FOREWORD

The driving role of consortia on the critical path to innovative therapies

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Launched a decade ago, the US Food and Drug Administration's Critical Path Initiative has helped catalyse the formation of many consortia focused on drug development challenges.

At the start of this century, a revolution in biomedical science — triggered by the sequencing of the human genome — had led to hopes of a similar 'boom' in ground-breaking medical products. Contrary to expectations, innovation stagnated and the gap between bench discoveries and new therapies widened.

This gap was due not only to the unknown development path for many next-generation therapies, but also to the unknown regulatory requirements. Pharmaceutical companies and regulatory agencies recognized that they could not rely on the tools of the past to evaluate novel therapies. However, most stakeholders were unable to invest the resources necessary to research, develop and evaluate both a new therapy and new assessment tools. For these reasons, some companies turned away from promising, albeit riskier, therapeutic opportunities to focus on areas where the development path was well worn. It became clear that progress in additional areas was needed to address these issues.

The term 'translational science' — also known as 'critical path science' or 'regulatory science' — is used as the moniker for the collection of disciplines that will drive the establishment of next-generation development pathways, tools and regulatory requirements. Translational science is often 'big science' that requires substantial resource investments, not only in terms of financial commitments, but also in acquiring relevant scientific expertise and large data sets. No single group has all of the necessary resources, and it is perhaps even more significant that there is no one entity charged with ensuring that this work gets done.

In 2004, both the US Food and Drug Administration (FDA) and the World Health Organization (WHO) identified public–private partnerships (PPPs) and consortia as the cornerstone of solutions to address mounting scientific questions and stimulate innovation in drug development (see Further information). Recalling earlier, successful collaborations among industry, academic institutions and the FDA to rapidly develop and approve antiretroviral therapies in response to the AIDS epidemic, stakeholders were quick to accept partnership as the path forward. Numerous consortia have since formed and substantial public investments in PPPs have been made in the past decade. A testament to the value of such partnerships was the launch of the European Innovative Medicines Initiative (IMI) with a €2 billion budget in 2008. In the United States, the President's Council of Advisors on Science and Technology recommended a similar model, and the Accelerating Medicines Partnership recently launched pilot projects with a US$230 million budget (see Further information).

Consortium partners undertake the challenging work necessary to stimulate modernization and innovation in medical product development, and do so by sharing in the investments, the risks and the rewards of translational research. Members often include pharmaceutical firms, academic institutions, regulatory agencies, patient organizations and independent third-party organizers. Stakeholders are brought together by a particular public health issue, and then pool their knowledge and expertise to devise solutions. Each consortium has its own particular impetus and mission. However, they share the goal of enhancing the consistency and scientific underpinnings of medical product development and regulation in order to decrease the time, risk and cost associated with bringing new products to patients.

In the following articles, representatives from some of the major stakeholder groups and consortia describe their roles, summarize progress so far and provide their perspectives on the opportunities, challenges and lessons learned for biomedical consortia in general.

Competing interests statement
The authors declare competing interests: see Web version for details.

FURTHER INFORMATION
Accelerating Medicines Partnership: http://www.nih.gov/science/amp/
Consortia-pedia: http://www.fastercures.org/assets/Uploads/Consortia-pedia
Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products: http://www.fda.gov/downloads/scienceresearch/specialtopics/criticalpathinitiative/criticalpathopportunitiesreports/ucm113411.pdf
Innovative Medicines Initiative: http://www.imi.europa.eu/
Priority Medicines for Europe and the World: http://archives.who.int/prioritymeds/report/final18october.pdf
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