

The Evolving Collaborative Biomedical R&D Ecosystem

Stakeholders in the biomedical R&D process such as patients, regulators, academics, governments and industry are adopting a multi-stakeholder approach and collaborating to bring better medicines to patients faster

“Greater collaboration between regulatory authorities, industry and academia is increasingly acknowledged as the answer to some of the thorniest problems in drug development, such as validation of biomarkers of efficacy and toxicity.”

— Editorial, Nature Reviews Drug Discovery

The Life Sciences sector has recognised that adopting a collaborative multi-stakeholder approach to improve the drug development process is more likely to be successful than pure conventional competitive approaches. As a result, a collaborative biomedical R&D ecosystem is evolving, which has the potential to transform R&D over the next 10 to 15 years.

The transformation will be based on a change from the current conventional environment, characterised by competitive R&D activity, to a future symbiotic environment, characterised by mixed competitive and collaborative R&D efforts. This transformation process will result in the creation and evolution of blended portfolios of competitive and pre-competitive R&D assets. For example, assets owned by a specific organisation, versus assets shared by a consortium of organisations who collaborated to create them. Like genes, these shared assets can be transferred and thus expand the entire asset pool of the entire R&D ecosystem.

Drivers of Collaborative R&D

The following initiatives support the evolving collaborative biomedical R&D ecosystem:

- The InnoMed Integrated Project: Part of the 6th Framework Programme of the European Commission
- Critical Path Initiative/The C-Path Institute: FDA, University of Arizona and SRI International

- The Innovative Medicines Initiative (IMI): Public-private partnership between the European Commission and Europe’s R&D-based pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA)

The InnoMed Integrated Project, which is the IMI pilot project, has demonstrated that successful collaboration and information sharing among 16 large pharmaceutical companies, 14 universities and 8 small and medium-sized enterprises is feasible and, importantly, creates shared R&D assets.

IMI will have a significant impact on the evolving collaborative biomedical R&D ecosystem and will become a key to improving the overall health of the ecosystem due to:

- Pan-European political support
- Pan-European academic support
- Pan-European industry support
- Large funding (€2 billion)
- Strong commitment to unprecedented levels of information sharing by the industry
- True power sharing and partnership
- Equal public-private investment
- Transparent leadership and governance structure

Challenges for Collaborative R&D

The evolving collaborative biomedical R&D ecosystem will present significant organisational and technical challenges to consortiums:

- **Organisational challenges:** Collaborative biomedical R&D projects will need outstanding leadership, project management, knowledge management and negotiation skills to turn multi-stakeholder consortiums into high-performing teams.
- **Technical challenges:** Collaborative biomedical R&D projects will require clear IT strategies and outstanding implementation capabilities that ensure robust knowledge management capabilities such as database design, database integration and clinical data migration to the Study Data Tabulation Model (SDTM) of the Clinical Data Interchange Standards Consortium (CDISC).

How Capgemini Can Help

Capgemini has designed a suite of professional services (see accompanying table) that are specific for collaborative biomedical R&D projects to help consortiums overcome these organisational and technical challenges. In addition to knowledge management services, Capgemini's Technology Services can also provide platform knowledge management, IT integration and infrastructure services for central coordinating bodies.

Capgemini's clients in the collaborative biomedical R&D ecosystem that use Capgemini's suite of professional services for collaborative biomedical R&D include:

- European Brain Council
- European Federation of Neurological Associations
- European Science Foundation
- International Agency for Research on Cancer
- The Global Fund to Fight AIDS, Tuberculosis and Malaria
- Helmholtz Centre for Infection Research (HZI)

Capgemini's Suite of Services for Collaborative Biomedical R&D Projects

CONSULTING SERVICES	
<p>Strategic advice/guidance for interested stakeholders:</p> <ul style="list-style-type: none"> • Strategy formulation • Business case • Direction setting <p>Consulting Services for Applicant Consortiums:</p> <ul style="list-style-type: none"> • Applicant Consortium Forming Services: <ul style="list-style-type: none"> – Connecting stakeholders so they can collaborate on Expressions of Interest • Applicant Consortium Facilitating Services: <ul style="list-style-type: none"> – Facilitated workshops to prepare Expressions of Interest 	<p>Consulting Services for Full Consortiums:</p> <ul style="list-style-type: none"> • Full Consortium Forming Services: <ul style="list-style-type: none"> – Facilitated workshops to prepare Full Proposals once full consortiums are formed • Full Consortium Facilitating Services: <ul style="list-style-type: none"> – Facilitated kick-off meetings – Facilitated workshops – Accelerated Solutions Environment (ASE) support¹ – Facilitated negotiations on intellectual property rights – Facilitated annual and ad hoc consortium meetings – Project Management Office support
TECHNOLOGY SERVICES	
<p>Technology Services for Applicant Consortiums:</p> <ul style="list-style-type: none"> • Applicant Consortium Knowledge Management Services: <ul style="list-style-type: none"> – Knowledge management strategy for inclusion in Expressions of Interest – Customised collaboration platforms for rapid information sharing 	<p>Technology Services for Full Consortiums:</p> <ul style="list-style-type: none"> • Full Consortium Knowledge Management Services: <ul style="list-style-type: none"> – Customised collaboration platforms – Architecture, implementation, maintenance and hosting – Knowledge management strategy for inclusion in full proposals – Architecture and integration services – Clinical data migration to the Study Data Tabulation Model (SDTM) of the Clinical Data Interchange Standards Consortium (CDISC) – Custom data federation – Clinical Data Management Systems – Accelerated Delivery Centre (ADC) support²

¹ Capgemini's Accelerated Solutions Environment® (ASE) combines world-class facilitation teams, patented, decision-making processes, global knowledge bases and innovative workspaces to enable organisations to make better and faster business decisions.

² Capgemini's Accelerated Delivery Centre® facilities apply world-class talent, processes and infrastructure to create industrial-strength systems for our clients with speed, predictability and quality, allowing them to more quickly realise business value.



About Capgemini and the Collaborative Business Experience®

Capgemini, one of the world's foremost providers of consulting, technology and outsourcing services, enables its clients to transform and perform through technologies.

Capgemini provides its clients with insights and capabilities that boost their freedom to achieve superior results through a unique way of working - the Collaborative Business Experience® -

and through a global delivery model called Rightshore®, which aims to offer the right resources in the right location at competitive cost. Present in 36 countries, Capgemini reported 2007 global revenues of EUR 8.7 billion and employs over 83,000 people worldwide.

More information about our services, offices and research is available at www.capgemini.com

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