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
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
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**
Suggested architecture of the project

- WP1: Project Management and Oversight
  - WP2: Research Quality
    - WP2.1: Historical Data Analysis (data from Neuroscience & Safety)
    - WP2.2: Development of Guiding Principles to Improve Preclinical Robustness
    - WP2.3: Prospective Cross-Site Validation of Guiding Principles in Specific Assays (Neuroscience & Safety)
  - WP3: Quality Processes
    - WP3.1: New Quality System in Emerging and Classical Technologies to Improve Preclinical Robustness
    - WP3.2: Governance of the New Quality System
- WP4: Educational Platform
- WP5: Data Management
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
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
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
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
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
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
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
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