



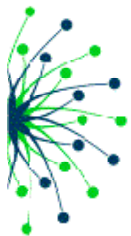
Innovative Medicines Initiative

# Testimonial from an industry partner

Ina Schuppe Koistinen, PhD

Senior Principal Scientist  
Molecular Toxicology/Safety Assessment  
AstraZeneca R&D Södertälje  
Sweden

Scientific Coordinator  
SAFE-T



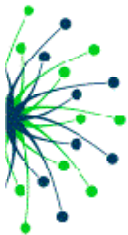
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Open Information Day - 17 November 2010 - Brussels Expo

# AstraZeneca at a glance



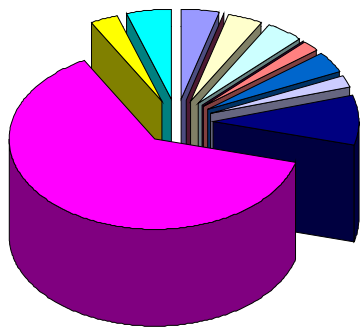
- **Pure play pharmaceuticals business**
  - Cardiovascular/Metabolism & Gastrointestinal
  - Neuroscience
  - Respiratory and Inflammation
  - Oncology and Infection
  - Small Molecules and Biologicals
- Over 65,000 employees worldwide
- 12,000 people in R&D
- 26 manufacturing sites in 18 countries
- Extensive sales & marketing network dedicated to meeting our customers' needs in over 100 countries.
- Sales 2008: 36.1 billion USD
- R&D spend 2008: over 5 billion USD



# Why drugs fail in development and how these vary by phase?

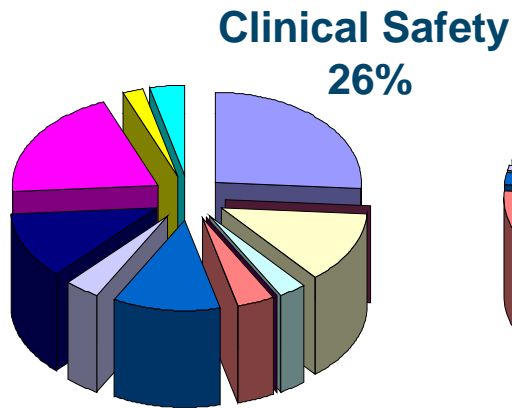


## Preclinical



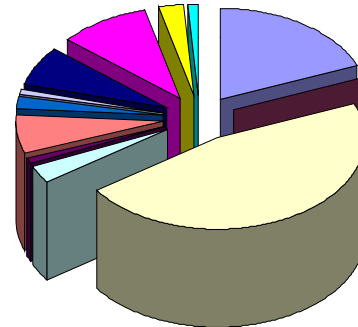
Toxicology  
62%

## Phase I



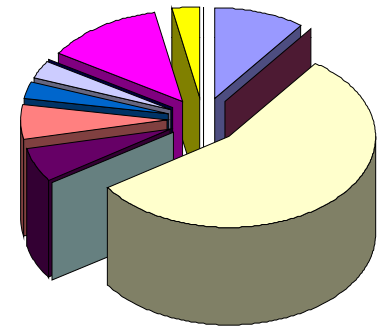
Clinical Safety  
26%

## Phase II



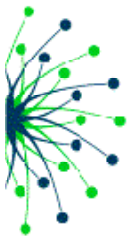
Efficacy  
47%

## Phase III



Efficacy  
55%

Problem to be solved at EU level: Only 1 of 10 CDs may become a product



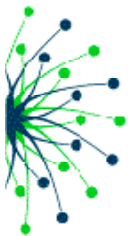
# SAFE-T

(Safer and faster evidence-based translation)

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- 3 target organs critical for drug-induced injury with non-appropriate clinical monitoring :
  - **Kidney:** Current standards (Serum Creatinine, BUN) are only increased when 50-60% of the kidney function is lost.
  - **Liver:** Current standards (AST, ALT, Bilirubin) are not specific and do not predict who will recover and who will develop fulminant liver disease.
  - **Vascular System:** There are currently no biomarkers to monitor drug-induced vascular injury in human.
- Goal:
  - To qualify translational safety biomarkers for monitoring DIKI, DILI and DIVI **in humans.**

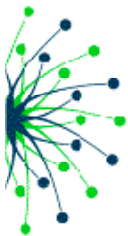


# SAFE-T: Partners

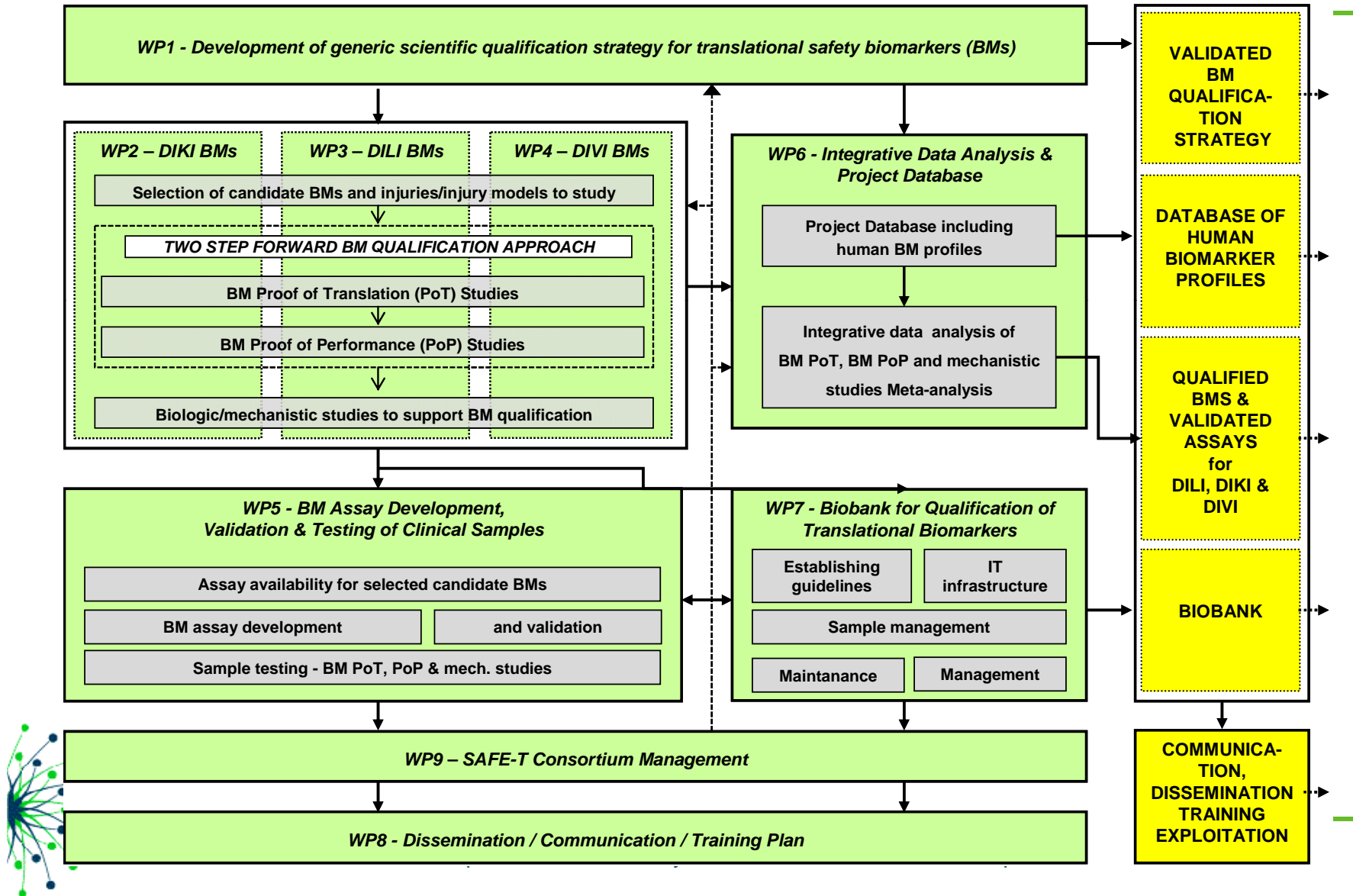
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- **EFPIA (11):**
  - **Novartis (Coordinator of the SAFE-T consortium)**
  - Almirall
  - Amgen
  - Pfizer
  - Hoffmann La Roche
  - AstraZeneca
  - Bayer Schering Pharma AG
  - Boehringer Ingelheim
  - Eli Lilly
  - GlaxoSmithKline
  - Sanofi Aventis
- **External Advisors :**
  - European Medicines Agency
  - FDA (proposed)
- **Academic (5):**
  - Barcelona Cardiovascular Research Center
  - Charité Hospital
  - Groupe d'Etudes et de Recherches en Médecine Interne et Maladies Infectieuses - APHP
  - Groupe Hospitalier Pitié Salpêtrière - APHP
  - Natural and Medical Sciences Institute
  - Tel-Aviv (Souraski) Medical Center
- **SMEs (4):**
  - **Firalis SAS (Coordinator of the Initial Applicant SAFE-T consortium)**
  - Argutus Medical Limited
  - Experimental & Diagnostic Immunology GmbH
  - Interface Europe



# SAFE-T: Project Overview

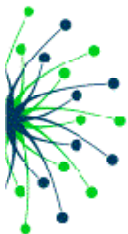


# SAFE-T: Facts and Status

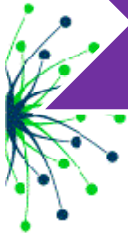
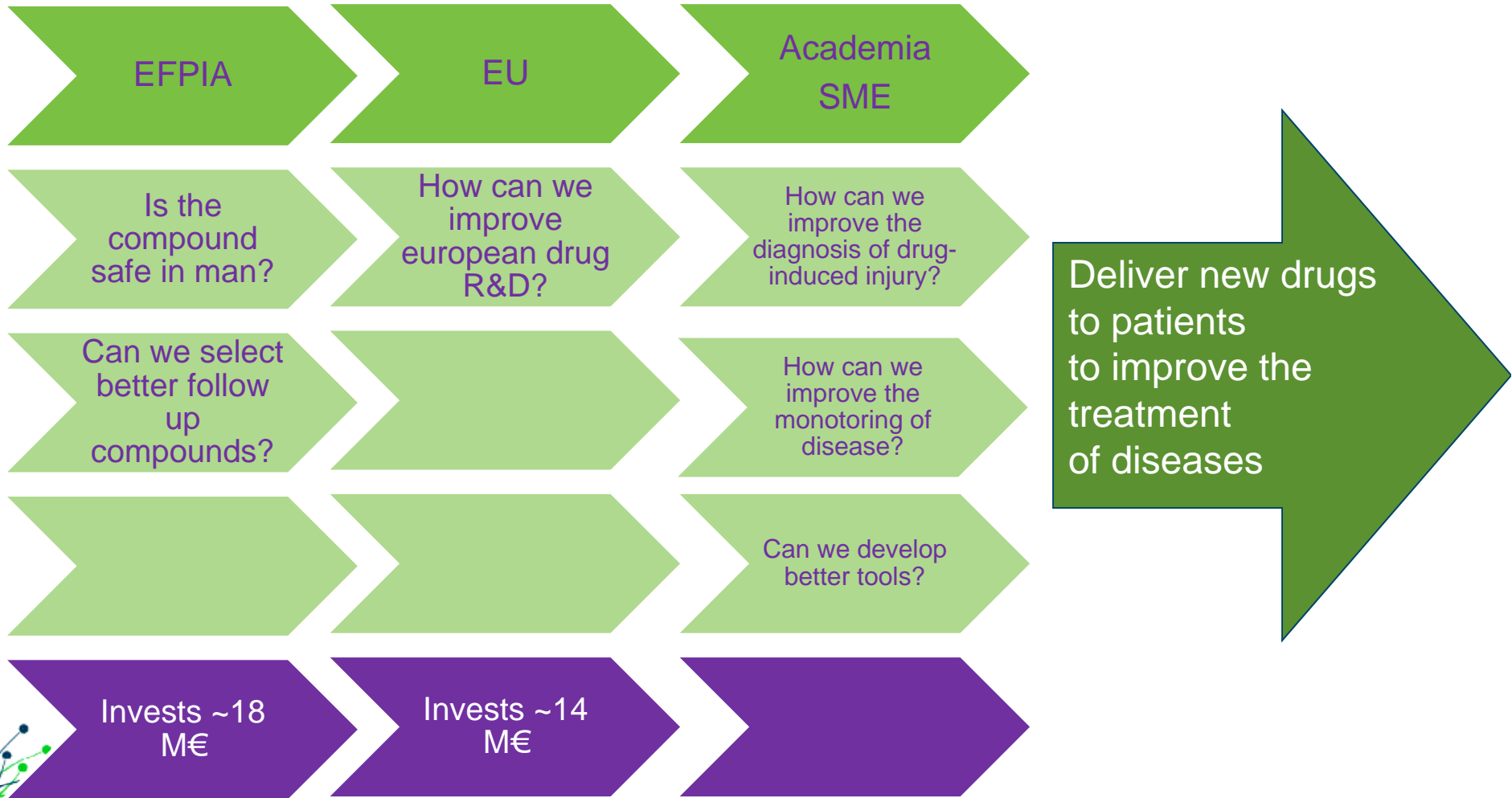
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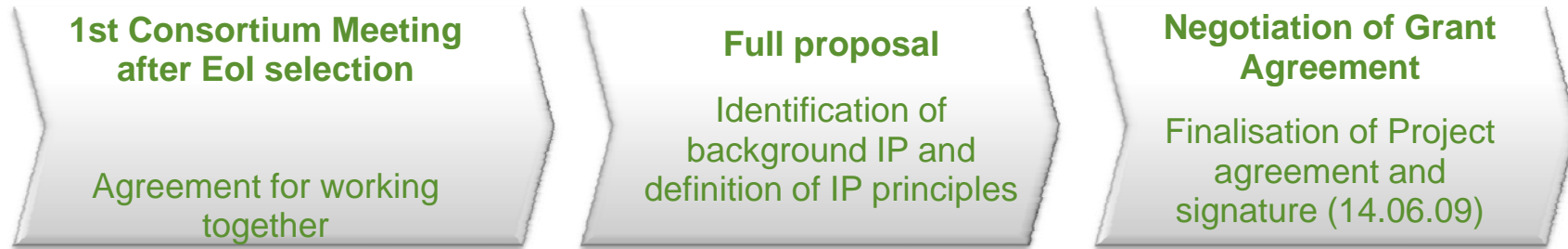
- Duration: **5 years, 35.8 Mio €** research budget
- Kick off meeting June 15, 2009 – first IMI project that started
- Governance structure
  - Steering Committee (Project coordinator Frank Dieterle, Novartis)
  - Scientific Advisory Committee (Scientific coordinator Ina Schuppe Koistinen, AZ)
  - Work package leaders, task leaders
  - Ethical Committee, IP Committee
- Project work ongoing according to plan, first deliverables
  - Scientific biomarker qualification strategy
  - Prioritised list of DILI/DILI/DIVI biomarkers for qualification
  - Clinical study templates/plans



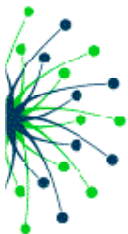
# SAFE-T: Common Goal



# SAFE-T: management of IP



- A need for good communication between partners:
  - Identify the various interest
  - Define who brings what?
- SAFE-T: definition of a specific IP regime
  - Biomarker IP
  - Technology IP
- The preparation of the Project agreement need to be supported by a neutral body to ensure that all interests are met.
  - SAFE-T Project Agreement prepared and agreed in 4 months

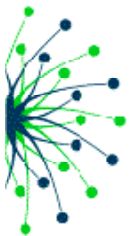


# Some words of advise

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- Study the Call text carefully
  - All components need to be addressed in the consortium
- Different from FP7:
  - Project coordination typically by EFPIA representative
  - Application + consortium formation process
  - The primary goal is not performing cutting edge research for the purpose of research but to achieve the stated objectives
- Include an appropriate number of partners
- Do not under-estimate the time required for preparation of the EOI
- Communication, communication, communication

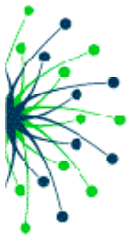


# Personal Reflections

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- **Focus on science**
  - Interaction with Pharma as scientists sharing the same vision
  - Possible to reach broad scientific consensus on new safety biomarkers
- **Focus on the common goal**
  - New medicines for the treatment of diseases
  - Improved understanding of the molecular mechanisms of drug-induced injuries
- **Recognise the power of the IMI-JU**
  - Unique opportunity to work across disciplines
  - Large project budget
  - Cross-fertilisation EFPIA, Academia/SME and EMEA



# The Scientific Challenge is to qualify translational safety biomarkers

