Current Status and Lessons Learned From the Implementation of the SWOG Lung Master Protocol:

S1400 LUNG-MAP

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Outline

- Overview of Lung-MAP
- Round One
- Overview of changes
- Where are we now?
- Lessons learned

Overview of Lung-MAP

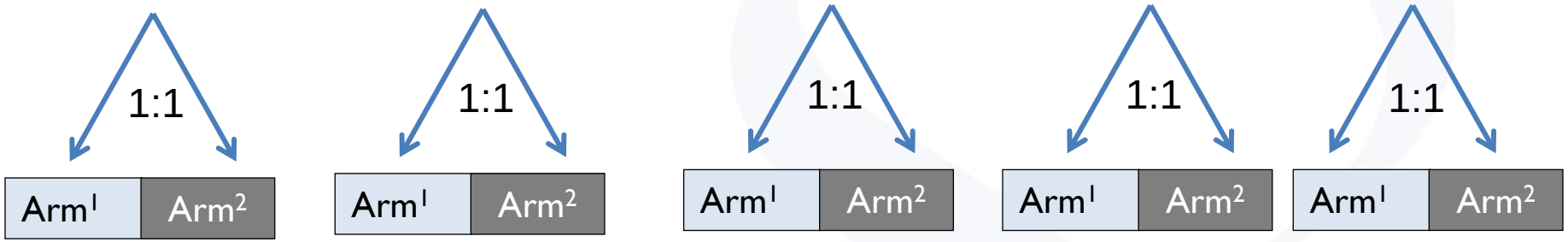
- Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer
- Public-private collaboration

Study Activated June 16, 2014

Lung-MAP: Round One

S1400 Screening:
FMI NGS/MET IHC

Non-match	PI3K	CDK4/6	FGFR	HGF
(Anti-PD-L1)	*PIK3CA mut*	*CCND1, CCND2, CCND3, cdk4 ampl*	*FGFR ampl, mut, fusion*	*c-Met Expr*



[1] MEDI4736 [2] Docetaxel	[1] GDC-0032 [2] Docetaxel	[1] Palbociclib [2] Docetaxel	[1] AZD4547 [2] Docetaxel	[1] Rilotumumab + erlotinib [2] Erlotinib

Study Design and Objectives

Design:

Independently conducted and analyzed parallel Phase II/III studies

Primary Objectives within each sub-study:

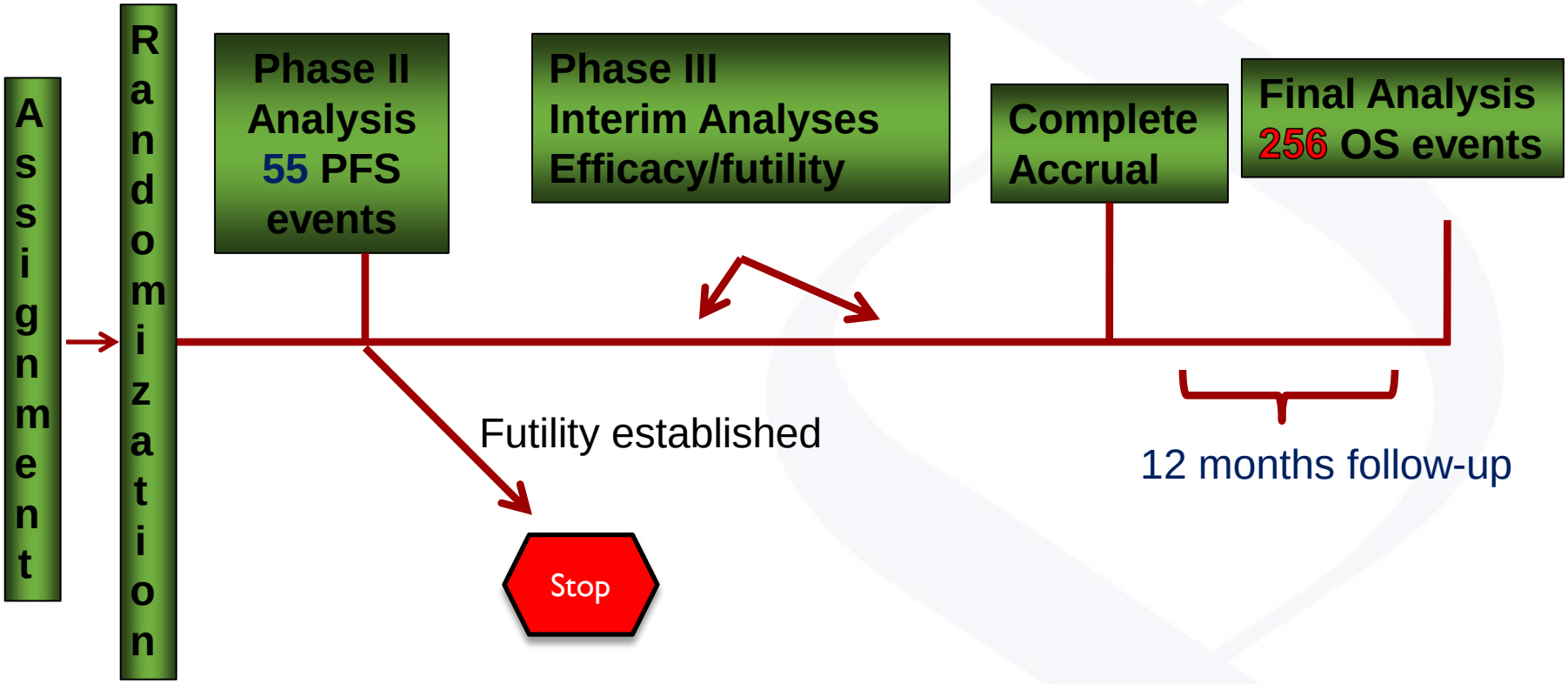
Phase II Component:

1. To evaluate if there is sufficient evidence to continue to the Phase III component by comparing progression-free survival (PFS) between patients randomized to experimental therapy versus SoC.

Phase III Component:

1. To determine if there is both a statistically and clinically-meaningful difference in PFS between the treatment arms.
2. To compare overall survival (OS) between treatment arms.

Study Design Within Each Sub-study



LUNG-MAP

Leading cancer research. **Together.**

SWOG

Some News…

Nov. 24, 2014

Amgen Announces Termination Of All Amgen-Sponsored Clinical Studies Of Rilotumumab In Advanced Gastric Cancer

THOUSAND OAKS, Calif., Nov. 24, 2014 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the termination of all Amgen-sponsored clinical studies of rilotumumab in advanced gastric cancer, including the Phase 3 RILOMET-1 and RILOMET-2 studies. Amgen's decision is based on a planned safety review by the RILOMET-1 independent data monitoring committee that found an increase in the number of deaths in the rilotumumab and chemotherapy treatment arm when compared to the chemotherapy treatment only arm. Protocol-defined futility criteria would likely have been met at the planned interim analysis, scheduled for March 2015. Detailed results of RILOMET-1 will be submitted for presentation and publication.

"While we are disappointed with these results, we will work with lead investigators to further analyze the

More News…

Bristol-Myers Squibb

FDA Approves Opdivo (nivolumab) for the Treatment of Patients with Previously Treated Metastatic Squamous Non-Small Cell Lung Cancer

Opdivo is the first and only immuno-oncology therapy proven to extend survival in patients treated with one prior therapy

CheckMate -017 achieved the benchmark goal of improving overall survival in previously treated squamous non-small cell lung cancer (NSCLC)

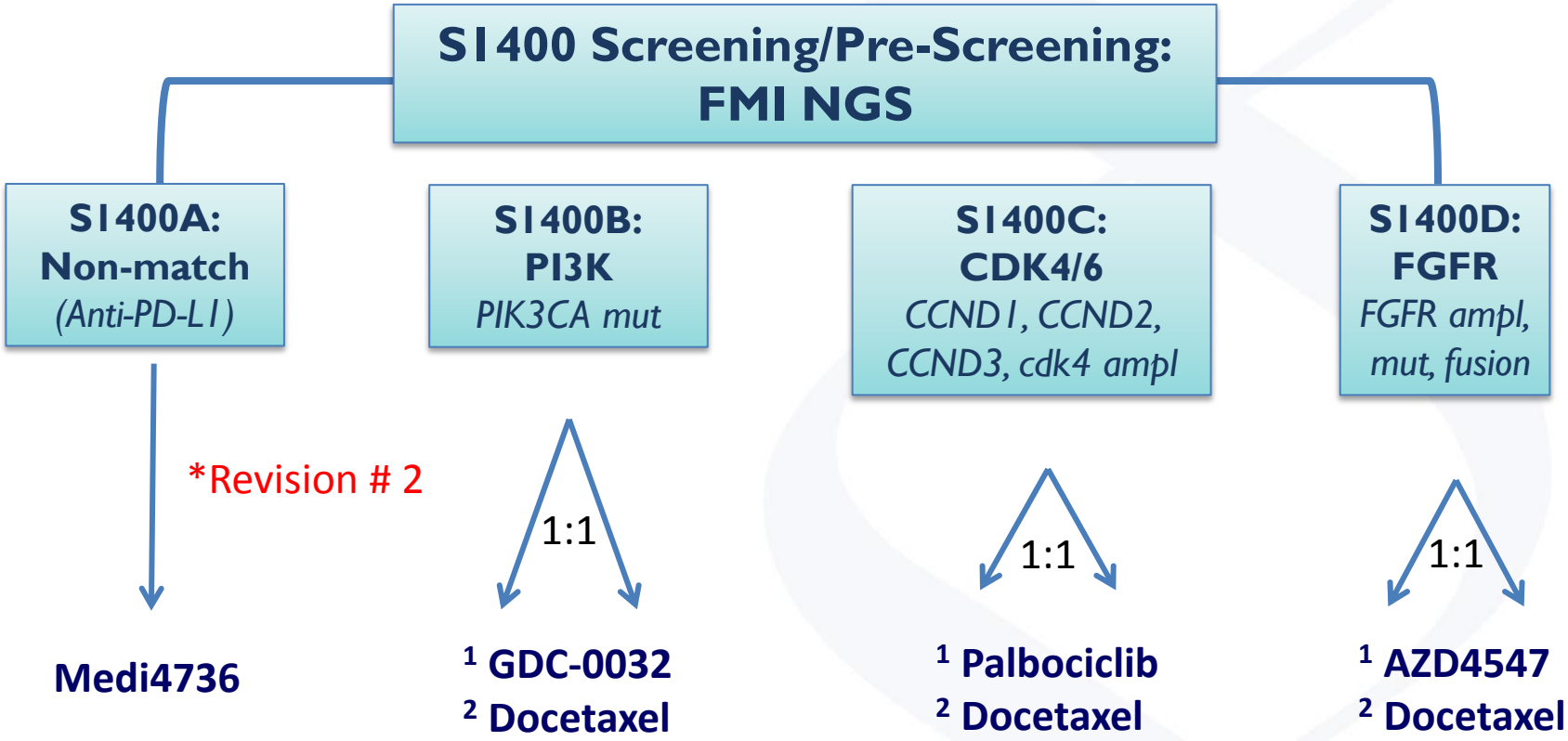
Wednesday, March 4, 2015 4:13 pm EST

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that the U.S. Food and Drug Administration (FDA) has approved *Opdivo* (nivolumab) injection, for intravenous use, for the treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. *Opdivo* is the first and only PD-1 (programmed death receptor-1) therapy to demonstrate overall survival in previously treated metastatic squamous NSCLC. *Opdivo* demonstrated significantly superior overall survival (OS) vs.

Overview of Changes

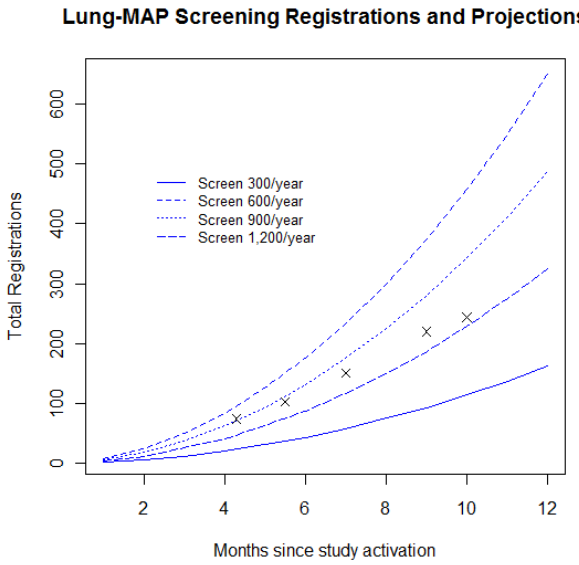
- Closure of S1400E (November 2014)
- Revision # 1 (January 2015)
  - Eligibility clarifications
  - Relaxation of timing from study assignment to registration
- Revision # 2 (Expected May 2015)
  - Allow 2nd and greater lines of therapy
  - Add in pre-screening during 1st line therapy
  - S1400A design modification to single arm

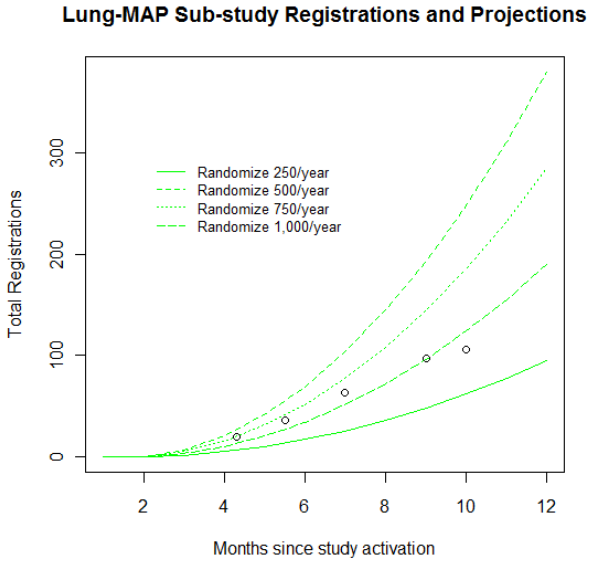
Updated Trial Schema



Accrual

Since June 16, 2014	N
S1400	270
Sub-study Assignments	221
S1400A (non-match)	73
S1400B (PI3K)	9
S1400C (CD4/6)	21
S1400D (FGFR)	10
S1400E (HGF/c-MET)	9
Total Sub-study accruals	122





Lessons Learned

- Adaptability
- Cooperation among partners
- Central Institutional Review Board (CIRB)
- Efficiencies gained are for the **patient**