The rewards of regulatory science

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Contributing to the delivery of innovative treatments to patients is one of the most rewarding aspects of a regulatory professional's role – and a great way to continue your professional development

At the time of writing, I'm at the annual workshop of the Critical Path to TB Drug Regimens (CPTR). CPTR represents an important approach to the development of new therapeutic approaches in tuberculosis (TB), bringing together pharmaceutical and diagnostic companies; public health experts; patients and other civil society groups; and regulators from around the world (see **www.cptrinitiative.org**).

CPTR is primarily focused on the development of new regimens, but also aims to improve drug development tools and regulatory pathways. During my career we have focused on the development of individual new medicines, however as very few diseases are treated with a single drug the search for the "magic bullet" was abandoned long ago. In the case of TB, we need new drugs, new regimens with lower toxicity, shorter treatment courses and solutions that address the challenges presented by delayed diagnosis and drug resistance.

The FDA launched its "**Advancing Regulatory Science Initiative**" in 2010, and in the same year the EMA held a conference entitled "**Regulatory science: are regulators leaders or followers?**" The FDA defines regulatory science as the "science of developing new tools, standards and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products." The CPTR programme exemplifies this and one of its early successes was the publication of guidance on co-development of novel investigational drugs by the FDA. Although this guidance is not specific to TB it is critical to support progression beyond the traditional approach of adding a new agent to existing regimens, and potentially shortening the time required to introduce new treatment options.

CPTR supports a range of other programmes for the progression of new drug development tools, the evaluation of potential early clinical endpoints and enabling the aggregation of data from clinical studies (TB-PACTS). One drug development tool supported by CPTR is the development of the *in vitro* hollow-fibre system model of tuberculosis (HFS-TB) which received a **CHMP Qualification Opinion in 2014**. This will allow better choices to be made in the selection of potential regimens and doses of new agents for subsequent clinical development. The TB-PACTS programme is currently evaluating the results of three recently completed clinical studies to support the future development of new regimen studies.

If you are looking to support your continuing professional development in regulatory science, I recommend reviewing the activities undertaken by CPTR – even if TB is not an area of interest – as it will provide a wide range of learning opportunities. My continued engagement is highly rewarding, but more importantly it was the catalyst for a change in the direction of my own career and the development of an interest in neglected infectious diseases beyond TB.