have an **academic or science arm**, or are effectively 'academic networks' themselves.
- **Project staff** of consortium, both public and private partners, have strong research or academic track record

- **Project Advisory Board** includes some of the most renowned and well respected academics in the field in Europe
- **EUPATI Network** will gather a wide range of academic expertise to feed into the project and provide a vibrant intellectual and challenging platform

Industry partners contributing to EUPATI

EUPATI
European Patients Academy on Therapeutic Innovation

Partners

efpia

vfa. · farmaindustria · NOVARTIS · AMGEN · genzyme A SANOFI COMPANY · AstraZeneca · gsk · novo nordisk · BAYER · janssen · Roche · Boehringer Ingelheim · Lilly · sanofi · Chiesi · MERCK · ESTEVE

Contribution

- In line with the IMI philosophy most major pharmaceutical companies (15) and two national pharma associations from major EU countries participating
- Contributing with expertise e.g. in modern R&D and IT, communication/dissemination and with cash contribution to fund logistics of the project
- Independence and governance will be closely monitored by EUPATI's advisory boards

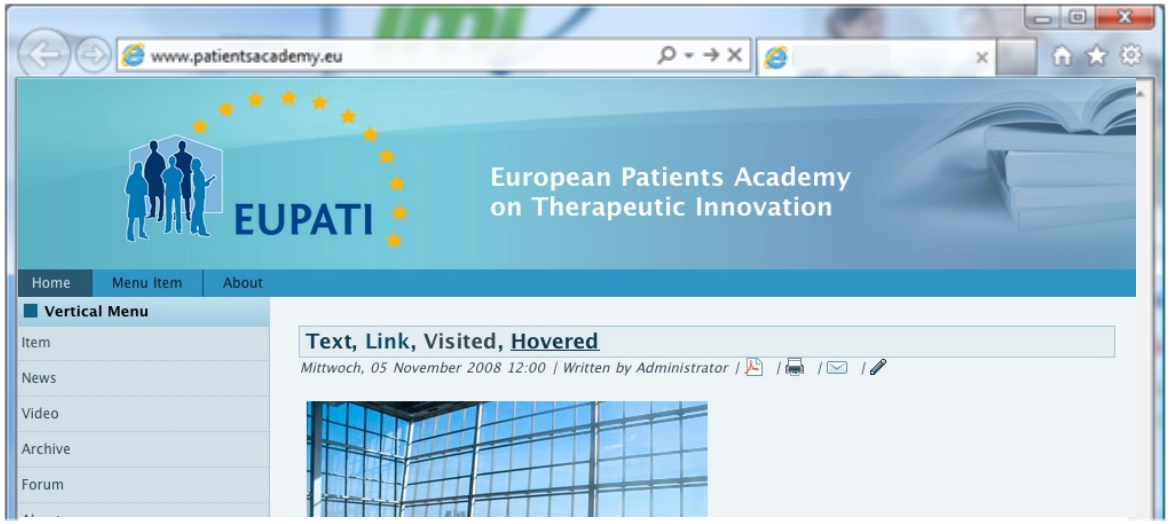
Uniqueness of the partnership

- **Unique and unprecedented partnership** between patient organisations, other public partners and pharmaceutical industry based on the philosophy of the IMI
  - **Unique in IMI** that EUPATI is patient- and not industry-led
  - Opportunity to establish an **effective, transparent and credible partnership**
  - **Exceptional learning experience** for industry representatives to work with patient organisations in a constructive and reflective manner, which could serve as a role model in other environments as well
  - **Making best use of industry expertise** in medicines R&D, incl. e.g. the legislative environment and development of ITP as required by law
- **Opportunity to strengthen the voice of the patients** in the search for innovation and new medicines
- **Chance to reduce fear, lack of trust and misconception** among patients regarding the pharmaceutical industry

Mechanisms to ensure independence and credibility of EUPATI

- **Quality control** in task forces and by experts. Materials will be tested/validated prior to dissemination
- **EUPATI Regulatory Advisory Panel** involving 4 regulatory bodies EMA, BfArM, Swissmedic, MHRA.
  - ensures objectivity, transparency, impartiality and independence of EUPATI's content
  - supervises adherence to the **'Core Quality Principles of information to patients on diseases and treatment options'** (Pharmaceutical Forum)
  - Provides guidance and advice to the project teams
- **EUPATI Project Advisory Board** with leading independent experts from different areas, including Cochrane
- **EUPATI Ethics Panel** with genuine ethics expertise,
- **Effective Codes of Practices in place**
  - **EUPATI Code of Practice**
  - **EUPATI Ethical Framework**
  - **EFPIA 'Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations'**
  - '

More Information on www.patientsacademy.eu



Web:

www.patientsacademy.eu

Twitter:

@eupatients

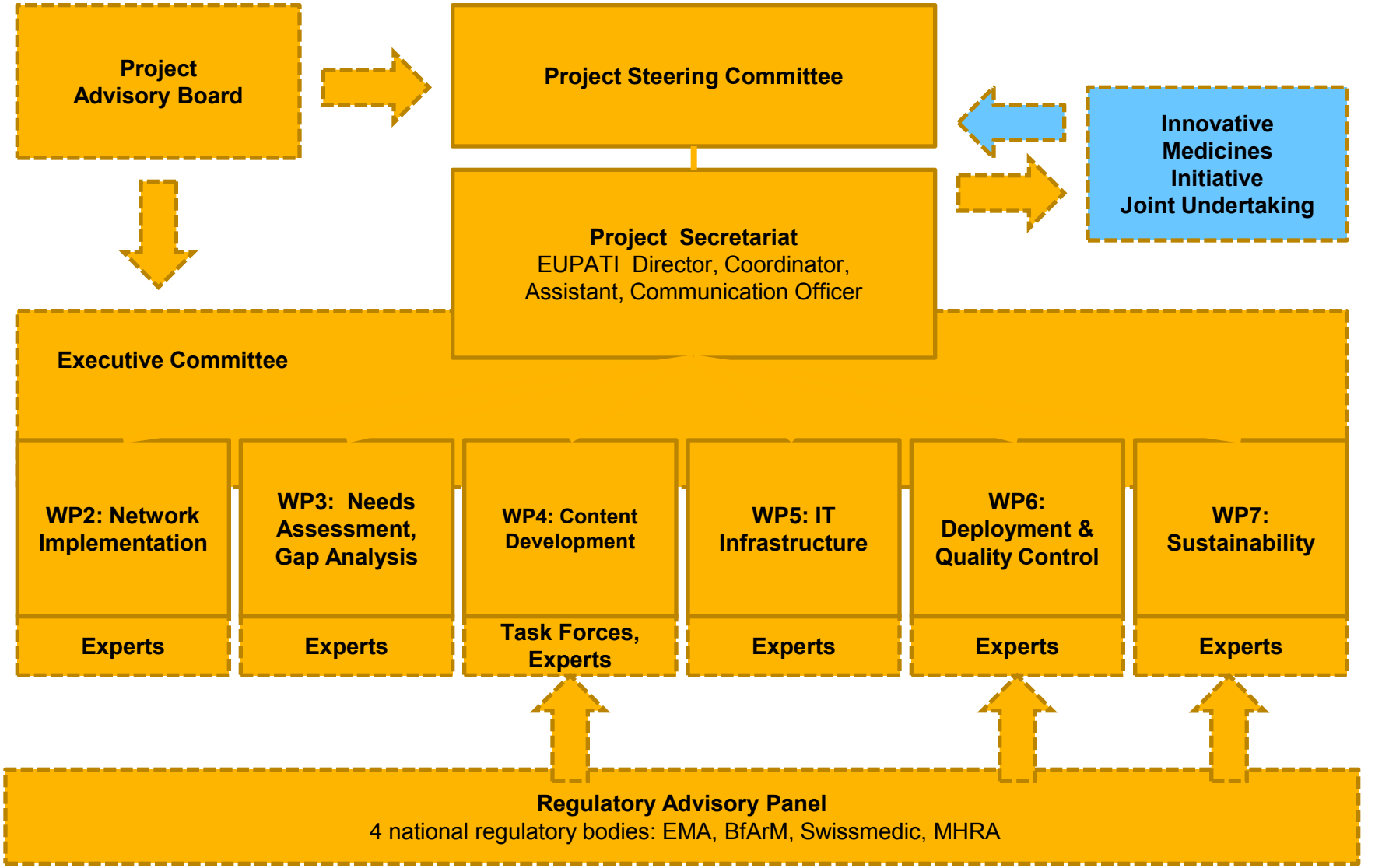
Thank you!

europeanpatients'forum
EORTC European Organisation for Research and Treatment of Cancer
vfa.
farmaindustria
novo nordisk
IPPOSI Irish Platform for Patients' Organisations, Science and Industry
AMGEN
genzyme A SANOFI COMPANY
EGAN Patients Network for Medical Research and Health
AstraZeneca
gsk
Roche
DIA Drug Information Association
sanofi
EURORDIS Rare Diseases Europe
BAYER
janssen
nowgen A Centre for Genetics in Healthcare
Lilly
HIBERNIA COLLEGE
Boehringer Ingelheim
MERCK
EATG EUROPEAN AIDS TREATMENT GROUP
Chiesi
ISPOR International Society for Pharmacoeconomics and Outcomes Research
NOVARTIS
EF GCP
ESTEVE
UNIVERSITY OF COPENHAGEN
BIO PEOPLE

http://www.patientsacademy.eu

backup slides

Governance structure



Work Packages and Work Plan

	Preparation Phase M1-18	Confirmation Phase M19-48	Sustain Phase M49-60
WP1 Coordination	Project management tools, communication tools, financial manual	Work plans, Project management, Communication activities, evaluation, reporting, IMI Interface	
WP2 Network Implem.	Establishment of the EUPATI Network	Annual Conferences, Network meetings, Regional Workshops, networking activities, Development of Ambassador Programme and National EUPATI Platforms	
WP3 Needs Assessment & Gap An.	Needs & gap analysis, Review of existing education material, focus groups	Quantitative survey, Peer review publication	
WP4 Content Dev.	Strategy development, e.g Syllabus for course+toolbox	Course teaching methodology and content development, development and production of material for Toolbox and IT Platform, translation work	Extension, refinement, quality control
WP5 IT Infrastr.	Design, Development and support of technical infrastructure, technical framework for EUPATI IT PIlatform and eLearning		
WP6 Deploy-ment & Quality Assurance		First course performed	EUPATI IT Platform launch Deployment dissemination & evaluation,, Events and trainings
WP7 Sustainability	Research on Patient Partnership models	Best practice guideline dev., Recommendation of new teaching methods Development of code of conduct for patient involvement	Sustainability concept dev. New technologies and future remit strategy

EUPATI in 2012-2016: What we will have achieved

- EUPATI platform fully loaded with training, education, information material in multiple languages
- EUPATI Patient Ambassador, Patient Journalist, Train-the-Trainer Programme in place
- Good practice guideline for patient involvement released
- Annual Conferences and at least 5 Regional Workshops performed. Expert network established.

Beyond EUPATI: Creating sustainable impact beyond 2016

EUPATI will develop:

- **New and innovative concepts** that will ensure more active involvement of patient experts in pharma R&D, HTA
- **Guidelines for interaction** between stakeholders, ethical principles and best practice procedures.
- **Best practice guidelines** for patient involvement in research and drug development from trial design to study implementation, safety monitoring, approval, access, reimbursement, pharmacovigilance and benefit/risk assessment.
- **Road map for future collaboration** with highly innovative sectors of industry, including and beyond the pharmaceutical industry, and Health Authorities

Supported by leading advisors, strengthening independence, governance

EUPATI
European Patients Academy on Therapeutic Innovation

Project Advisory Board

- **Prof. Jean-Jacques Cassiman,** Head of the Centre for Human Genetics, Catholic University of Leuven, Belgium
- **Dr. Vincenzo Costigliola,** President, European Medical Association, Brussels, Belgium
- **Dr Karen Facey,** HTAi Interest Group for Patient/Citizen Involvement, UK
- **Prof. Jozef Glasa,** Professor of Clinical Pharmacology & Therapeutics, Hepatology and Medical Ethics/Bioethics at the Slovak Medical University in Bratislava, Slovakia
- **Prof. Panos Kanavos**, Senior Lecturer in International Health Policy at London School of Economics, London UK
- **Dr. Klaus Koch**, Institut für Qualitat und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), Germany
- **Prof. Finn Børlum Kristensen**, Director of Coordinating Secretariat and Chairman of Exec Committee, EUnetHTA
- **Britta Lang ,** German Cochrane Centre, Germany
- **Peter O'Donnell**, Associate Editor, European Voice, Brussels, Belgium
- **Kathy Oliver,** Patient advocate, Director of the International Brain Tumour Alliance (IBTA),UK
- **Prof. Munir Pirmohammed,** Department of Health, Chair of Pharmacogenetics, University of Liverpool, UK
- **Ysbrand Poortman,** Patient advocate, Vice President of the WAO, The Hague, and Secretary General IGA, Washington
- **Anke Steckelberg**, EBM Expert, University of Hamburg, DE
- **Victoria Thomas,** Head of Patient and Public Involvement Programme, National Institute for Health and Clinical Excellence, UK

Regulatory Advisory Panel

- **BfArM** - Birka Lehmann, Dir. and Prof, Alternate: Dr. Anne-Isabel Roth, Clin. Assessor
- **EMA** - Isabelle Moulon, Head of Medical Information Sector
- **MHRA** - Prof. Sir Alasdair Breckenridge, Chairman of the Board. Alternates: Dr. June Raine, Director of Vigilance Risk Management of Medicines (VRMM); Jeremy Mean, Access and Information for Medicines and Standards Group Manager
- **Swissmedic** - Dr. Petra Dorr, Head of Management Services and Networking, Member of the Management Board, Alternate: Cordula Landgraf, Head of Networking