

BRING THE PROTOCOL  
TO THE PATIENT



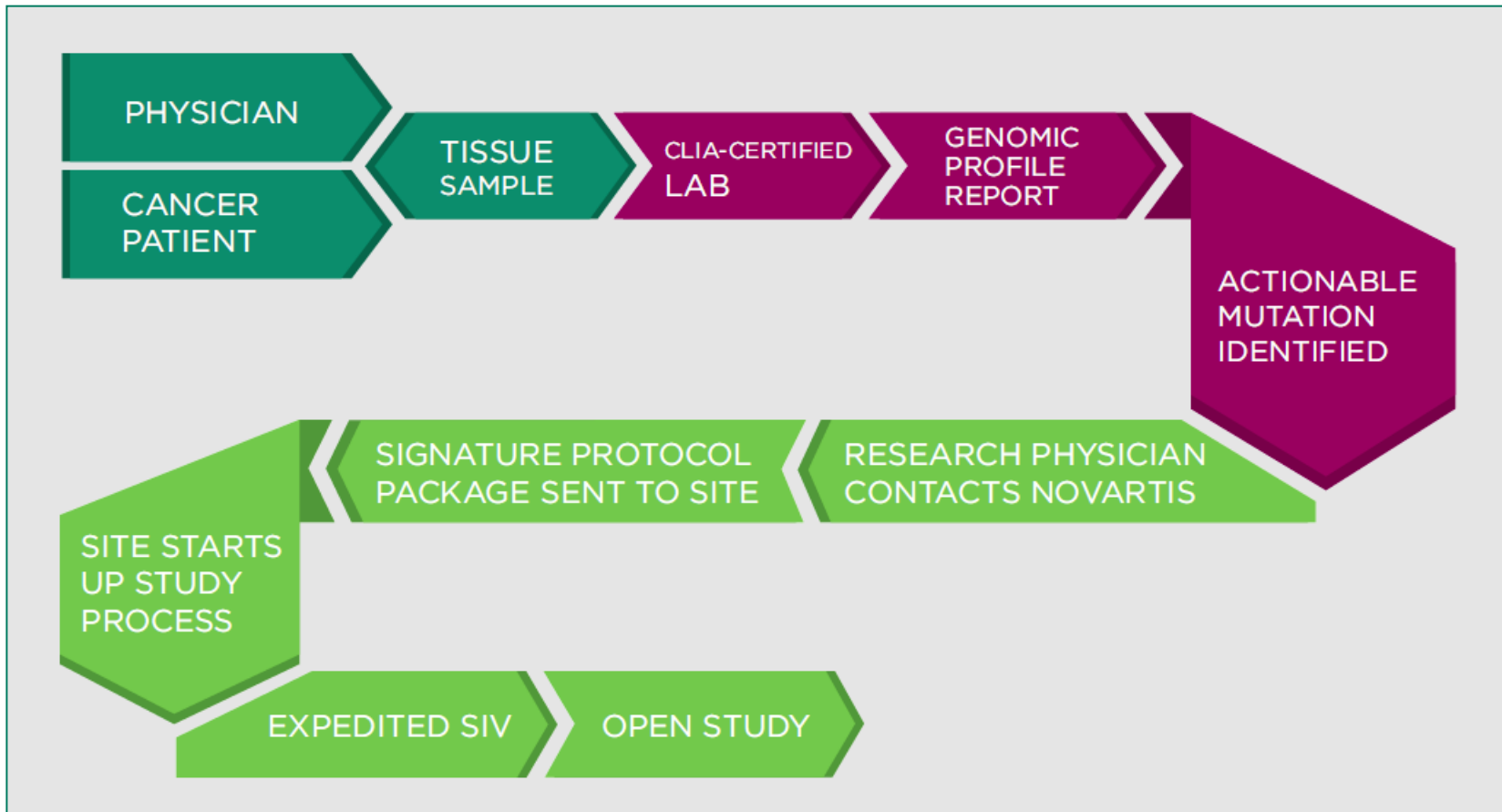
 *Signature*

**Protocol to Patient (P<sub>2</sub>P)**

**Cancer Progress by Defined Health**  
New York, NY | March 17-18, 2015

 **NOVARTIS**  
ONCOLOGY

# Signature Trial Workflow



# Signature (P2P) Program Study Schema

N= 70-100/protocol

Solid tumors or heme malignancy pts with allowed genetic aberration

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## Primary Objective:

- Clinical benefit rate (CR+PR+SD @ 16 wks)

## Secondary Objective:

- Overall Response (PR or better)
- PFS
- OS
- Safety & tolerability

## Exploratory Objectives

- Pathway activation and response



- ▲ Biopsy or Archival Tissue
- ▲ Mutational analysis (anytime during the trial)

- Adaptive patient sparing statistics design in pre-selected patients based on genetic aberrations
- 70-100 pts /protocol (approx. 800-1000 pts total for program).
- Non competing with ongoing Novartis Sponsored trial

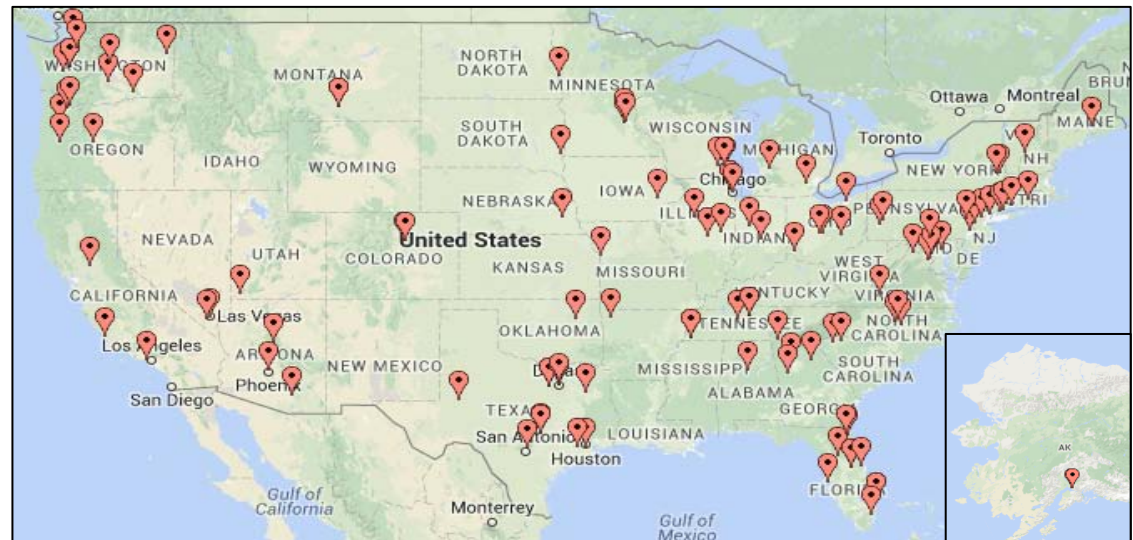
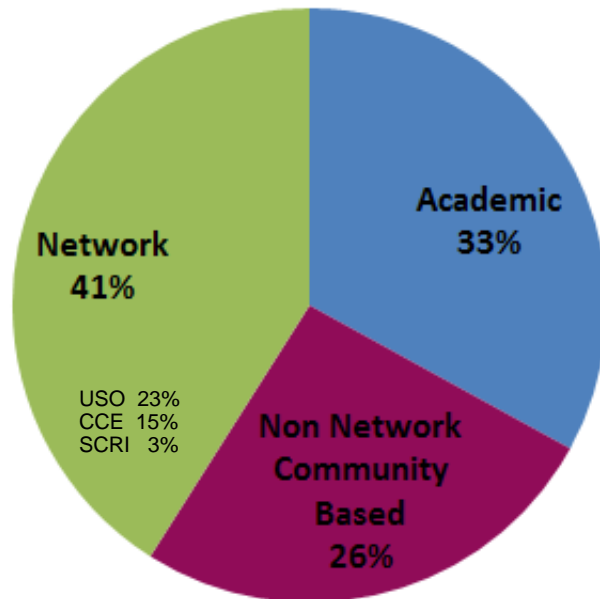


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# Site Metrics

*Broad participation from many research customer categories*

- 218 open sites across 8 protocols; 289 patients dosed
- 5.7 week average time to initiate a site (including academic centers) vs. 34 week industry average
- Eliminates approximately 30% non-enrolling sites (Novartis historical internal data)



(As of 15Oct2014)