Retrospective FDA Submission: Lessons Learned and Moving Forward for S0777

S0777: A RANDOMIZED PHASE III TRIAL OF LENALIDOMIDE AND LOW DOSE DEXAMETHASONE (LLD) VERSUS BORTEZOMIB, LENALIDOMIDE AND LOW DOSE DEXAMETHASONE (BLLD) FOR INDUCTION, IN PATIENTS WITH PREVIOUSLY UNTREATED MULTIPLE MYELOMA

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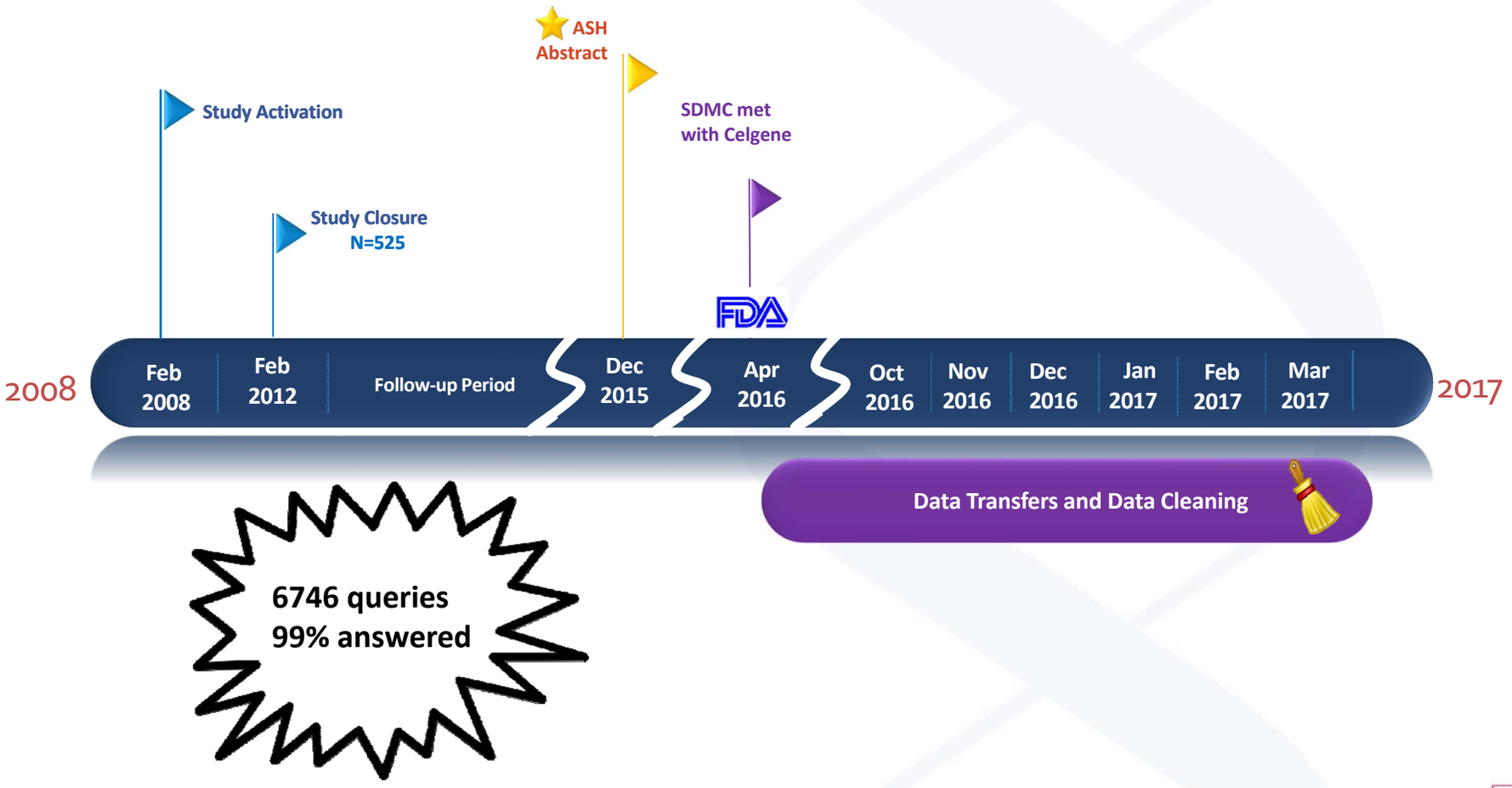
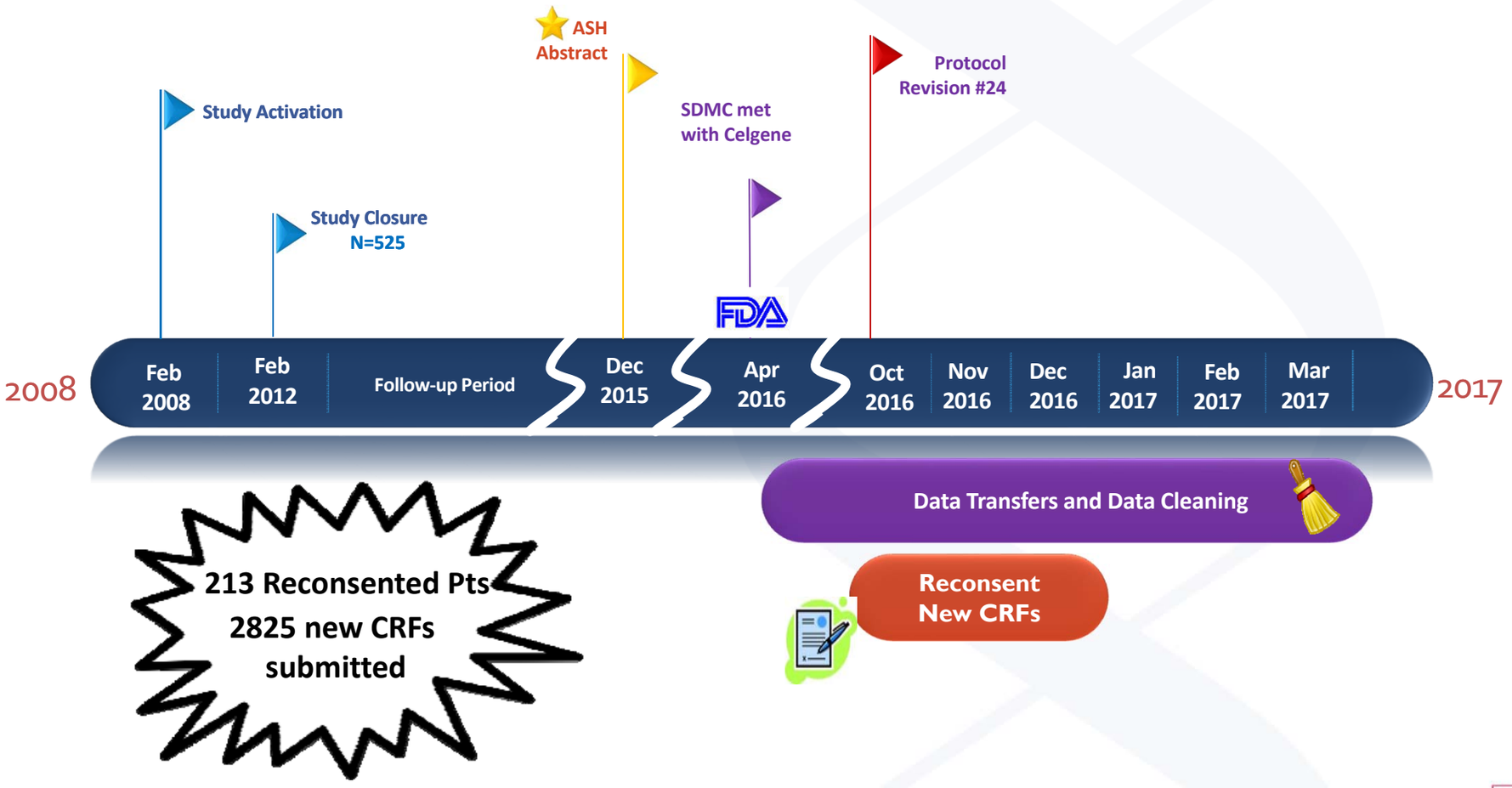
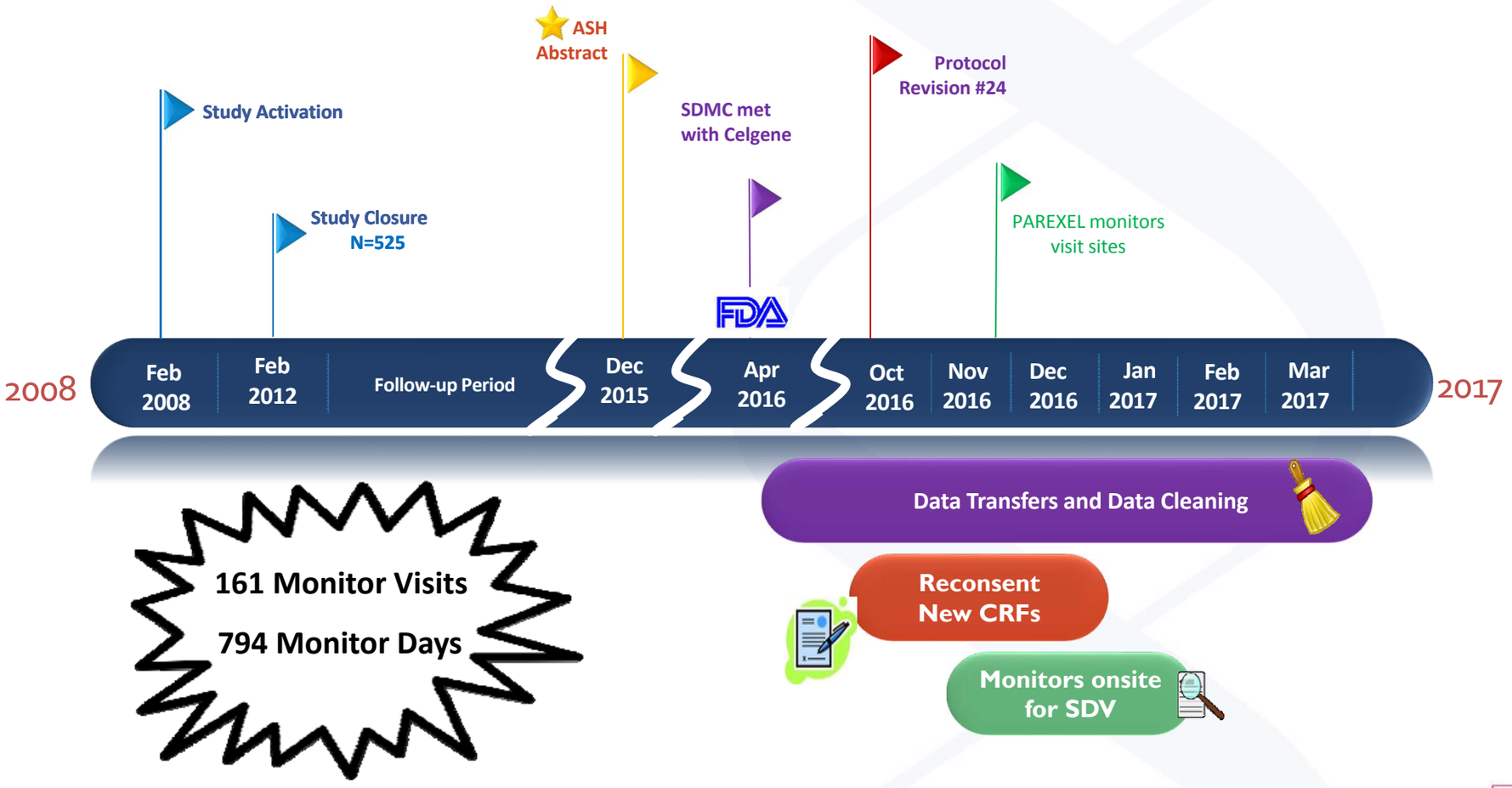
S0777 Timeline



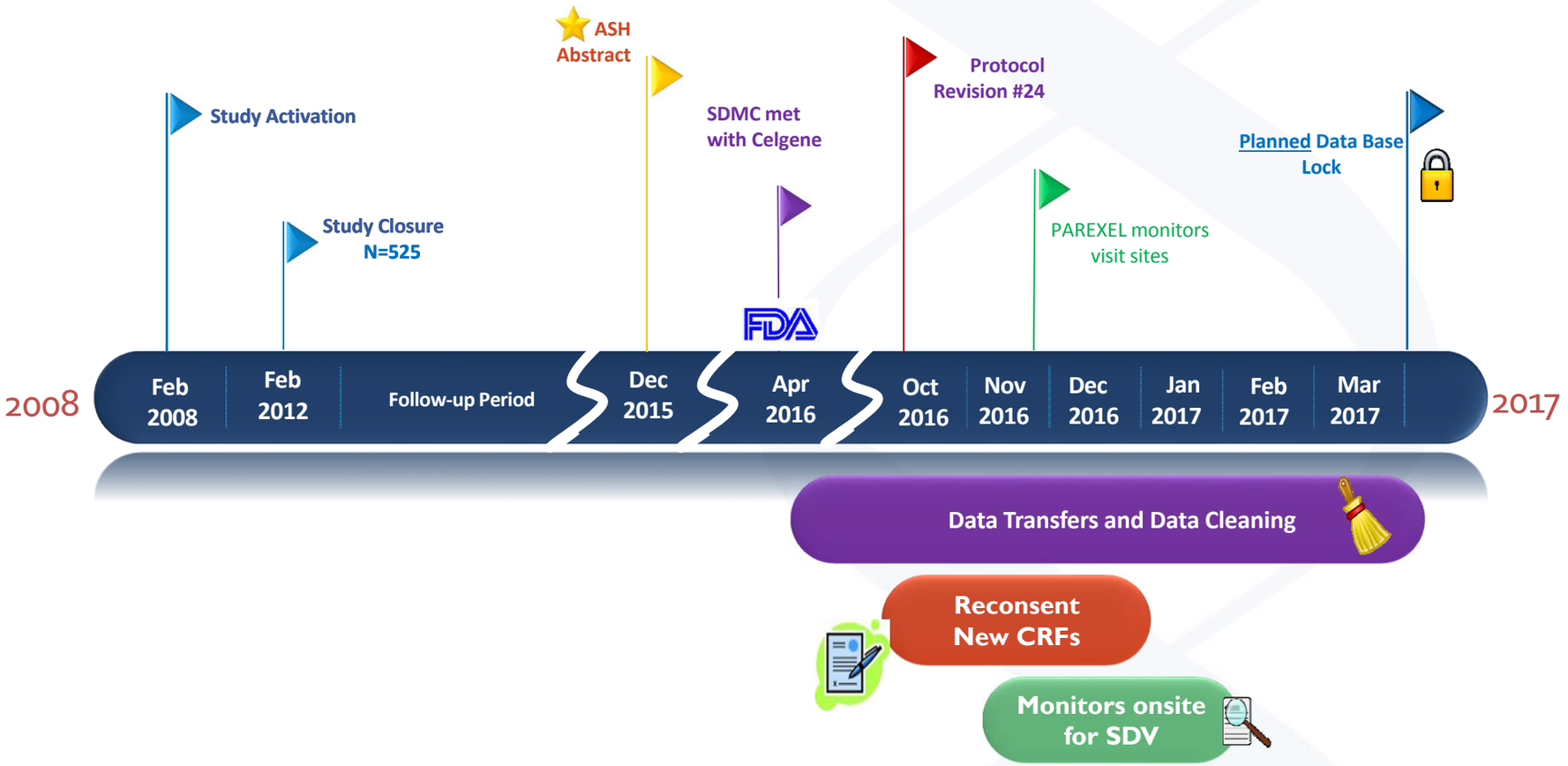
S0777 Timeline



S0777 Timeline



S0777 Timeline



What changed?

- Mid-March the FDA saw preliminary data
- Difference between how SWOG and FDA define PFS (primary endpoint)
- Although this was run under the NCI and SWOG standards, FDA will re-analyze the primary endpoint according to their standards
- For successful submission we need more…

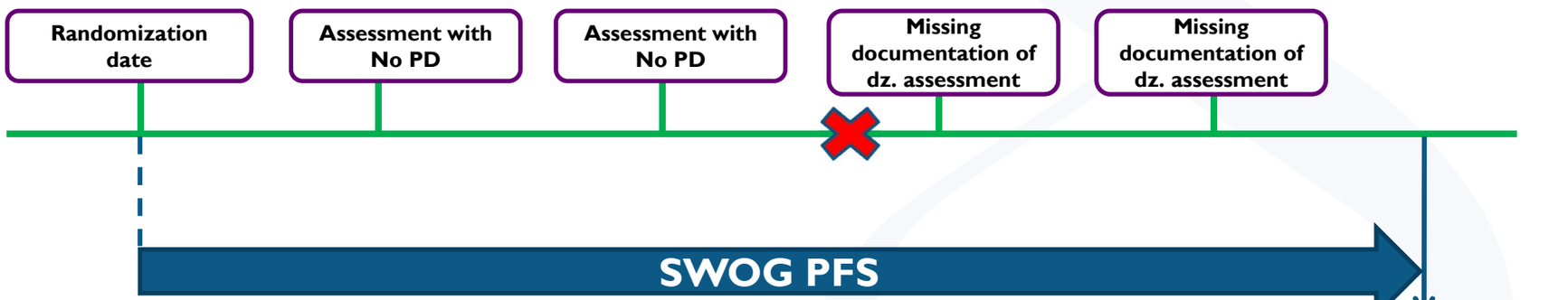
Progression-Free Survival (FDA vs SWOG)

Original protocol asked for disease assessment forms (*Baseline and Follow-up Tumor Assessment*) completed every 3 months until end of protocol treatment.

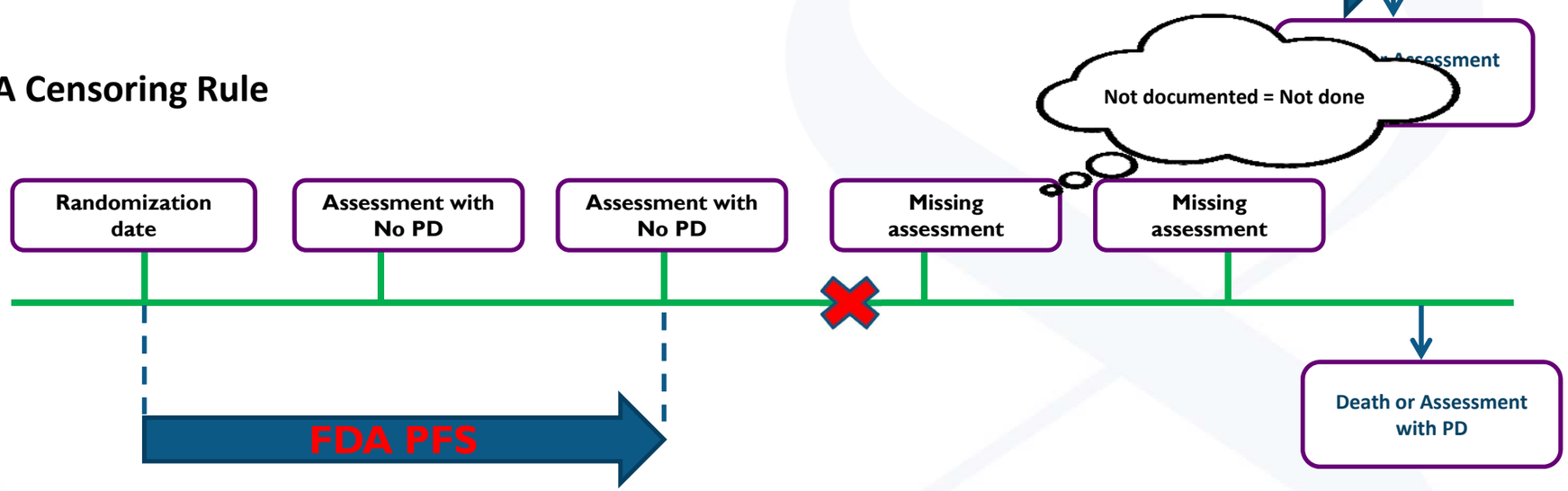
If no progression was documented at time patient came off treatment, *Follow-Up Form* captured progression with (1) YES/NO and (2) Date of Progression (no *BFTA* forms required).

Progression-Free Survival (FDA vs SWOG)

SWOG (and EMA) Censoring Rule



FDA Censoring Rule



What's next?

- For approximately 250 patients, we will query for completed BFTA forms for any and all disease assessments until the patient progresses.
- Parexel CRAs will return to sites and help identify any missing assessments to be submitted.
- Sites will need to enter BFTA forms before Parexel CRAs depart.
- Myeloma patients world-wide will hopefully have access to additional treatment choices.

60 Day Timeline for Additional Data Collection

- Sites to be notified now of cases requiring new data collection
- Webinar mid-May
- Parexel CMAs to begin scheduling visits in next few weeks
- Parexel CRAs on site one or more days (depends on the number of cases requiring additional data collection)

Special Thanks to the Following People

Katie A. - Michigan

Mary S. - Nevada

Mariann G. - Texas

Everyone!

For working toward the common goal of presenting quality data to the FDA to improve treatment choices for myeloma patients around the globe


Thank
you
for
everything