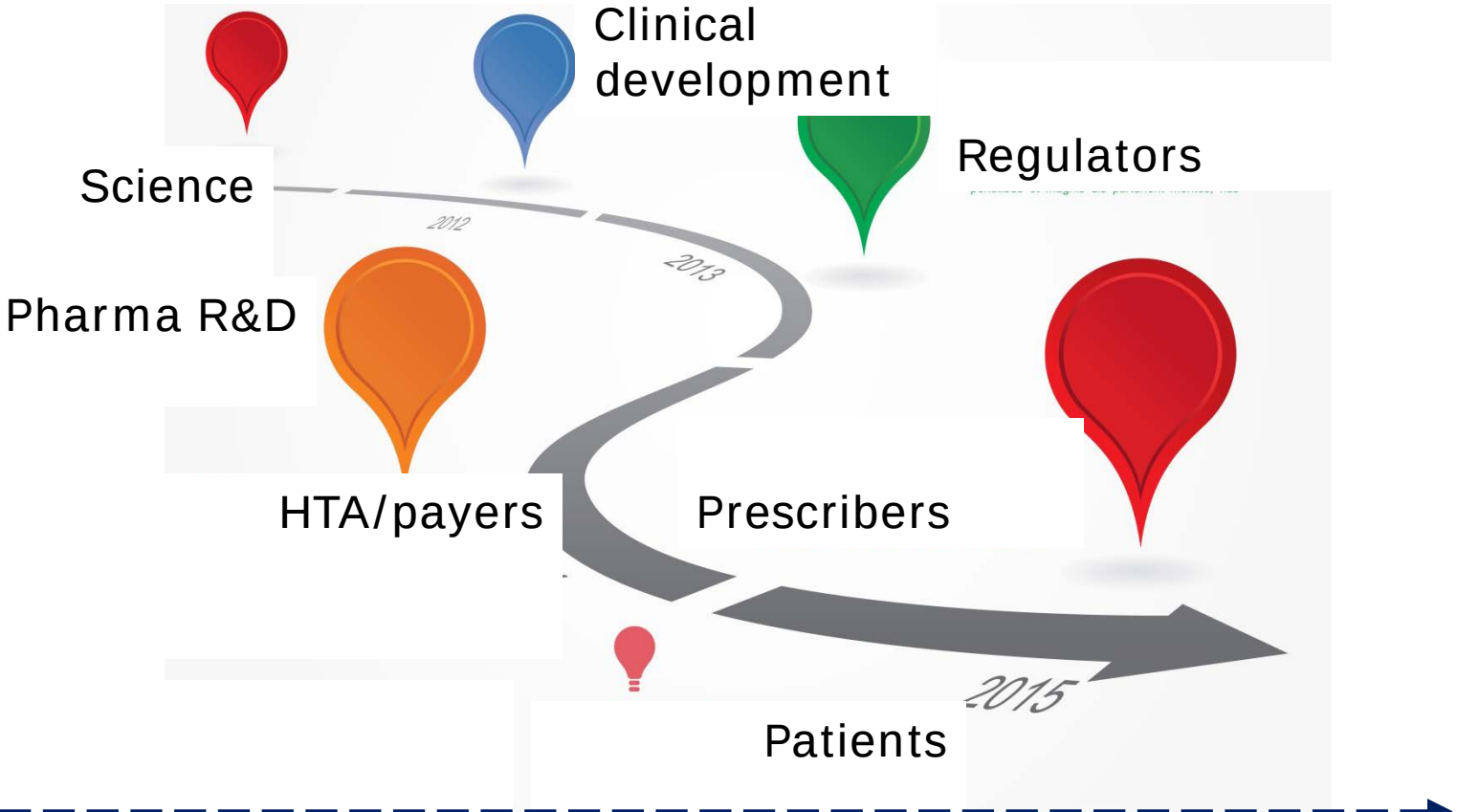
Up- and downstream in pharmaceutical development



Leufkens 2017

The Large Pharmaceutical Company Perspective

Michael Rosenblatt, M.D.

LARGE PHARMACEUTICAL COMPANIES CO
uate efficacy and identify safety issues f
efficiently, and expeditiously as possible,
the requirements of regulatory authorities acr
people at risk and to learn the most, these tria
evidence for health care providers, regulatory a
health agencies. Because there are so many un
and development is a high-risk business with
product candidates of any industry.

N Engl J Med 2017; 376: 52-60.

Table 1. Increasing Complexity of a Typical Phase 3 Clinical Trial.*

Trial Design Characteristic	2002	2012
Total no. of end points	7	13
Total no. of procedures	106	167
Total no. of eligibility criteria	31	50
Total no. of countries	11	34
Total no. of investigative sites	124	196
Total no. of patients undergoing randomization	729	597
Total no. of data points collected	NA	929,203

Division and discord in the Clinical Trials Regulation

David Shaw,[1,2] David Townend[1] Shaw D et al. J Med Ethics 2016; 42: 729–732.

ABSTRACT
The Clinical Trials Regulation is intended to harmonise and streamline the review and conduct of clinical trials in the European Union. In this
analyse several serious issue
imposed by the Regulation
ethical review. We conclude
compromise the objectives

Despite the general distinction between part
and part 2, this text states that ethics committee
can also consider part 1 issues in its deliberations

Need for a proactive and structured approach to risk analysis when designing phase I trials

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BMJ 2015; 351: h3899.

Good news from Emanuel and colleagues[1]—apparently, phase I clinical drug trials are safe. However, given the very low frequencies of serious adverse events, retrospective associations of trial characteristics with adverse events are of no use for predicting safety problems in future trials. None of these

Only one of three of phase I trials gets published

PLoS One 2016 Dec 14;11(12):e0167709.