EATRIS

The one-stop-shop to Europe’s high end academic infrastructure
VPM days, Sep 17 - 18 2015

EATRIS positioning

Vision

Making translation of scientific discoveries into medical products more effective to improve human health and quality of life.

Mission

To support researchers in developing their biomedical discoveries for novel preventive, diagnostic or therapeutic products up to clinical proof of concept.

Supporting academia, biotech, pharma & funders

Jan 2014 - EATRIS ERIC

European Research Infrastructure Consortium

Born from Europ. Strategy Forum on Research Infrastructures (ESFRI)

- Legal form - directly applicable across EU
- Permanent, independent & non-commercial
- Long term commitment of member governments
- VAT exempt

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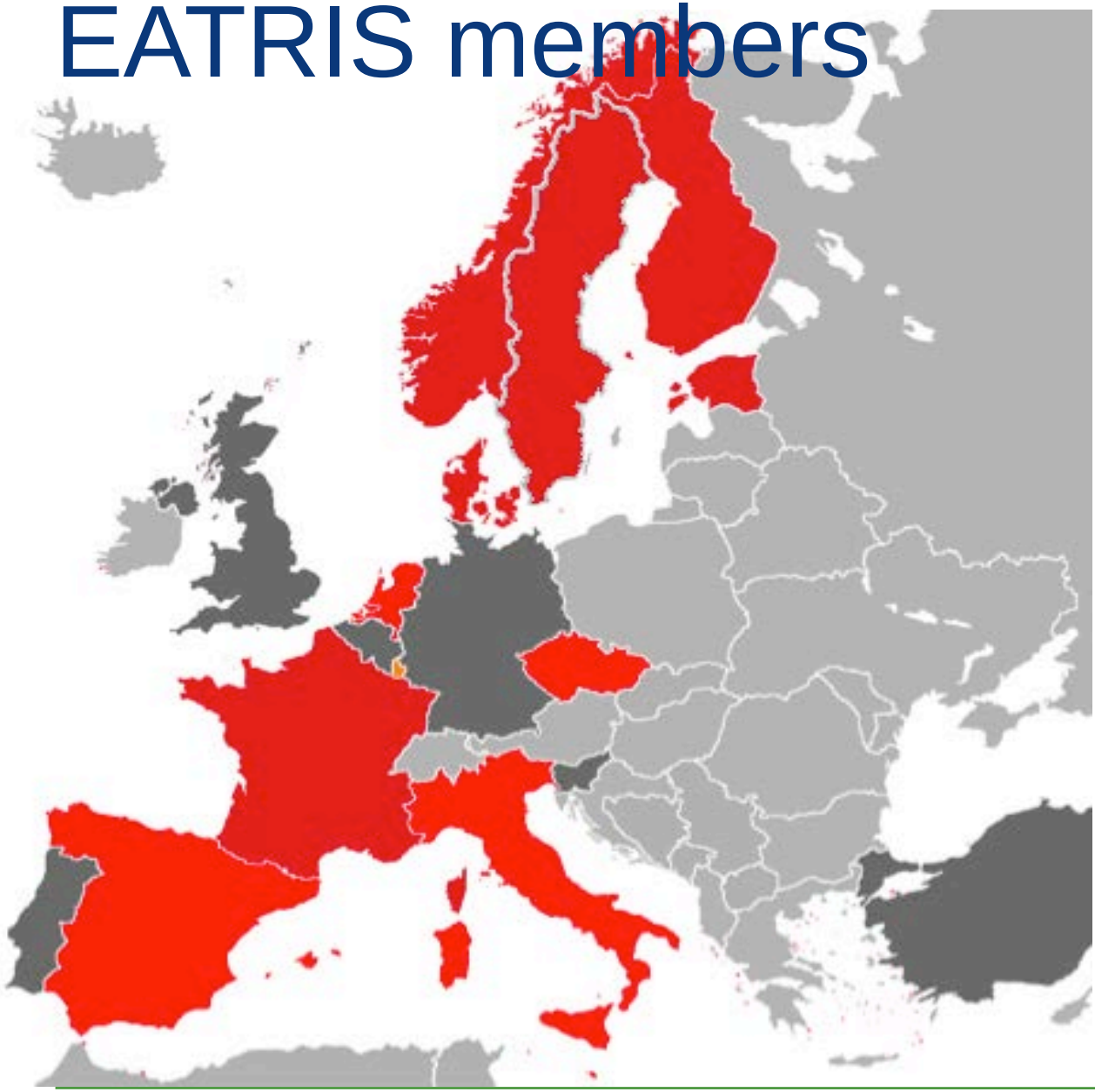
EATRIS members



Participating countries : CZ, DK, ES, FI, FR, IT, NO, EE, SE, NL (Host)

Negotiations ongoing with: BE, CRO, DE, LUX, PT, SI, TR, UK

The Infrastructure: 75+ Academic & non-profit research institutions of excellence in translational medicine

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EATRIS Infrastructure

Composed of academic & non-profit research institutions

- Active in translational research
  - Track record in entering clinical development
  - Unique infrastructure, expertise and licenses
  - Access to broad array patient cohorts (also rare diseases)
  - Working at top quality level in harmonized manner
- Working together to create a complete translational pipeline
  - Via distributed infrastructure
  - Using hub-and-spoke model
  - Supported by C&S ‘hub’

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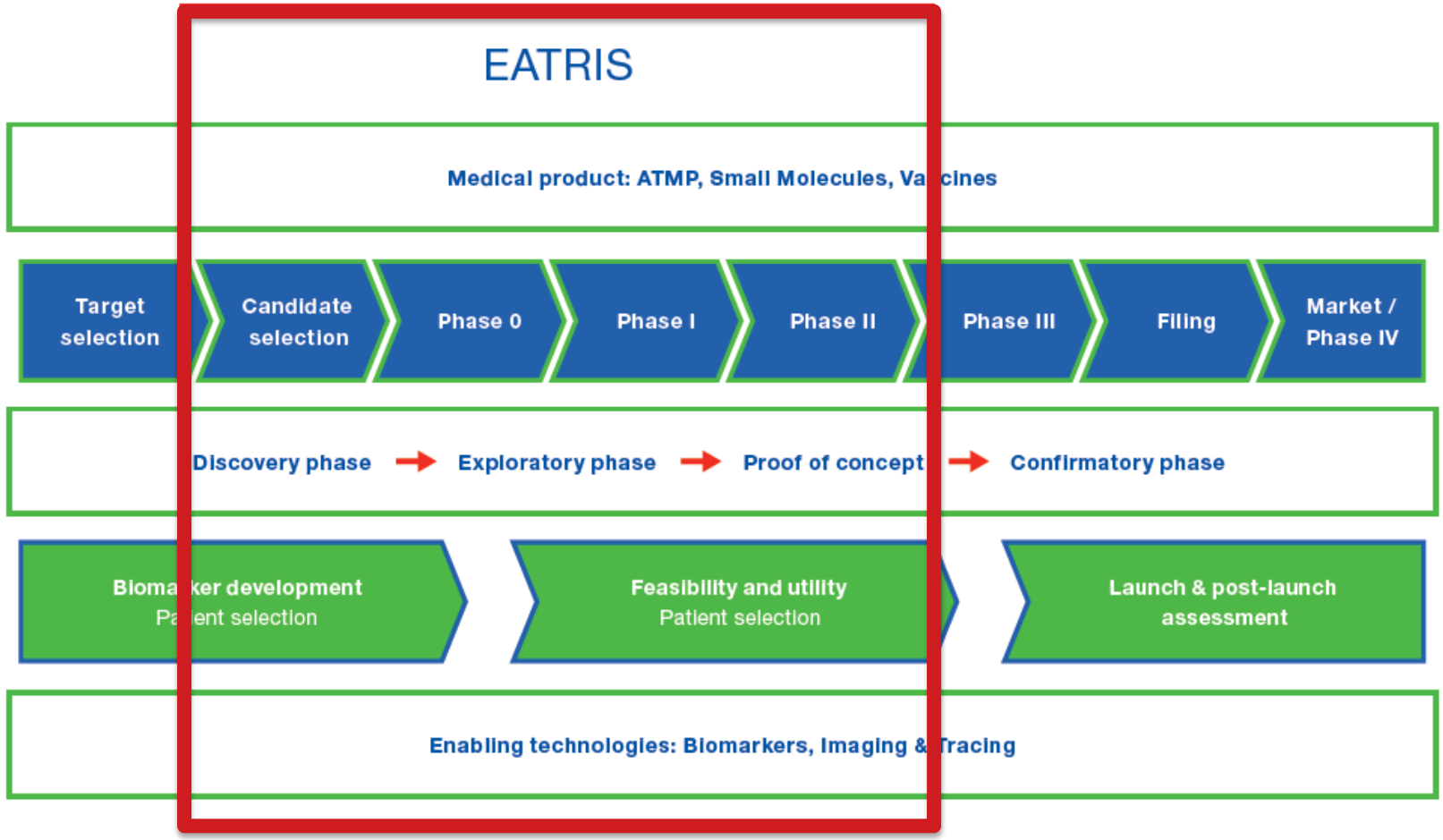
EATRIS scope of operations



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EATRIS offering: five product platforms

- Advanced Therapy Medicinal Products
  - Tissue engineering, Gene therapy, Cell therapy, GMP facilities, etc.
- Biomarkers
  - Biobank facilities, Multiplexed immunostaining, deep genome sequencing, etc
- Imaging and Tracing
  - Imaging-enabled drug development: (Pre-clinical) PET imaging, GMP tracer development and production, (Ultra) high field MRI, Optical and hybrid imaging, etc

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EATRIS offering: five product platforms

- Small molecules
  - Advanced screening (also for instance in 3D cultures), Development of xenograft and in vivo models, Drug (re-)formulation, (Pre-)clinical validation nanomedicines, etc

- Vaccines
  - Antigen characterisation, Vaccine formulation, Process development, etc

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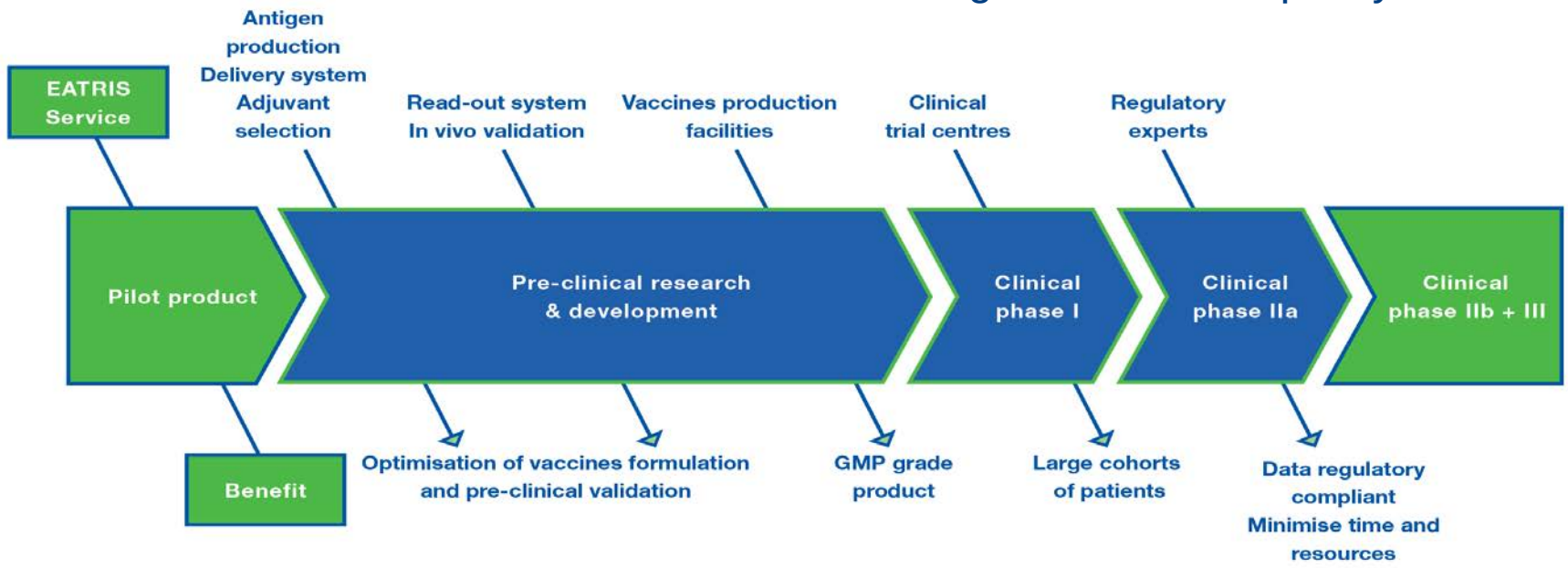
EATRIS-Vaccines Platform

Jan Langermans, BPRC

- 12 European high-end facilities
  - Antigen characterisation
  - Specialised GMP manufacturing facilities covering USP and DSP; Formulation & adjuvantation
  - Animal facilities up to BSL3
  - Animal models including non-human primates and GLP-toxicology
  - Immunomonitoring and clinical capacity



EATRIS – How do we work?

1) Provide fast and professional access to high end academic expertise and facilities; market the services

2) Develop long-term solutions to challenges in the translational field (develop the infrastructure)

- ✓ Through large-scale technical development projects
- ✓ By engaging policy-makers, funders, regulators

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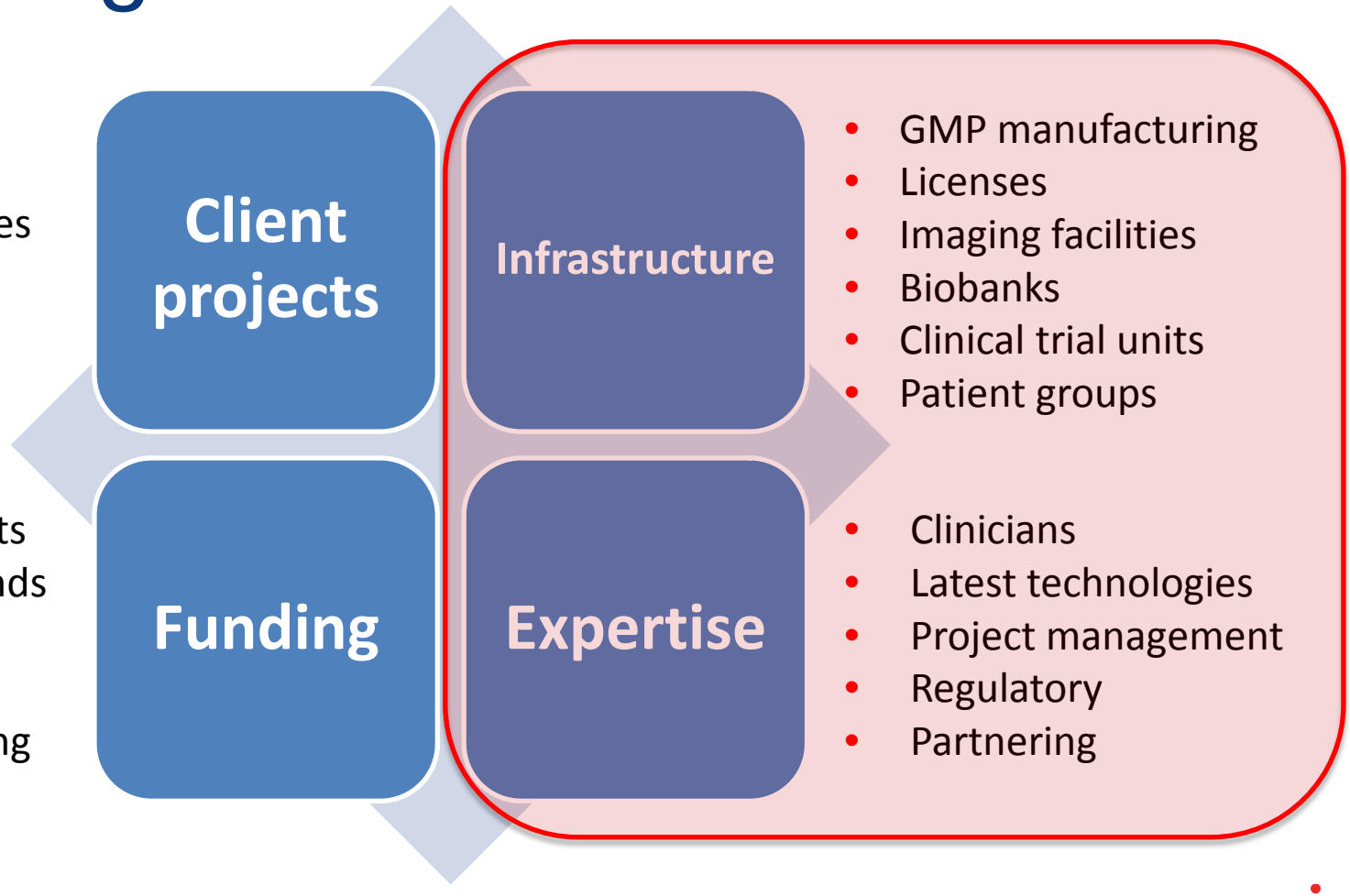
1.1 Matching clients with infrastructure

- Academia
- Research /charities
- SME/biotech
- Pharma



- GMP manufacturing
- Licenses
- Imaging facilities
- Biobanks
- Clinical trial units
- Patient groups

- Nat'l governments
- Regional dev. Funds
- H2020
- Venture capital
- Pharma partnering

- Clinicians
- Latest technologies
- Project management
- Regulatory
- Partnering

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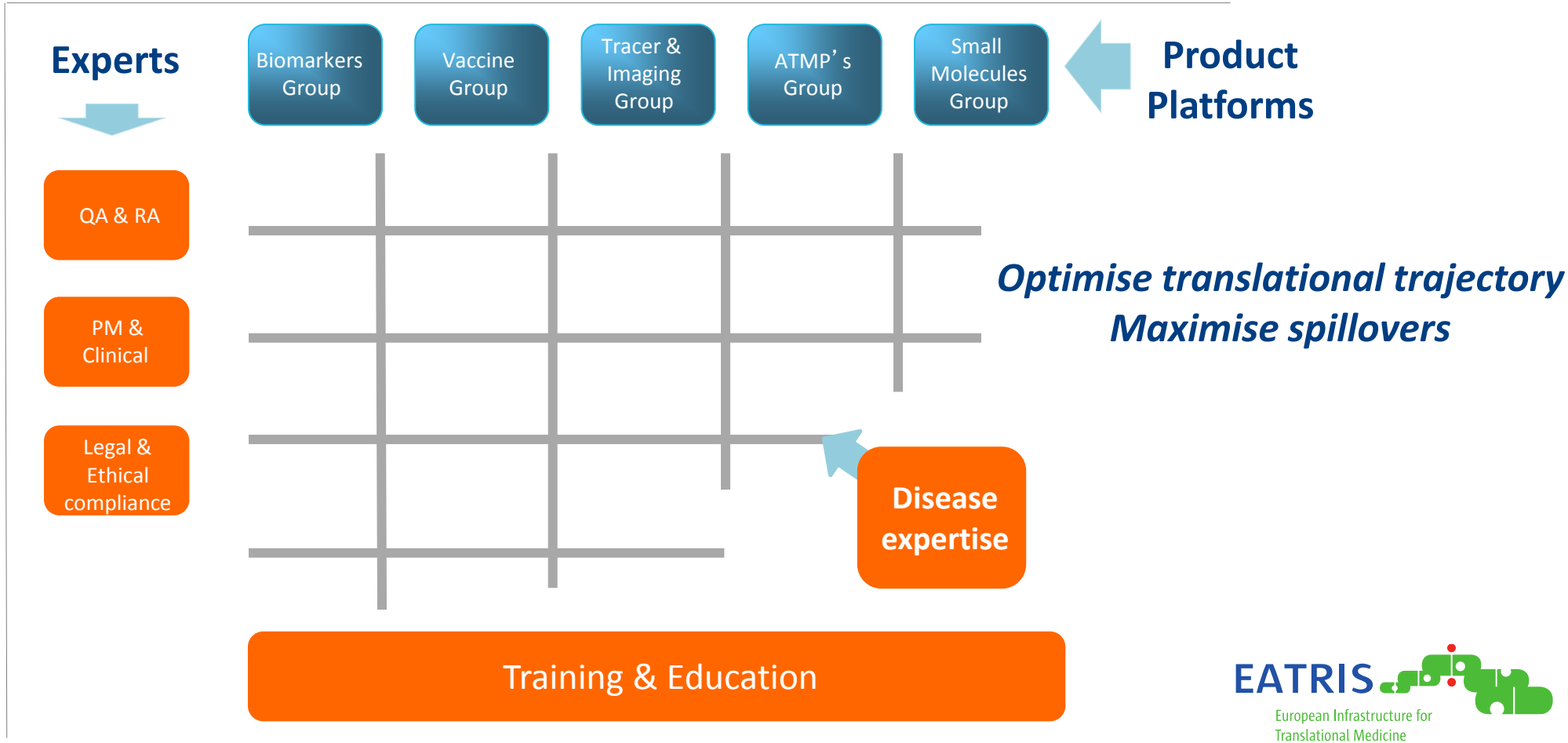
1.2 Matching clients with infrastructure

Consortia of centres of excellence in a 3D matrix model



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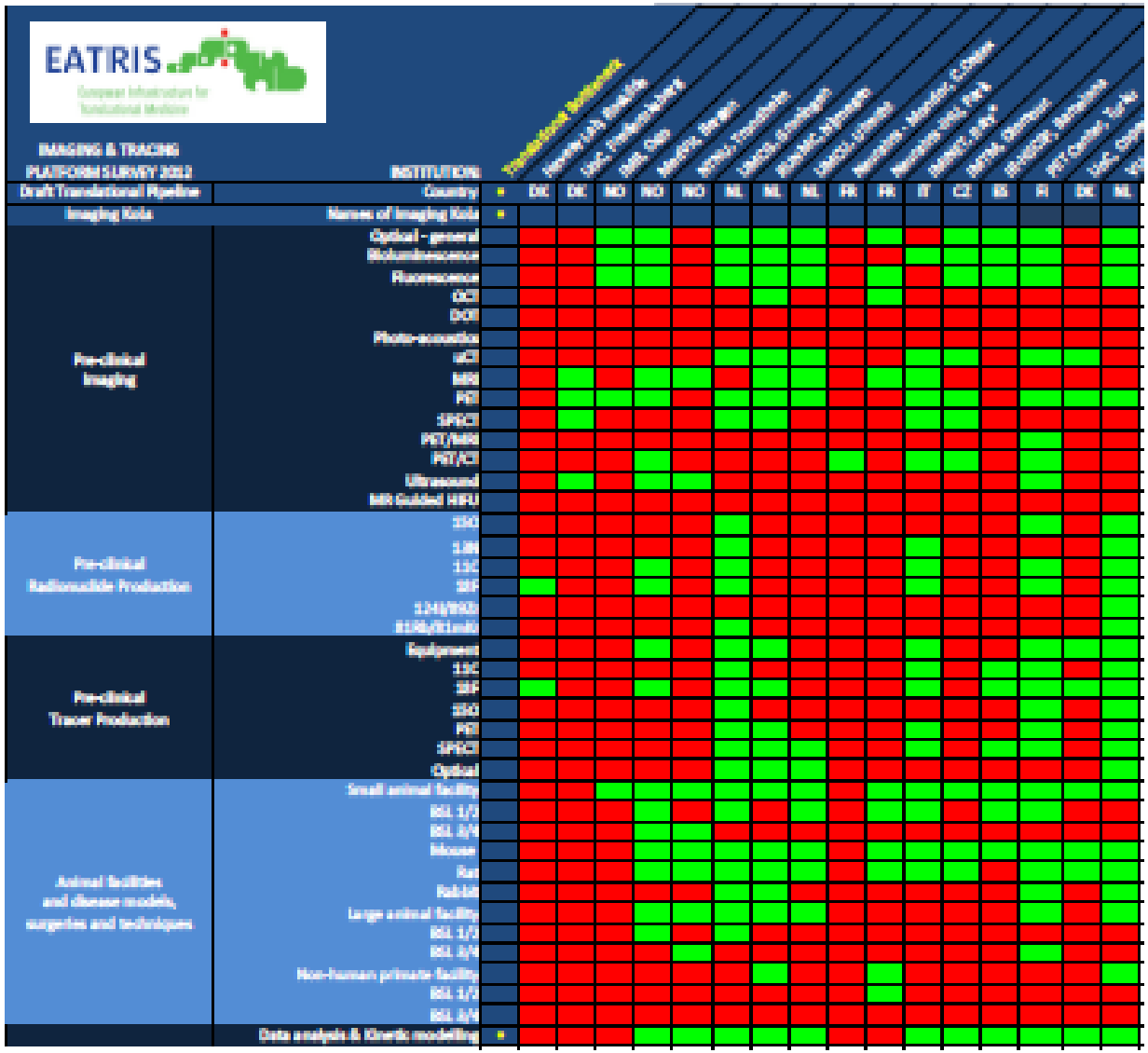
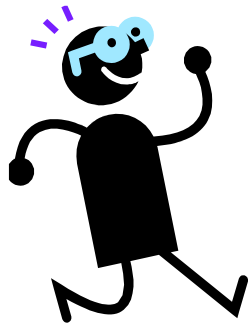
1.3 Matching clients with infrastructure



1.4 Matching client with infrastructure in 4-steps



1. Service request

- Letter of engagement
- Outline of project goals & service request

2. Matchmaking

- Database identifies relevant infrastructure, disease knowledge and patient cohorts
- Client has lead in selecting partners

3. Exploration

- Institutes explore project with client
- Client chooses institute(s)
- Project Plan created

4. Initiation

- Define steps, milestones, budgets
- Draw up bilateral contracts - from template or master agreement

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How do we add value?

- Improve and accelerate access to high-end infrastructure and expertise (across Europe)
- Support in optimising translational trajectory of each project
- Support portfolio management, reduce risk, waste and cost – translational feasibility, imaging tools
- Harmonisation to facilitate multi-centre (clinical) trials
- Improve effectiveness and return on investment

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2. Improving pipeline productivity

In- & External collaboration focusing on 3 areas

- Tools, technologies and methodologies
- Funding, policy and collaboration models
- Regulatory affairs

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2.1 Tools, technologies and methodologies

Identification of technical bottlenecks, validation of solutions: examples

- Biomarker Factory
  - Generic framework to ensure optimal QA/QC for BM validation for any given disease/technology
  - Collaborate with industry and sister infrastructures
  - Seeking funding
- Zr-89 accreditation
  - With EANM – enabling imaging-enabled multi-centre trials for antibody development

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2.2 Funding, policy & collaboration models

Improving the translational process: examples

- "EATRIS Inside"
  - Public funders use EATRIS to support shortlisted PIs
  - To optimise translational strategy
  - To embed translational tools in project
  - To identify feasibility issues

- Global collaboration: finding solutions to common translational bottlenecks
  - NIH-NCATS (USA), Therapeutic Innovation Australia, CDRD (Canada), MRC technology (UK), EATRIS

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2.3 Regulatory Affairs

Access to expertise & working with regulators: examples

- Regulatory Knowledge & Support Centre
  - Provides reg support for any given project
  - Makes reg. intelligence & resources available
  - Engages regulators in dialogue
- MoU - NL Medicines Agency
  - Provide mechanism for early, non-binding advice for projects not yet mature enough for Sci. Advice procedure
  - Similar agreement with CZ and FI competent authority

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Project activities performed (Aug 2015)

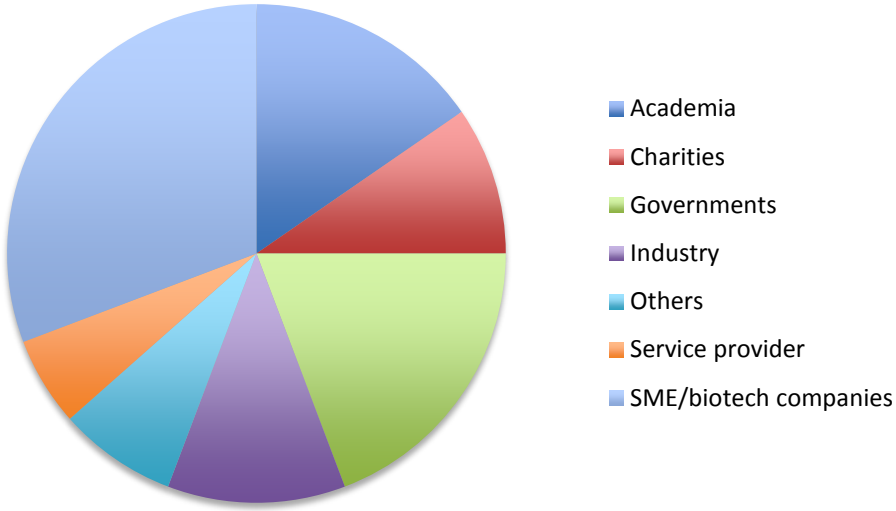
Lead **163**

Enquiry **58**

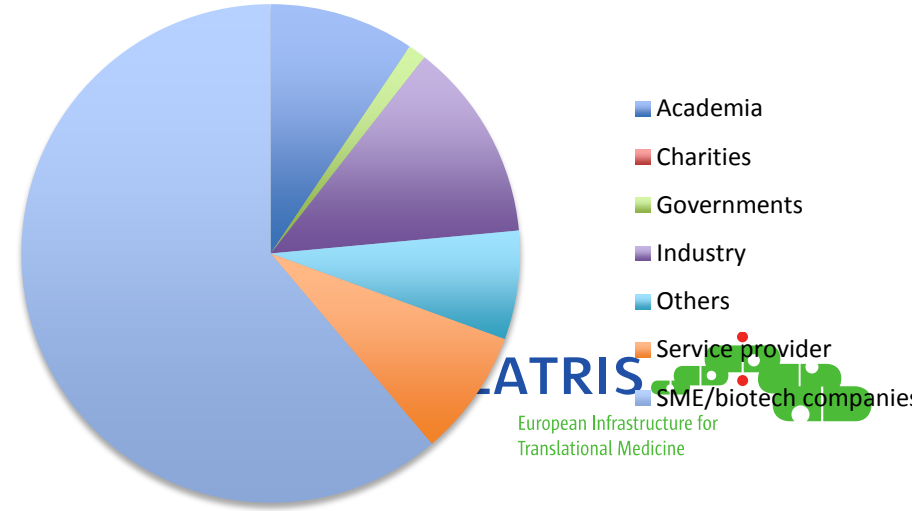
Fast matching	**18**
Matchmaking	**11**
EATRIS inside	**14**
EU project	**5**

Client groups

2014



2015



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