

Precompetitive Collaboration: Requisites from Pharma

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Insert Group Name or Division

Pre Competitive Consortia: Pfizer Participation – some examples

Consortium Name	Consortium Space
Serious Adverse Event Consortium	Genetic markers for drug safety
Biomarkers Consortium	Biomarkers for disease & drug development
Predictive Safety Testing Consortium	Preclinical & translational markers
Structural Genomics Consortium	Protein structure to enable drug design
Coalition Against Major Diseases	Clinical Trial Design
Innovative Medicines Initiative	Broad ranging: prediction of safety & efficacy; knowledge management & platform technologies; education & training
Human Blood Plasma Consortium	Platform technology



Consortia

- **What do we want to achieve?**
 - Break down barriers to drug discovery and development
 - Disease understanding, biomarkers to enable safety and efficacy determination, enabling technology development
- **Why and How?**
 - Leverage capabilities beyond what one company can do
 - Pooling of resources to access substrate for enabling research
 - Samples and data collected from clinical trials
 - Pooling across pharma companies, academic institutions
 - Enrichment of access to intellectual capabilities
 - Develop new enabling processes



Challenges

- **Define what's pre-competitive**
 - Biology, understanding of disease, biomarkers of prognosis and even drug response
 - Chemistry, execution and quality is where the competition is – is this an inviolate rule?
 - Different understanding from different stakeholders on what's competitive versus non – competitive: academia vs pharma vs diagnostic companies
- **Align stakeholders' interests**
 - 'Political science precedes the real science'
- **Design and manage the research/work plan**
 - Real investment of time and energy required to make it work
- **Contract**
 - How long to put in place – do all parties have the same view?
 - Internal issues often illustrate some internal inconsistency in relation to how we think of what needs to be protected from an IP standpoint
- **Establish IP boundaries and processes**
 - Critical issues are Freedom to Operate (FTO)
 - Agree approach to establish: e.g. file patents or publish
- **Establish decision-making and stopping criteria**
 - Also what about new members
 - What do latecomers get



The Future

- **There will be a greater financial driver to collaborate in future. Pre-competitive space will expand**
 - Pharma product margins being eroded year on year – governments, legislation, insurance companies
 - Pharma R&D costs escalating dramatically year on year – less third party substrate, high compound attrition, increasing regulatory requirements etc.
 - Austerity measures in public sector will continue to drive need for non-grant income in universities especially UK – double edged sword
 - Access to data, especially omics data, more important = more collaborative efforts
- **How will this be enabled?**
 - Organizations placing greater resources/expertise in constructing appropriate pre-competitive consortia
 - Ensuring innovative new IP structures to promote Freedom To Operate – (e.g. “Essential IPR” licensing model per mobile comms sector)
 - Continued drive to publish pre-competitive findings
 - Governments creating more appropriate financial incentivization for pre-competitive collaborative research – more enlightened public funding structures, improved tax breaks etc.

