DEVELOPING AN AETIOLOGY-BASED TAXONOMY OF HUMAN DISEASE

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Need for public-private collaboration

Technical knowledge

Disease biology

Resources

Change > 200 years of disease classification
Objectives of the full project

• Propose new aetiological / mechanism based taxonomy in 2 disease areas
  – Immunoinflammatory disorders (RA and SLE)
  – Neurodegeneration (AD and PD)

• Initial clinical validation

• Create vision of new mechanistic approach to the classification of human disease

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Pre-competitive nature

• Mechanistic classification of disease is **pre-competitive** and will help
  – Patients,
  – Physicians
  – Regulators
  – Industry

• Agreed new classification will aid in driving getting the right drug to the right patient
Expected impact on the R&D process

• Increased homogeneity of disease will:
  – Decrease trial sizes
  – Improve benefit risk profiles of drugs
  – Increase speed to patients

• Improved understanding of the disease
  – Ensures patients can access the right treatments for them regardless of phenotypic presentation
  – Increased confidence in target

• Reduce drug discovery costs by impacting attrition
Suggested architecture of the project

• Build evidence base from:
  – Literature
  – Current data
  – Shared data

• Develop potential new classification

• Prospective validation
Expected contributions of the applicants

- Disease area expertise
- Multidisciplinary approach
- Access to pilot data and samples
- Access to patients to test new classification system
- Thinking beyond current confines of “today’s phenotypic classification”
Expected (in kind) contributions of EFPIA members

• Baseline clinical data from clinical trials
• Some molecular data and samples
  – Genetics
  – White cell mRNA
• Pharmacology expertise from current therapies
• In-vivo assay expertise
• Informatics and biostats expertise
What’s in it for you?

• A mechanistic taxonomy
  – Optimise benefit risk of therapies (remove patients with no chance of responding)
  – Identifies patients likely to benefit from new therapies despite different phenotypic features
  – Reduce overall cost of clinical development by reducing trial sizes and increasing success
  – Improves academic research by providing more homogenous diseases to study
Key deliverables of the full project

- Proposed taxonomy for:
  - RA
  - SLE
  - AD
  - PD
  
- Topic A
- Topic B

- Initial validation
- Formal validation plan
- New diseases nominated

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Taxonomy call

• 2 topics initially to form 2 separate projects
• The successful applicant consortia will work together where approaches are similar to create harmonisation
• Expect successful applicants to collaborate with other initiatives which will add value to this one e.g. eTRIKS
• If successful then additional calls focusing on other disease areas will follow
Questions?

• Contact the IMI Executive Office

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