

# 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

The logo features the words "CANCER" and "PROGRESS" in a bold, black, sans-serif font. "CANCER" is positioned above "PROGRESS". Below "PROGRESS" is the tagline "by Defined Health" in a smaller, italicized, black font. The entire text is overlaid on a large, light blue, tilted oval shape.

**CANCER**  
**PROGRESS**  
*by Defined Health*

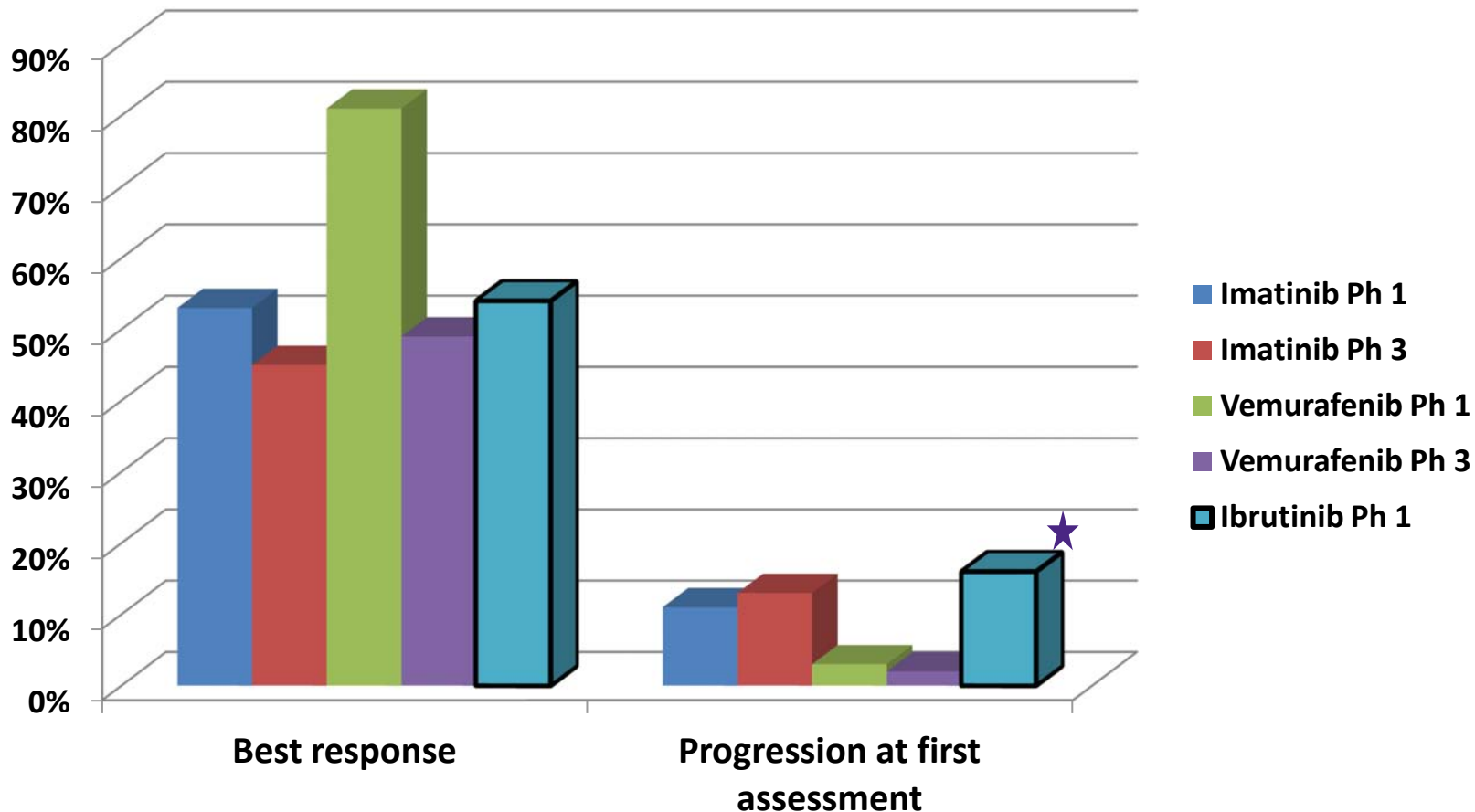


## Cancer Progress: Translational Oncology

**PPD**<sup>®</sup>

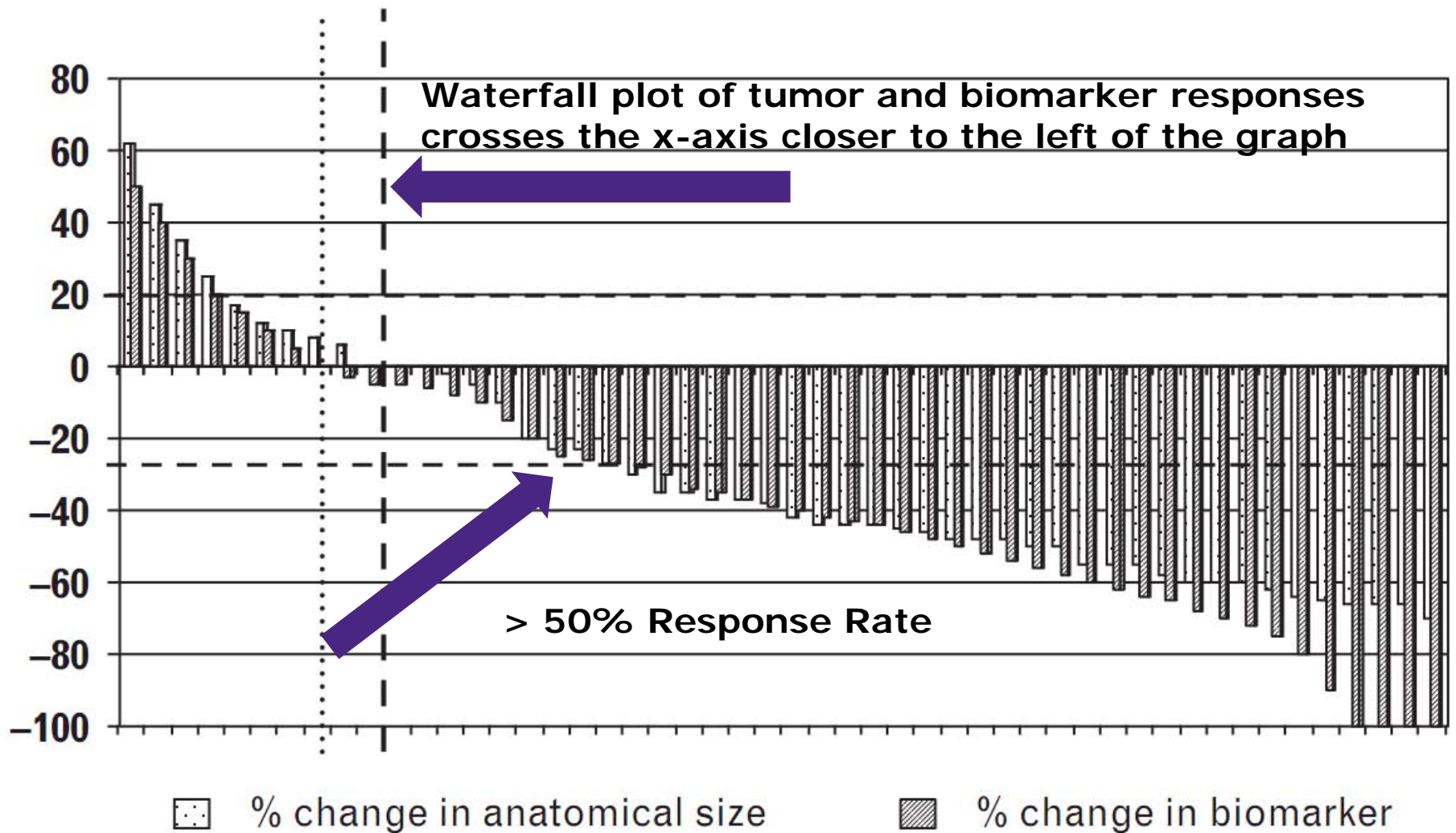
Dirk Reitsma, M.D. VP, Global Product Development

# Translation from Phase 1 to 3



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

# Dual Waterfall-plot





# I-SPY Trial Design

## PERSONALIZED MEDICINE | How redesigning a clinical trial can speed drug development

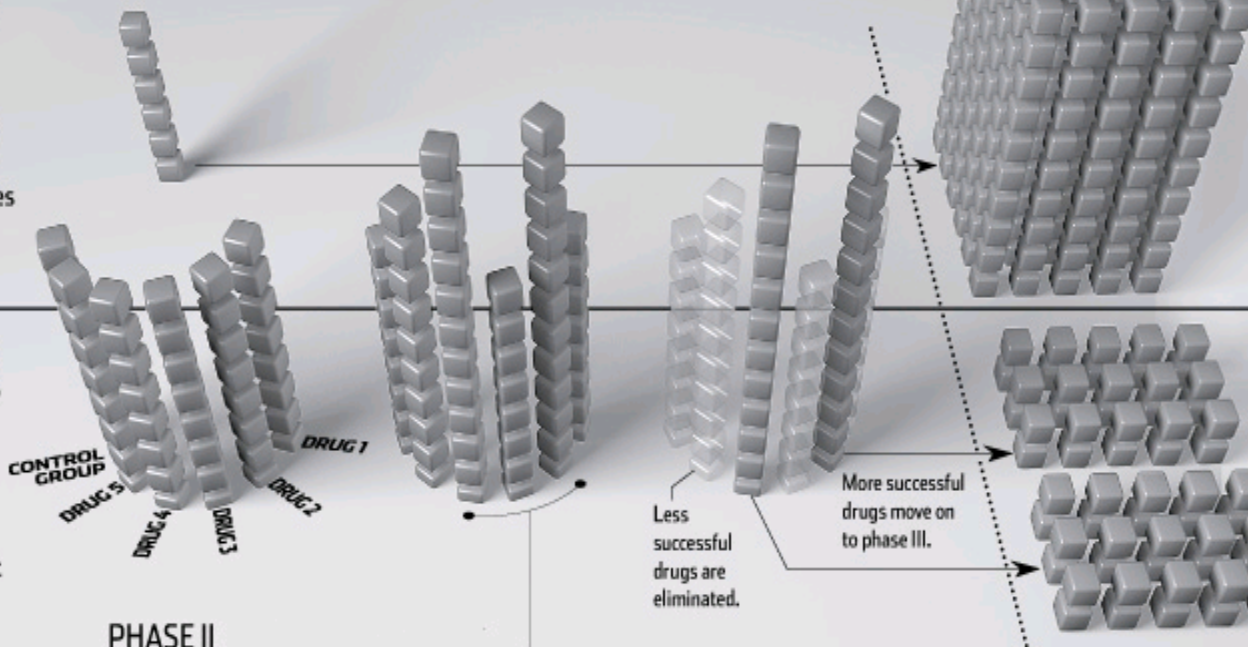
1 cube = 10 patients

### Traditional clinical trial

Takes essentially all patients with a disease being studied and is typically intended to eliminate differences in patient characteristics that could bias measures of drug effectiveness.

### PHASE II

**Randomized or non-randomized trial:** In a randomized trial, about 60 patients are put in two groups: One receives the experimental drug and the other serves as a control group. In a non-randomized trial, about 40 patients receive the experimental drug.



### PHASE III

If a drug graduates to phase III, it typically takes **3,000 patients** and about three years to determine if it is safe and effective enough for approval.



HISTORIC SUCCESS RATE  
**30 TO 40%**

### New trial design

Uses genetic profiles to highlight 'biomarker' differences among patients and to match drugs to patients with biomarkers that predict a benefit.

### PHASE II

Patients are placed in groups based on genetic profiles and are **randomly assigned to either standard therapy or one of five different drugs** plus standard care.

Early results increase chances that **patients entering the trial later will be assigned to a drug showing benefit** against tumors with their genetic profile.

It will take up to 120 patients for each drug to determine which ones graduate to phase III studies.



### PHASE III

Researchers expect that drugs graduating from I-Spy 2 to phase III can be tested with **300 patients** selected according to genetic profiles found to respond to the drug in phase II. It is hoped that this will shorten the time to approval.



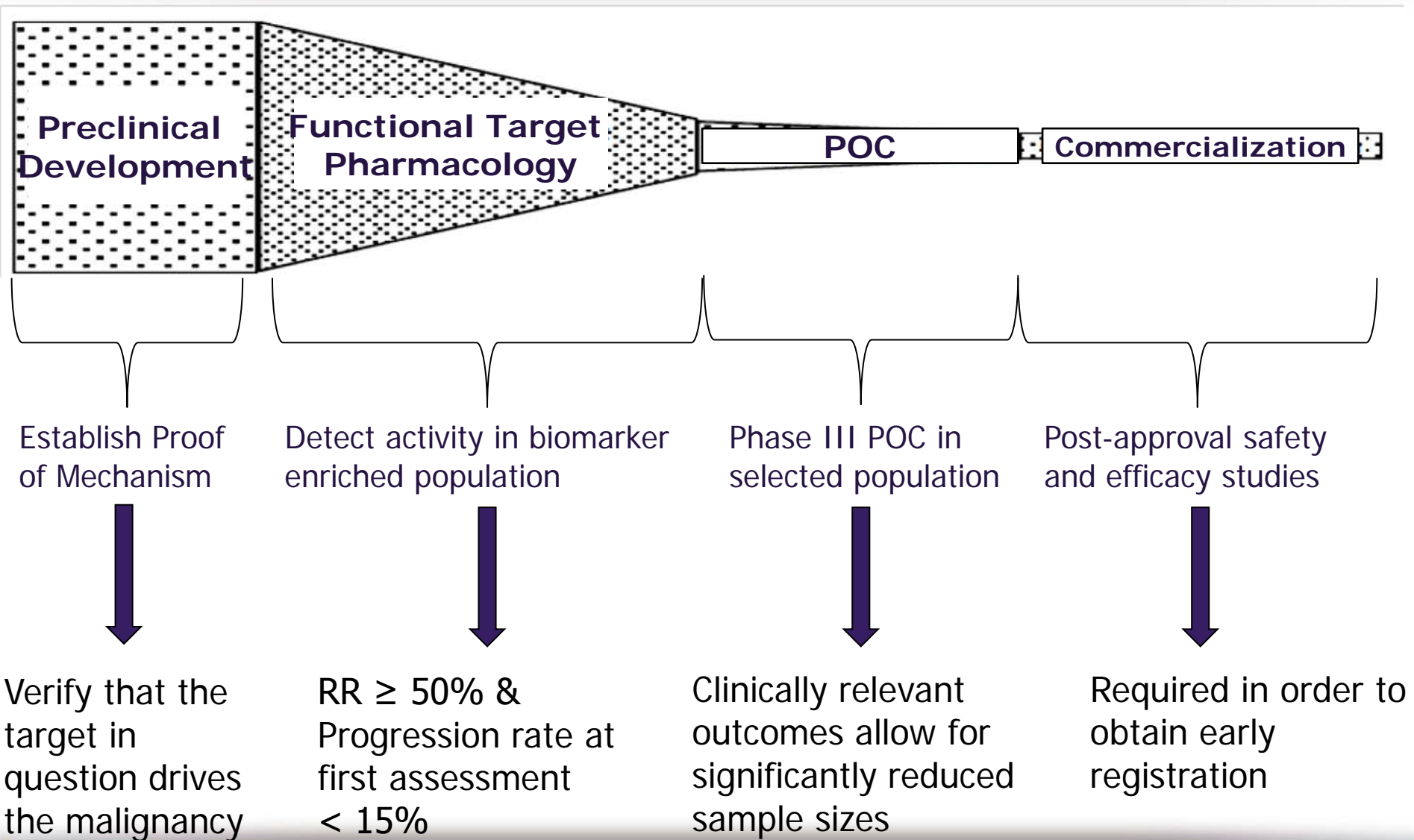
PROBABILITY OF SUCCESS  
**85%**

Note: In all clinical trials, phase I consists of testing on human subjects to determine toxicity levels.

Graphic by Marianne Murray/WSJ

Source: Donald Berry, M.D. Anderson Cancer Center

# Streamlined Investigational Product Development



# 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

The logo features the words "CANCER" and "PROGRESS" in a bold, black, sans-serif font. "CANCER" is positioned above "PROGRESS". Below "PROGRESS" is the tagline "by Defined Health" in a smaller, italicized, black font. The text is overlaid on a large, light blue, tilted oval shape that serves as a background for the logo.

**CANCER**  
**PROGRESS**  
*by Defined Health*