Biomarker - A key regulatory tool to facilitate drug development

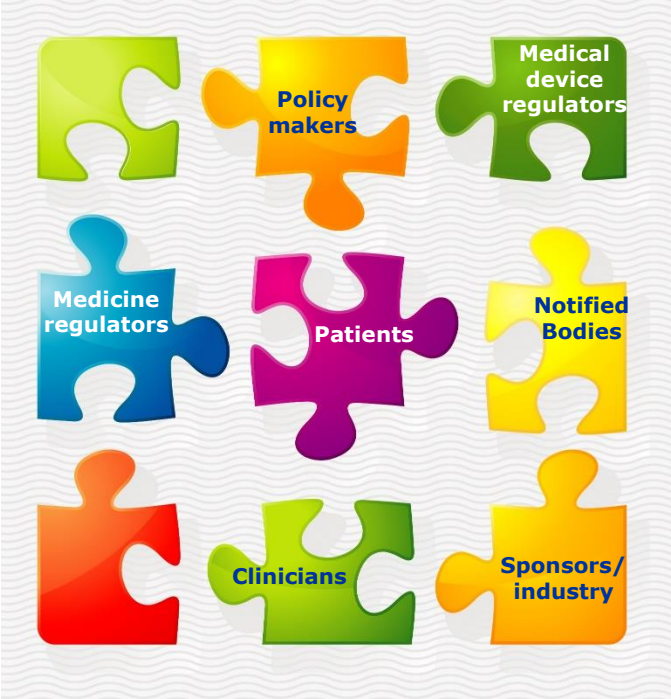
REGULATORY SCIENCE CROSS-TALKS-SESSION
RSNN LEVERAGING THE VALUE OF COLLABORATION
from regulatory science to regulatory innovation

Presented by Falk Ehmann
Regulatory Science and Innovation Task Force – European Medicines Agency

Disclaimer

The presenter does not have any conflict of interests.

EMA Regulatory Science Strategy 2025 → Biomarker



Catalysing the integration of science and technology in medicines' development

→ Support developments in precision medicine, biomarkers and 'omics

- Enhance early engagement with novel biomarker developers to facilitate regulatory qualification:
  - » Critically review the EMA's biomarker validation process in order to encourage greater uptake and use;
- Address the impact of emerging 'omics' methods and their application across the development life cycle;
- Evaluate, in collaboration stakeholder, the impact of treatment on clinical outcomes measured by biomarkers;
- Optimise the European research infrastructure for developing personalised medicine.

What is a Biomarker?

Biomarker: A measurable characteristic that is an indicator of normal biologic or pathogenic processes, and/or response to therapeutic or other interventions.

Modified from ICH E15

Preclinical development
- **predict activity/safety**
- PK/PD modelling
- toxicogenomics

Clinical development
- **dose/exposure-response**
- **enrich/stratify population**
- **surrogate endpoint**
- Early detection of safety signals

Drug utilisation
- optimise target population
- guide treatment regimen

CHMP Qualification of novel Methodologies (Biomarker)

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Vision: Speed up/optimise drug development and utilisation, improve public health

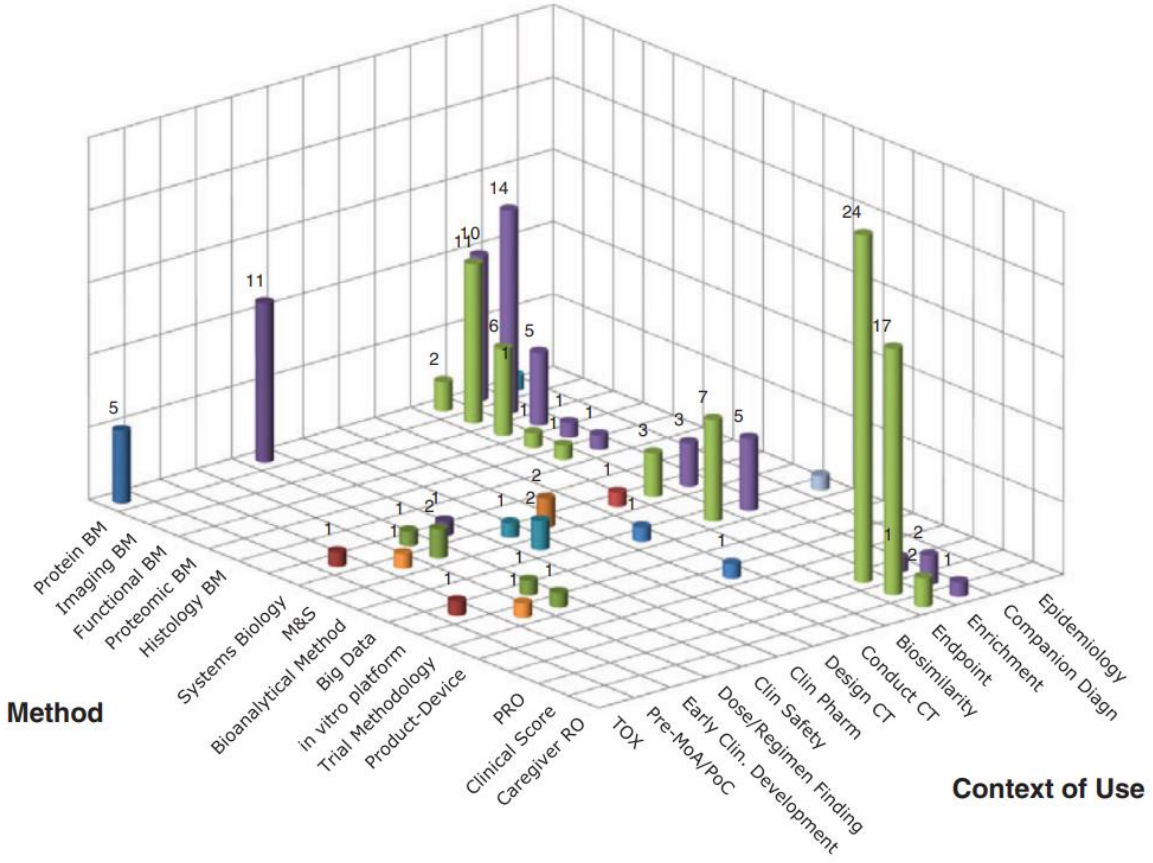
Who can apply?

Consortia, Academia, Networks, Public/Private partnerships, Learned societies, Pharma, CROs, Software developers,…

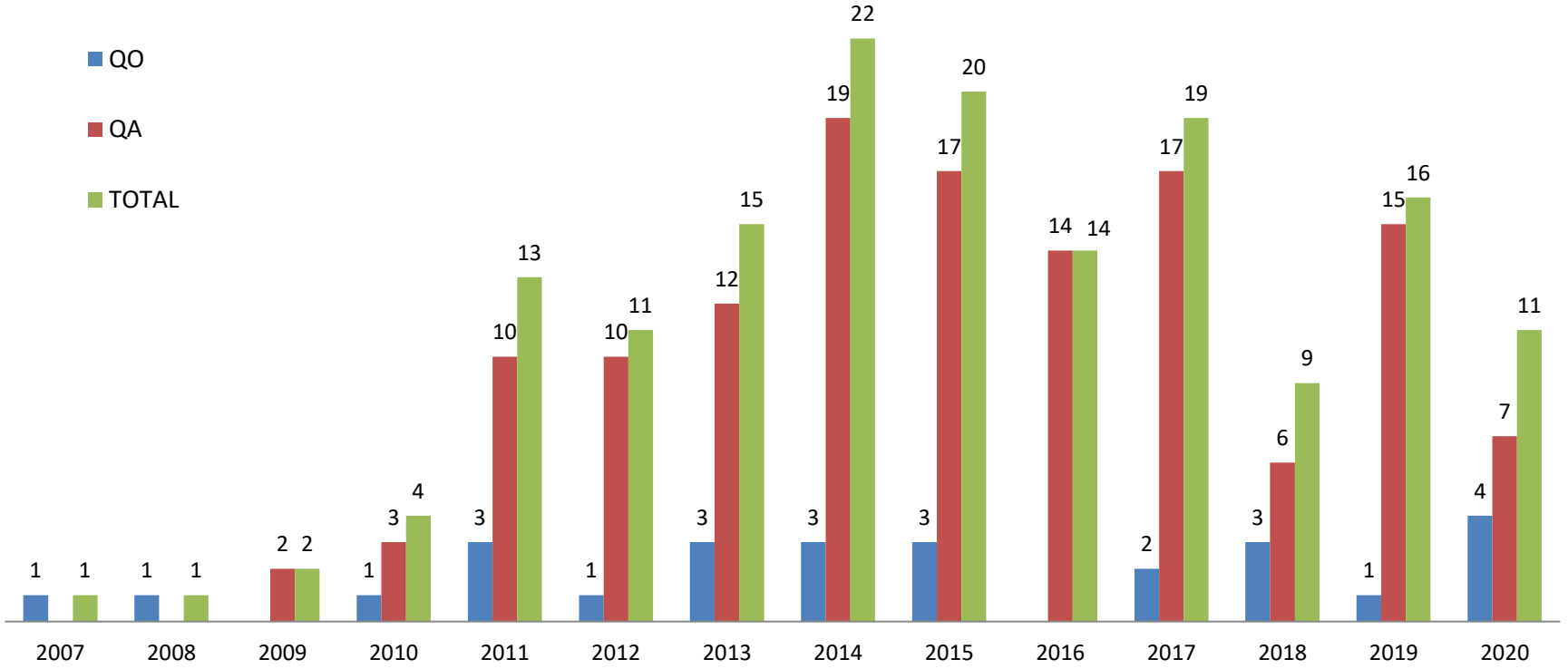
CHMP Qualification Opinion ***(Publicly Available)*** on the acceptability of a specific use of the proposed method in an R&D context based on the assessment of submitted data

CHMP Qualification Advice (Confidential) on future protocols and methods for further method development towards qualification - **Letter of support** is possible

Contexts of Use and methods proposed



Qualification of novel methodologies– type of procedure



to July 2020

Letter of support

Based on qualification advice, when the novel methodology under evaluation cannot yet be qualified but is shown to be promising based on preliminary data.

Aim to encourage data-sharing and to facilitate studies aimed at eventual qualification for the novel methodology under evaluation.

A high-level summary of the novel methodology, context of use, available data, and on-going and future investigations. The Agency publishes letters of support if the sponsors agree.

Innovation Task Force (ITF) – an early interaction platform

Multidisciplinary platform for preparatory dialogue and orientation on **innovative methods, technologies and medicines**

- Support **innovative** drug development
- **Early informal** dialogue with opinion leaders on
  - **Scientific, legal and regulatory** issues
  - Products, **methodologies and technologies**
- Free of charge

- Brainstorming "style" on innovation in areas without existing guidance
- First step to engage is submit completed 3-page template: https://www.ema.europa.eu/en/human-regulatory/research-development/innovation-medicines#applying-for-a-briefing-meeting-section

Enabling the translation

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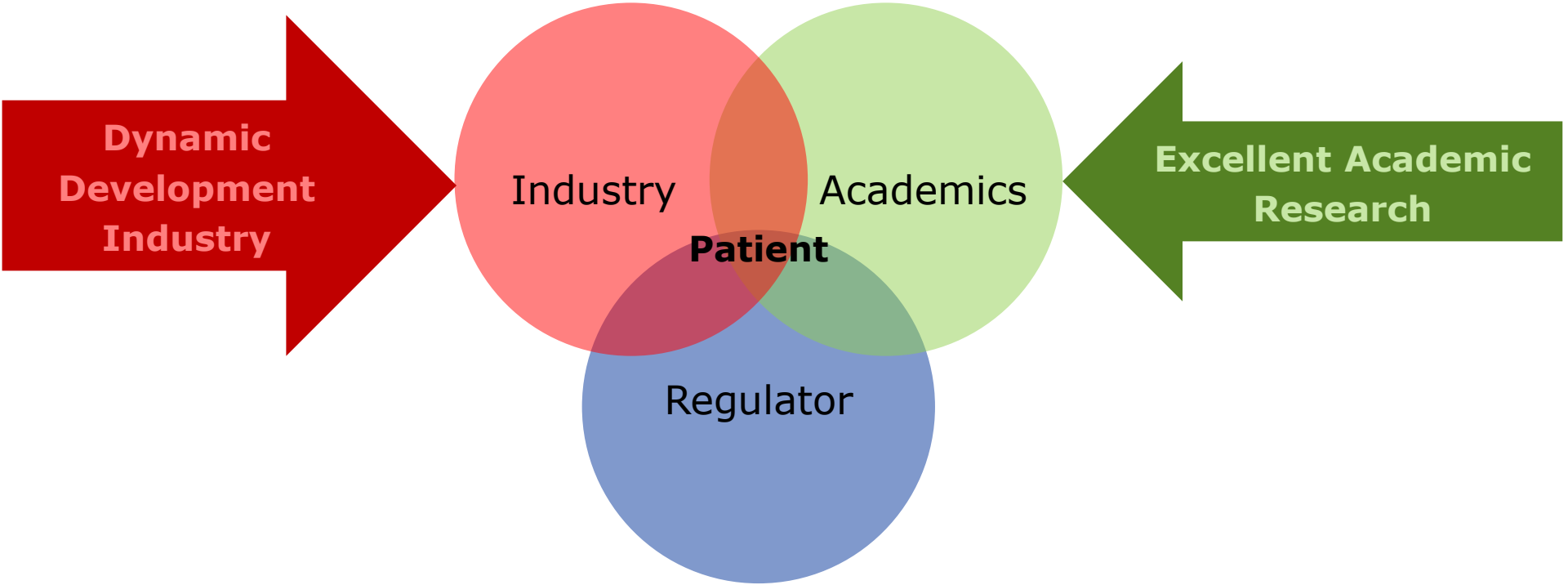
Triple Helix model for innovation



Future trends and challenges

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- Evolution of "Regulatory Science" in medicines regulation is essential to enable patient access to innovative medicines addressing unmet medical needs
- Europe has a world class life sciences ecosystem with an opportunity to provide global leadership in emerging new areas of science and technology
- Significant research funding of collaborative public private partnerships pursuing ambitious strategic research agendas should continue to have real impact on innovative medicines development
- The EMA offers opportunities to gain acceptance of new technologies and applications to enable access to innovation and drive the global convergence

Thank you for your attention

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Further information

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