Webinar | IMI2 - Call 9
‘Data quality in preclinical research and development’

Thomas Steckler

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Need for public-private collaboration

Low quality data hamper innovation and progress in academic research, and increase risks and costs in R&D

- **Pooling of industrial and academic resources to:**
  - **Establish best practices** on how to improve data quality
  - **Complement expertise** in developing simple, evidence-based and sustainable solutions that facilitate data quality
  - **Safeguard innovation** and freedom of research
  - **Maximize impact** in the field of science by ensuring broad acceptance of recommendations made by the consortium
- Initially **3 years**, option to extend for another 2 years

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Objectives of the full project

To advance the quality and the exploitation potential of academic and R&D, explorative and hypothesis-testing, data

- **Objective 1:**
  - Data-driven determination of the primary variables in study design and analysis that affect data quality and levels of robustness
    - *Retrospective analysis of pooled, historical data*
    - *Prospective, cross-site validation studies*

- **Objective 2:**
  - Development of consensus quality management recommendations in preclinical research based on outcome from Objective 1

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Objectives of the full project (cont.)

- **Objective 3:**
  - Electronic training platform on scientific quality principles
    - Facilitation of a culture of quality in biomedical research via increased awareness and sharing of criteria and principles to ensure robustness and quality of data
  - Part of a joint training scheme for students to foster understanding of needs in academia and commercial organizations

Pre-competitive nature

- **Need for combined expertise from various fields:**
  - **Drug discovery and basic research**
  - **Quality assurance**
  - **Information technology and data management**
  - **Educational expertise**
  - **Funders**
  - **Publishers**
  - **Regulatory advice**
- Pooling of resources can best be achieved by a pre-competitive, public-private collaborative effort
  - Pre-competitive data sharing, sharing of tools and infrastructure
  - Joint **Young Researchers Exchange Scheme**

Pre-competitive nature (cont.)

- A joint, collaborative effort is required:
  - To **facilitate understanding** of the different perspectives and to allow cultural exchange of best practices
  - To **foster the interaction** between scientists from different organizations and between quality and research organizations
  - To **ensure wide acceptance** of recommendations to improve the quality of research data originating from the consortium

- Industrial/academic joint **Young Researchers Exchange Scheme**
  - Young Researchers (PhD student level or equivalent)
  - Usability testing of the newly developed quality principles
  - Nucleus from where knowledge of best practice will expand

Expected impact on the R&D process

- **Better trained researchers**
- **Common standards** for preclinical research
  - Reliable and reproducible models
  - Harmonized, standardized protocols and procedures
- **Harnessing collaborations** among big pharma, start-ups, public and private research organizations and academia
  - Integration of transformational external innovation into R&D
  - Reduced need for duplicate assessment
- **Strengthened IP** protection and regulatory success
- **Significant contribution to the 3Rs**

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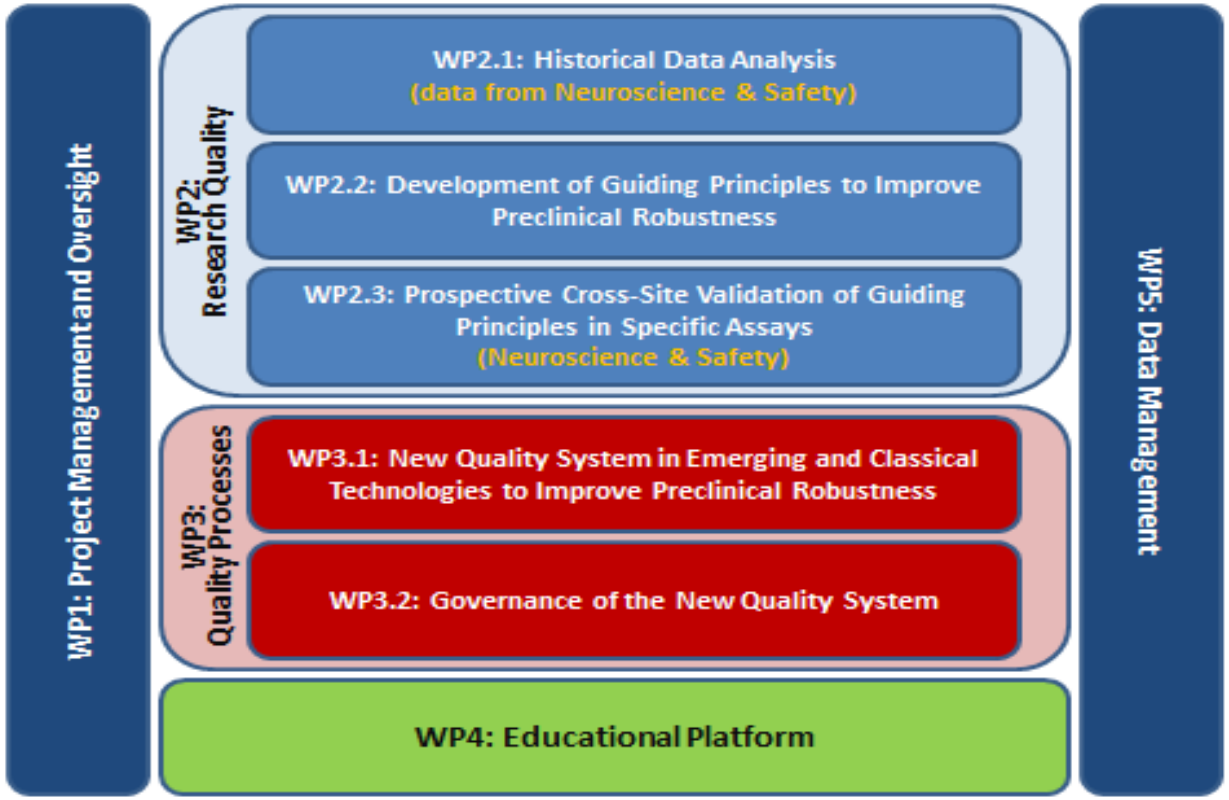
Suggested architecture of the project



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Suggested architecture of the project

WP1:

- Strategy and implementation
- Planning, budgeting, follow up and tracking, and consolidation of Work Package Reports
- Facilitation of consortium entity and regular team meetings

WP 2.1: Historical Data Analysis

- Determination of the primary variables in study design and data analysis that affect data quality and levels of robustness

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Suggested architecture of the project

Work Package 2.2: Guiding Principles to Improve Preclinical Robustness

- Development of key principles for the development of standard assays to improve robustness, reproducibility and research efficiency

Development of initial criteria based on literature and policy reviews → **Refinement of principles and criteria based on input from WP 2.1 (and WP 2.3)** → **Working system to systematically evaluate reproducibility and validity of published work**

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Suggested architecture of the project

WP 2.3: Prospective Cross-Site Validation

- Validate the identified principles in multiple research settings (initial focus on Neuroscience and Safety) to determine if the identified variables do affect robustness
- Development of key principles for the development of standard assays

WP 3.1: Development of New Quality System

- Arrival at generally applicable, lean and efficacious quality principles for biomedical research
- Measurement of success by beta-testing

WP 3.2: Governance of the Quality System

- Maintenance system for quality principles
- Tool to evaluate whether the principles are being followed and to update quality principles as required

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Suggested architecture of the project

WP 4: Educational Platform

- Development of an electronic training on scientific quality principles
- Apply in the industry/academic young researchers joint exchange scheme
- Disseminate the principles

WP 5: Data Management

- Development of a data management system to host historical and newly generated assay/test data and study protocols
- Should allow easy access and retrieval

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Anticipated applicant expertise

- Preclinical **neuroscience**, neuropharmacology
- Preclinical **safety**, systems biology, toxicology
- Pharmacokinetics, **translational** (biomarkers, imaging)
- Ongoing **PhD student programs**/schemes!
- **Statistical expertise**; analysis of **large datasets**; contribution of **old and newly generated data**, esp. in vivo animal model, electrophysiological and behavioral, data
- **Quality assurance**, academic research integrity / ethics / quality groups focusing on non-regulated biomedical research
- Synergies with health authorities (the latter in an advisory role to benefit from experience in the regulated space); patient, (neuro)science or quality organizations
- Research intensive SMEs

Expected contributions of the applicants

- **Statistics:** joint study of the applications of Bayesian and frequentist methods, including meta-analytic approaches; identification of factors determining robustness and generalizability of commonly used assays (**WP 2.1, WP 2.3**)
- Contribution to **literature and policy reviews** (**WP 2.2**)
- Contribution to development of key principles for guiding the development of standard assays to improve robustness, reproducibility and research efficiency (**WP 2.2**)
- Contribution to establishment of a system that allows **systematic evaluation of the reproducibility and validity of published work** (**WP 2.2**)
- Joint development of **harmonized test protocols** for the assays to be used to test the principles developed in Work Package 2.2 (**WP 2.3**)

Expected contributions of the applicants (cont.)

- Contribution to **prospective cross-site studies** (**WP 2.3**)
  - *Focus on behavioral, electrophysiological and neurochemical studies in rodent models (esp. in transgenic animals) for cognitive dysfunction and synaptic plasticity in neurodegenerative (esp. Alzheimer's disease) and psychiatric disorders*
  - *Involving studies of memory, attention, cognitive control, basal synaptic transmission, connectivity and translational EEG methods*
- Definition and implementation of **quality criteria** specific to the assays used across sites (**WP 2.3**)
- Contribution to the development of proficiency testing for quality and robustness (**ring testing**) (**WP 2.3**)

Expected contributions of the applicants (cont.)

- Joint delivery of a **quality system** ready for implementation in industry and academia; generate metrics to define success (**WP 3.1**)
- **Beta-testing** of the quality system (**WP 3.1**)
- Generation of a **risk assessment tool** (**WP 3.2**)
- Development of **cross site criteria for audit outcomes;** exploration of informal audits across partners (**WP 3.2**)
- Development of **third party accreditation system** (**WP 3.2**)
- Contribution to the development of an **electronic training** on scientific quality principles (**WP 4**)
- Contribution to the **development of data sharing platform** (**WP 5**)
- **Supervision** of shared young researchers (e.g. PhD students) as part of the joint Young Researchers Exchange Scheme

EFPIA member expertise

- Contribution from pharmaceutical, quality and IT sectors
- Expertise at industry partners:
  - Preclinical in vivo and in vitro **neuroscience**
  - **Safety** drug discovery activities/experimentation
  - **Translational** research
  - **Quality management**
  - **Statistical expertise**
  - **Data management** and **project management**

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Expected (in kind) contributions of EFPIA members

- Indicative in-kind budget EUR 4.5 MM
- Provision of **existing data sets and study protocols** from Neuroscience (focus on psychiatry and neurodegeneration) and Safety in vivo and in vitro assays (**WP 2.1**)
- Provision of specific **transgenic model organisms and tool compounds** (**WP 2.2**)
- Joint study of **statistical applications** (**WP 2.1, WP 2.3**)
- Contribution to **literature and policy reviews** (**WP 2.2**)
- Contribution to **development of key principles** for guiding the development of standard assays (**WP 2.2**)
- Establishment of a **system for systematic evaluation** of published work (**WP 2.2**)
- Joint **development of harmonized test protocols** (**WP 2.3**)

Expected (in kind) contributions of EFPIA members (cont.)

- Contribution to **prospective cross-site studies** (**WP 2.3**)
- Definition and implementation of **quality criteria** (**WP 2.3**)
- Contribution to the development of preclinical proficiency testing for quality and robustness (**ring testing**) (**WP 2.3**)
- Joint delivery of a **quality system** and **beta-testing** (**WP 3.1**)
- Generation of a **risk assessment tool** (**WP 3.2**)
- Development of **cross site criteria for audit outcomes** (**WP 3.2**)
- Development of **third party accreditation system** (**WP 3.2**)
- Contribution to the development of an **electronic training** on scientific quality principles (**WP 4**)
- Contribution to the **development of data sharing platform** (**WP 5**)
- **Supervision** of shared young researchers (e.g. PhD students)

What's in it for you?

- **Join** effort to address concerns about limited robustness, rigor and validity of research data
- **Shape** the research environment and contribute to:
  - Quality criteria for preclinical tests
  - Consensus quality management recommendations
  - Educational efforts to enhance scientific quality principles
- Have a high perceived **credibility** and become a more attractive partner for industrial collaborations
- Develop a generation of **attractive** future employees
  - PhDs with experience in both academia and industry, adhering to highest quality / ethical standards
- **Improve** your own and other's day-to-day research practice, learn about best practices

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Key deliverables of the full project

1. Generally applicable, lean and efficacious **quality principles** for preclinical research in the biomedical field
2. A **quality assurance system** fit for purpose
3. Cross site **criteria for audit outcomes**; third party accreditation system
4. **Database for open sharing** of information of replication attempts
5. **Factor analysis** to understand variables that affect robustness and generalizability of commonly used assays
6. **Feasibility testing** of agreed principles in prospective studies
7. A preclinical **ring testing** scheme
8. A comprehensive **training platform**

Questions?

Contact the IMI Programme Office
infodesk@imi.europa.eu • www.imi.europa.eu

www.imi.europa.eu
@IMI_JU