Translational Oncology: How Far Have We Come & Where Do We Need to Go Next?

Moderator: Jeff Bockman, PhD, Vice President, Defined Health

Panelists:

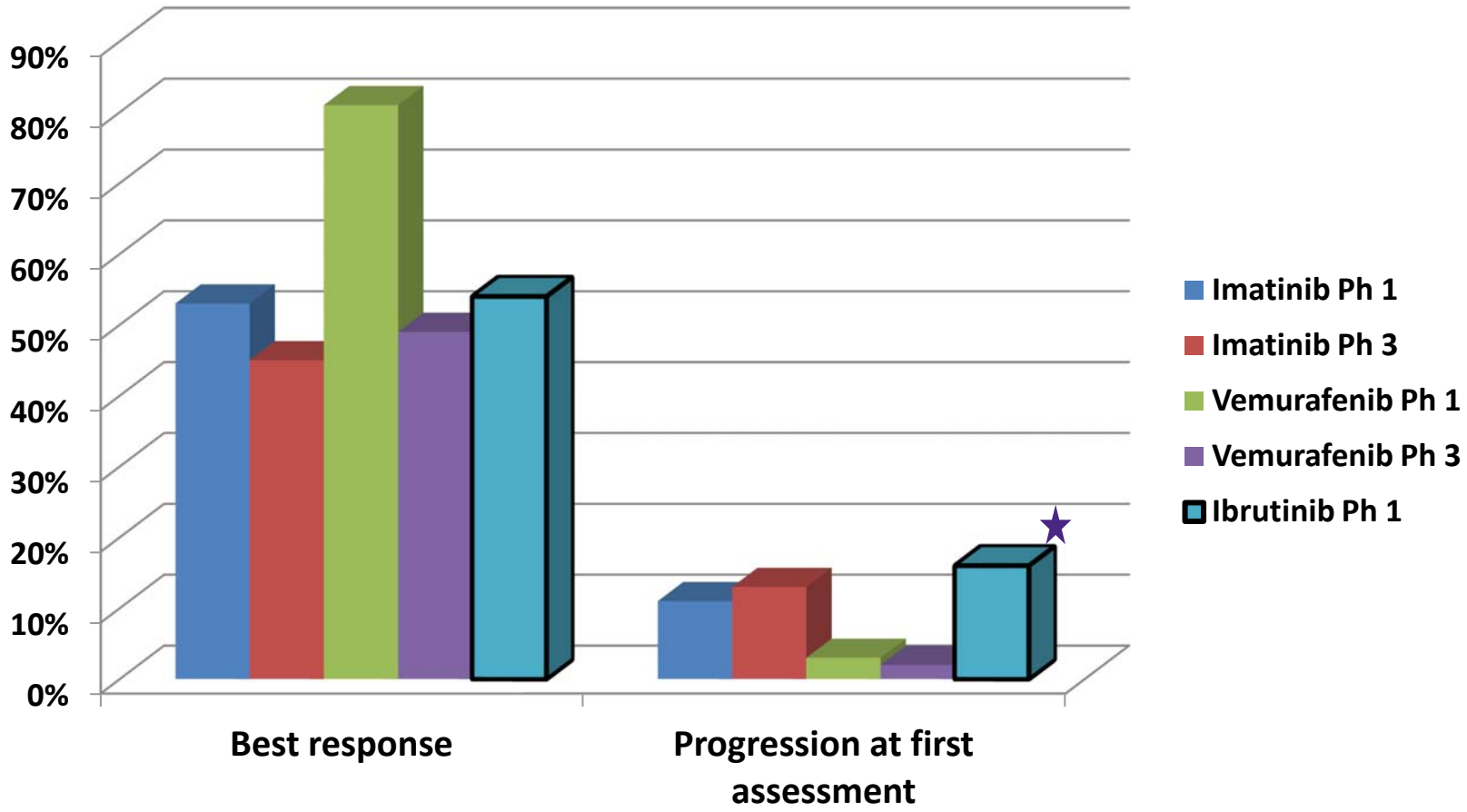
- Chris H. Takimoto, MD, PhD, Vice President, Translational Medicine Early Development, Oncology Therapeutic Area, Janssen
- Greg Plowman, MD, PhD VP Oncology Research, Eli Lilly
- Pamela Carroll, PhD, Vice President, Oncology, Innovation Center, Janssen
- Dirk Jan Reitsma, MD, Vice President, Global Product Development Head, Oncology, PPD

CANCER PROGRESS by Defined Health

Cancer Progress: Translational Oncology

Dirk Reitsma, M.D. VP, Global Product Develoment

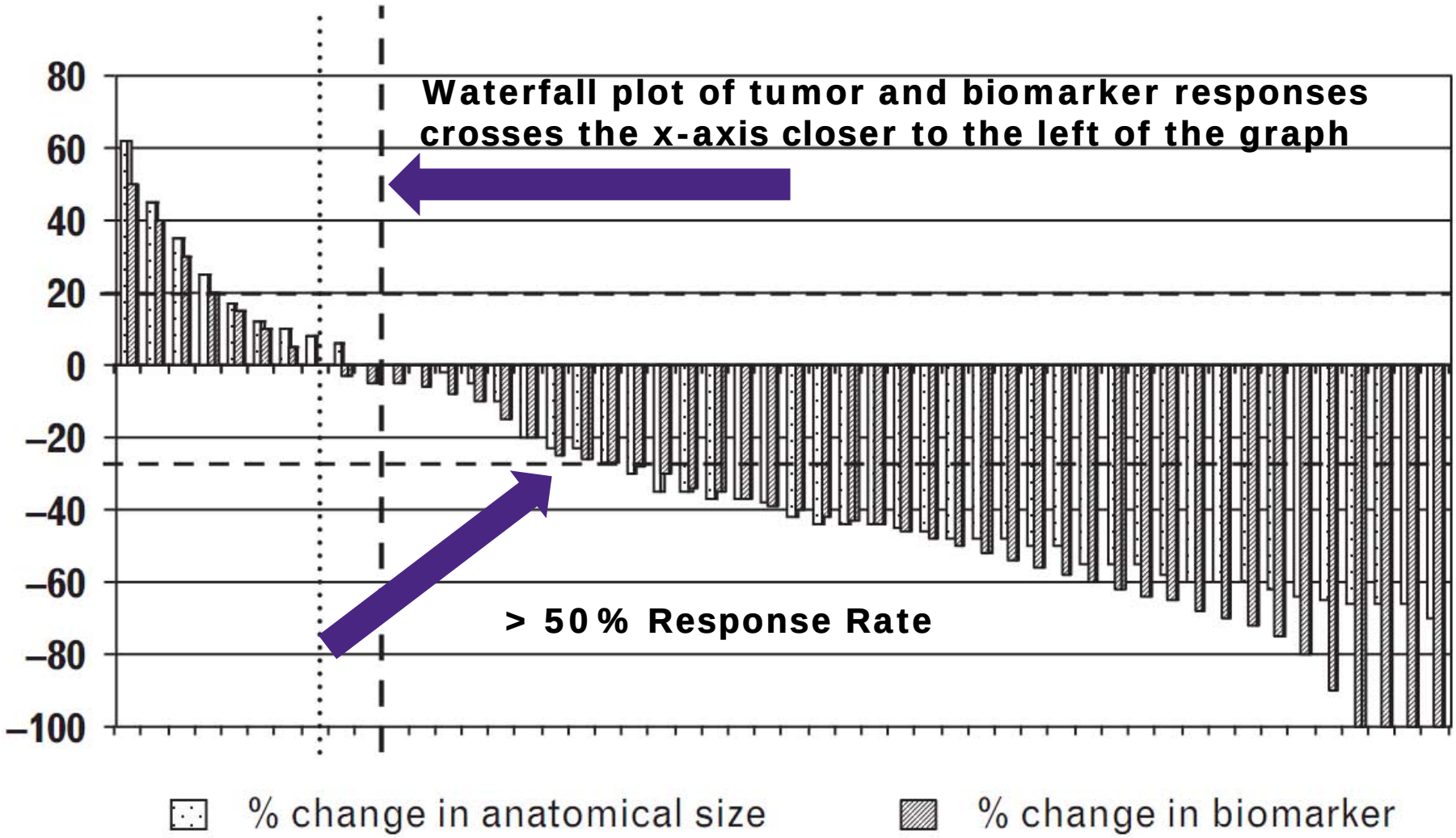
Translation from Phase 1 to 3



★16% progression at first assessment among ITT, 3 were in initial dose cohort

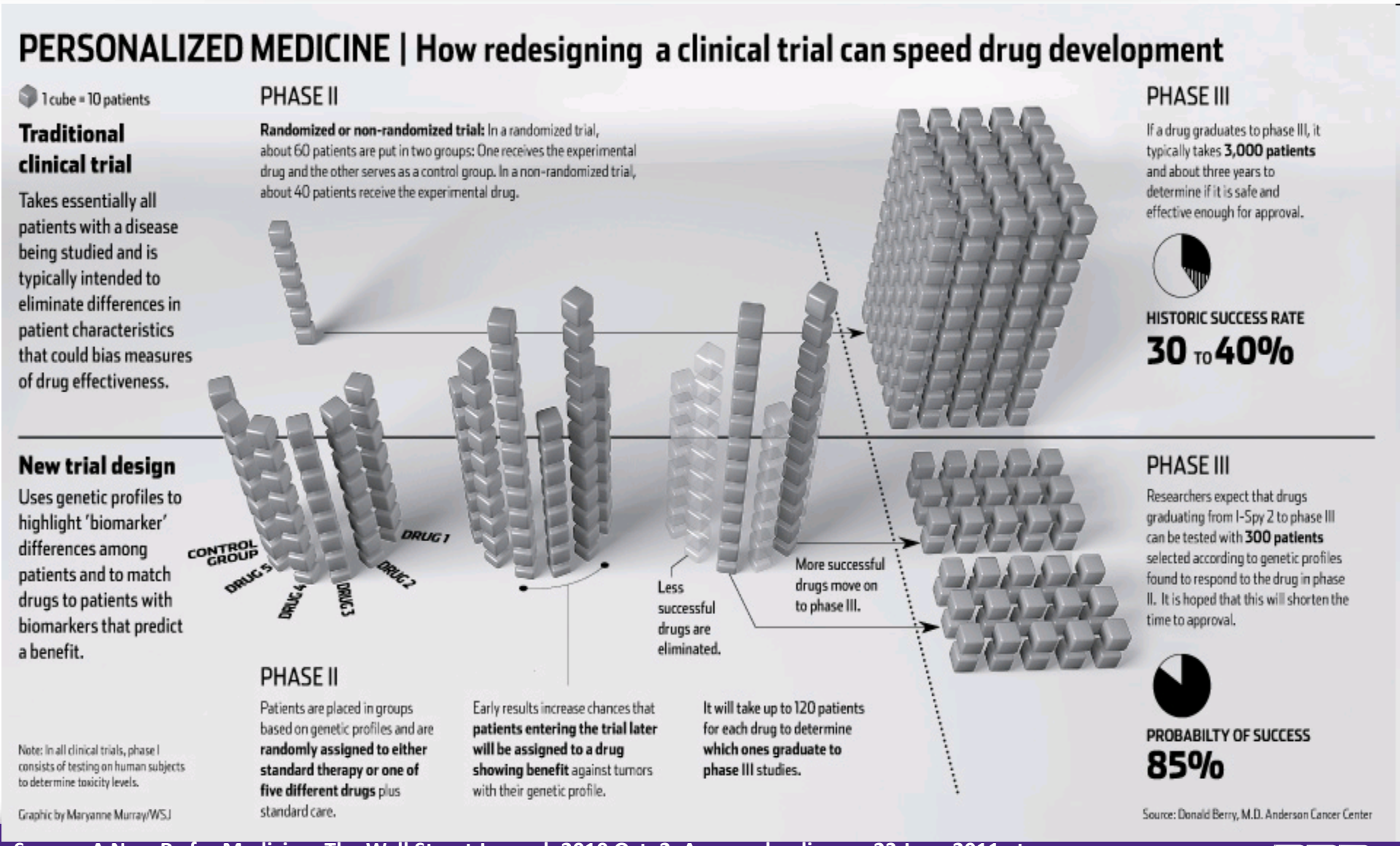
Sources: Adapted from Verweij, Curr Opin Oncol 2012, 24:332–337
Advani RH et al, JCO. 2013

Dual Waterfall-plot



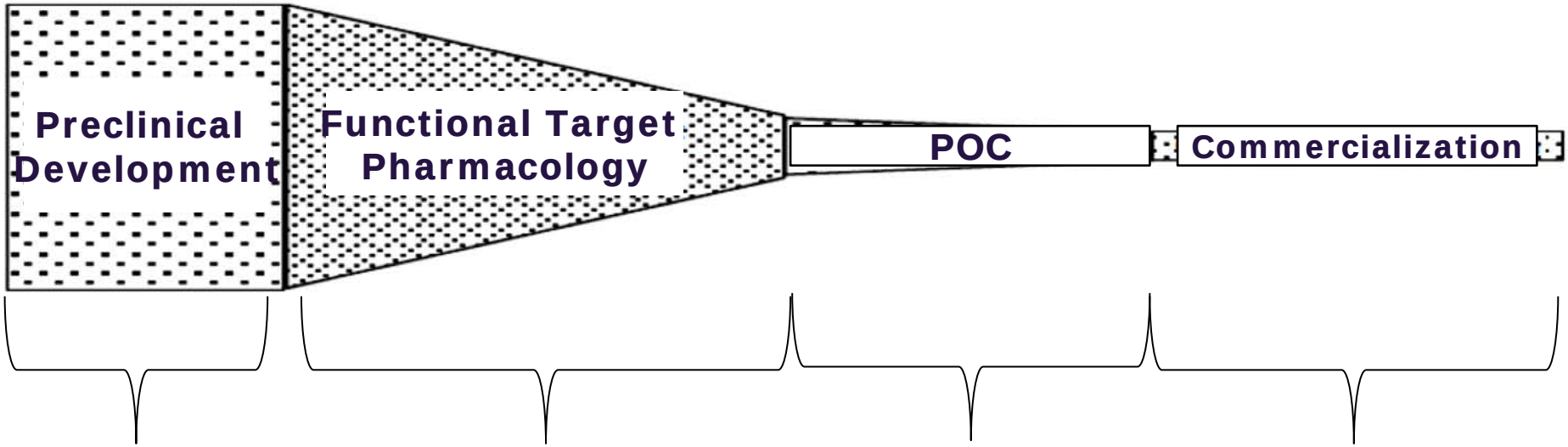
Source: Verweij, Curr Opin Oncol 2012, 24:332–337

I-SPY Trial Design



Source: A New Rx for Medicine. The Wall Street Journal. 2010 Oct. 2. Accessed online on 23 June 2011 at: http://online.wsj.com/article/SB10001424052748703882404575520190576846812.html

Streamlined Investigational Product Development



Establish Proof of Mechanism	Detect activity in biomarker enriched population	Phase III POC in selected population	Post-approval safety and efficacy studies
Verify that the target in question drives the malignancy	RR ≥ 50% & Progression rate at first assessment < 15%	Clinically relevant outcomes allow for significantly reduced sample sizes	Required in order to obtain early registration

Source: Verweij J, *Curr Opin Oncol*. 2012

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