

Meeting Enrollment Goals in a Competitive Environment:

Development, Implementation &
Monitoring of Site Patient Recruitment
& Enrollment Plans

Presenter

Jacqueline Zarro, Ph.D.

Vice President

Clinical Project Management - US

Premier Research Group Limited

United States



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Topics

- Basis for Meeting Enrollment Goals
 - Foundation and Tools
- Recruitment and Enrollment Plan
 - Site Specific
- Maximize Enrollment
 - Tracking and Additional Tools



Enrollment Statistics

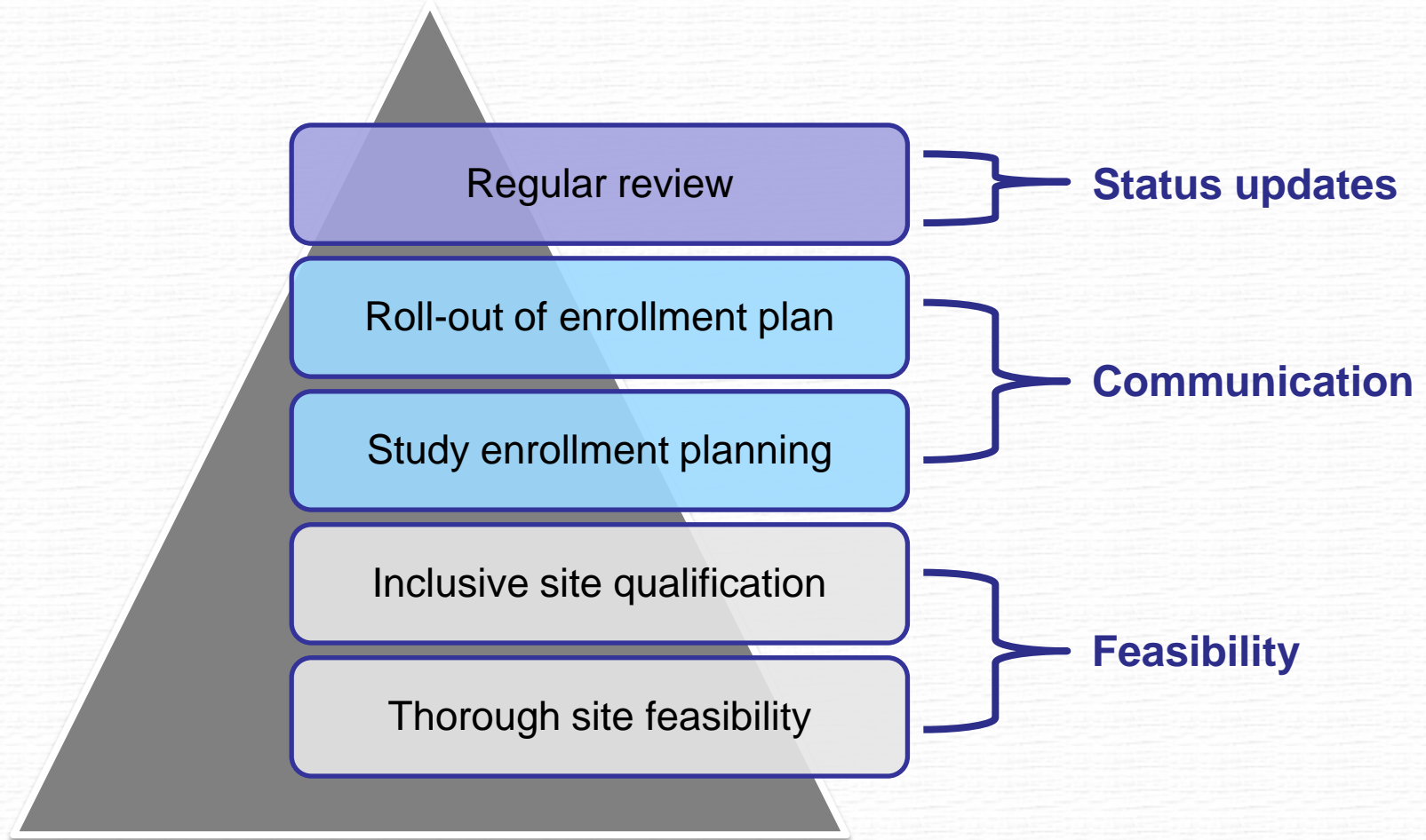
Statistics show most clinical trial delays are a result of poor enrollment:

- More than 70% of U.S. and 55% of European clinical sites reported delays of more than one month beyond contracted enrollment timelines
- Only 7% of U.S. and 18% of European sites reported meeting enrollment timelines (U.S. down from 10% in 2005)
- Delays also occurring at high rates in other regions of the world

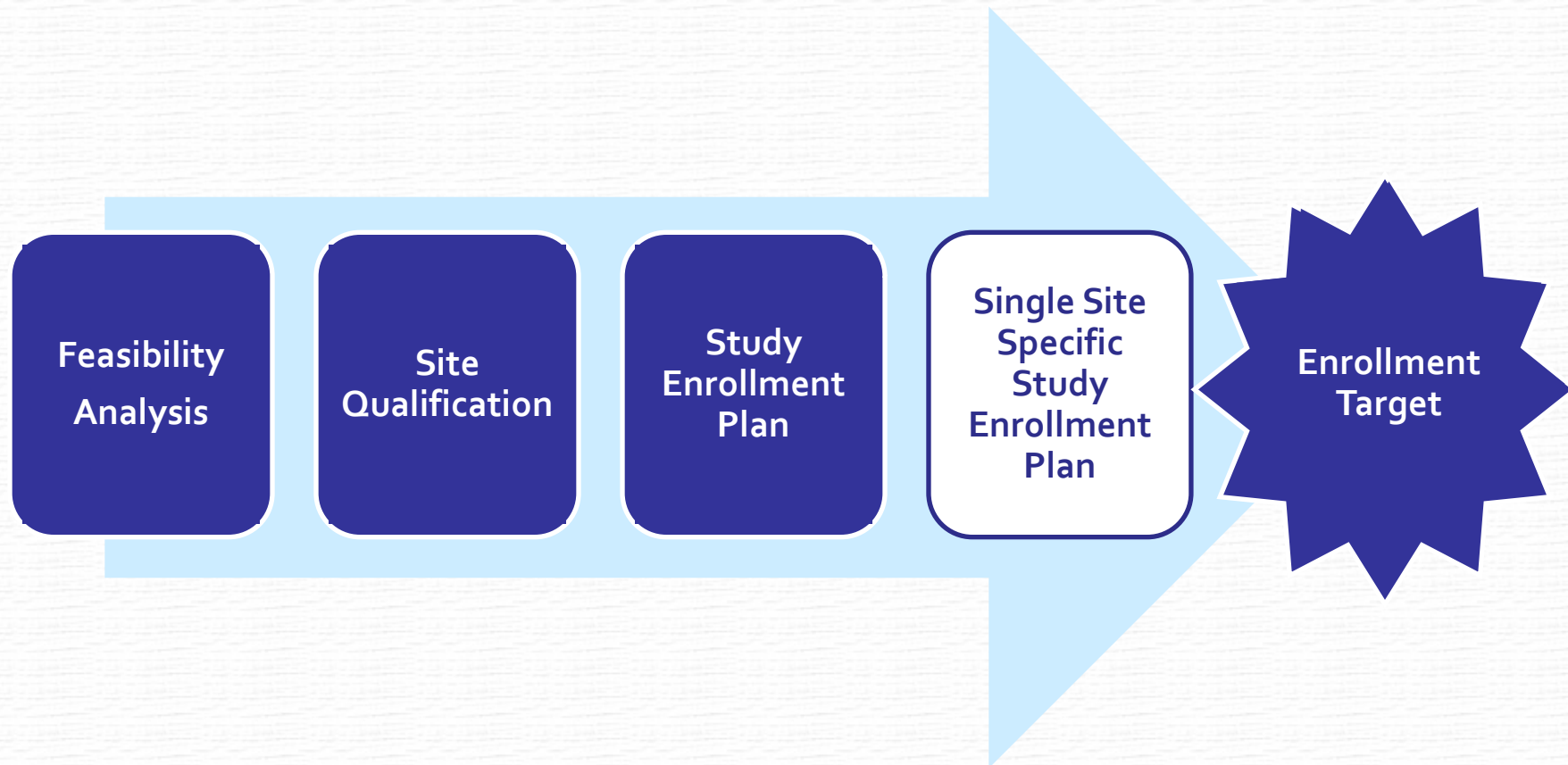
* 2007 CenterWatch Survey Results



Basis for Meeting Enrollment Goals: *Foundation to Enrollment Success*



Basis for Meeting Enrollment Goals: *Tools*



Recruitment and Enrollment Plan: Single Site Specific Study Enrollment Plan

Development Plan (Site Enrollment Strategy) (week)

Develop Sites and the plan to:

Site Name: _____ Site ID: _____
 Site Address: _____ Contact Name: _____

Site Name for this study is complete. This information is required for the study. This information will be used to identify the study.

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Site Enrollment Strategy

Do you have a plan to recruit a specific number of subjects? Yes No

If you have a plan, how many do you expect to enroll by _____?

In regards to subject recruitment, (what percentage of) overall potential sites will be used to recruit the study?

Direct: _____ %
 Indirectly: _____ %
 Other: _____ (please specify) _____

Site Enrollment Strategy

Do you anticipate having been identified as a site? Yes No

If Yes, how much time will be needed to recruit to the database system. This is due to your potential subjects?

If No, how long will be required to recruit to the database system. This is due to your potential subjects?

Based on current information, is it anticipated that the above will be completed?

If Yes, please list the information below:

Site	Site to be Recruited	Expected Date of Enrollment	Additional Comments

Development Plan (Site Enrollment Strategy) (week)

Do you have a plan to recruit a specific number of subjects to: _____

Site Enrollment Strategy

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Recruitment and Enrollment: *Site Specific Plan Definition*

- Template tailored to indication, study design
- Includes recruitment resources / approach and targets for enrollment
- Written hard-copy document
- Site specific
- 'Agreement' signed by site staff

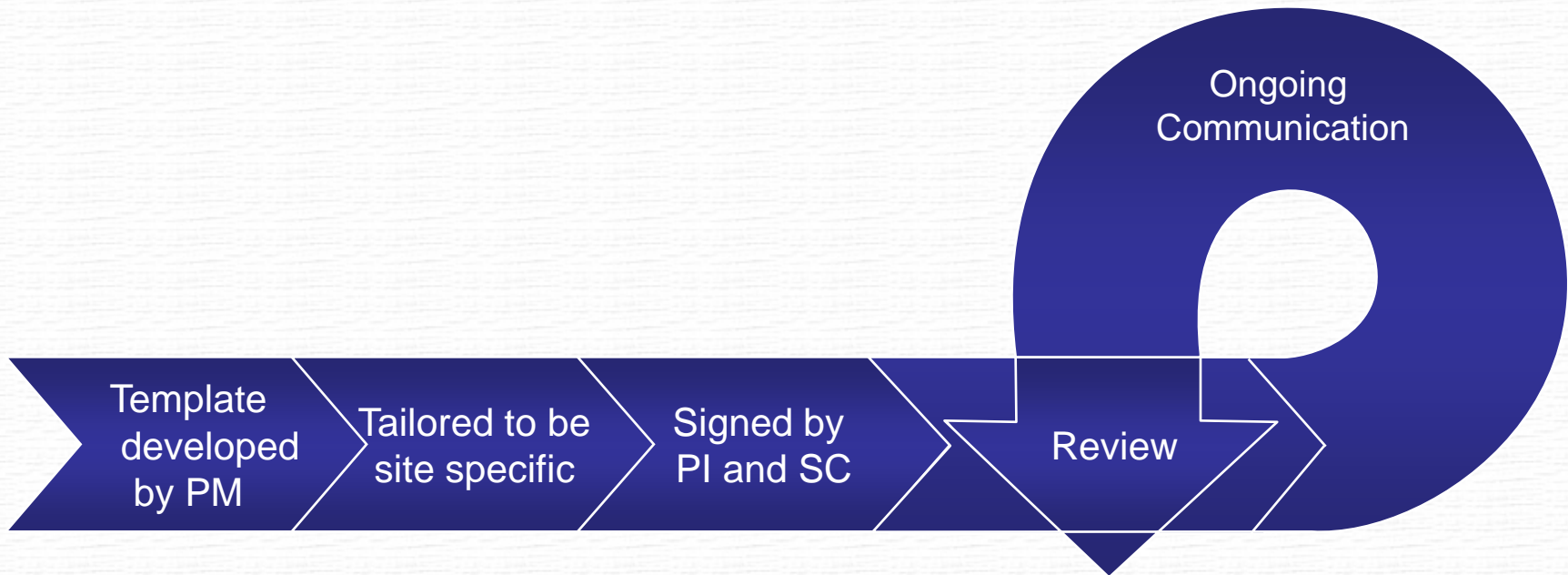


Recruitment and Enrollment Plan: *Site Specific Plan Content*

- Site's:
 - Enrollment target
 - Timeframe
 - Recruitment sources
 - E.g.: database, advertising, referrals, outreach
 - Subject identification activity to date
 - Barriers to recruitment and enrollment



Recruitment and Enrollment Plan: *Site Specific Plan Implementation*



Recruitment and Enrollment Plan: *Site Specific Plan Implementation*

- Sample template plan, tailored by Site

Enrollment Plan / Site Recruitment Strategy

Protocol Name (and number): _____

PI Name: _____ SC Name: _____
Site Number: _____ Monitor Name: _____

Enrollment for this study is competitive.
Total enrollment over approximately # sites will be # subjects.

The purpose of this form is to document the expectations and plans for recruitment along with the associated timelines for these endeavors. The following is for completion through discussion between Site Staff (PI and SC) with the Site Monitor during the Site Initiation Visit.

Overall Recruitment Objective

How many subjects do you expect to screen by [date] ?

Of those above screened, how many do you expect to enroll by [date] ?

In regards to subject recruitment, what percentage of your study participants will come from the following:

Private Practice: _____ %
Advertisements: _____ %
Referrals: _____ %
Other: _____ % (please specify: _____)

Study enrollment expectations

Site enrollment expectations



Recruitment and Enrollment Plan: *Site Specific Plan Implementation*

- Proactive identification of pitfalls
- Signed by PI and Study Coordinator

Recruitment Challenges	
After reviewing the protocol and preparing for the study start, what do you foresee as potential problems / challenges in patient recruitment efforts and how will you overcome them?	<div style="border: 1px dashed blue; padding: 5px;">Identification and review of challenges to enrollment<ul style="list-style-type: none">• Past study challenges• Challenges unique to current protocol• Creative approaches to proactively addressing</div>
Investigator's Signature: _____ Date: _____ <i>(indicating participation in the enrollment / recruitment discussion)</i>	
Study Coordinator's Signature: _____ Date: _____ <i>(indicating participation in the enrollment / recruitment discussion)</i>	

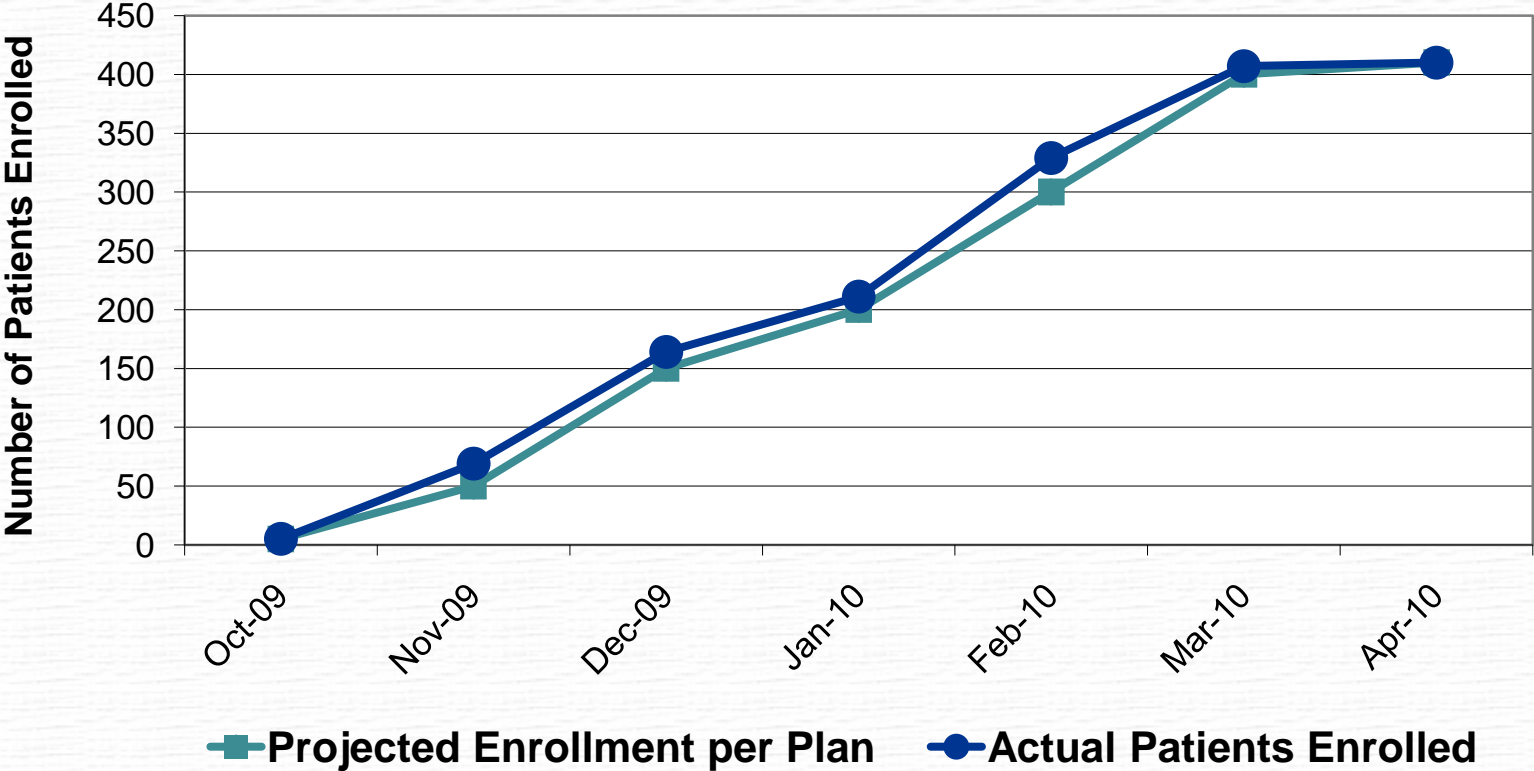
Recruitment challenges

Site signatures



Maximize Meeting Enrollment Goals: *Tracking*

Cumulative Enrollment Graph



Maximize Meeting Enrollment Goals:

Additional Tools

- Study Coordinator teleconferences
- Outreach
 - Advertising
 - Flyers/brochures in office
 - Local resources
 - Health Fairs
 - Community Groups
 - Hospital / health community newsletters
 - Clinical study postings on websites



Maximize Meeting Enrollment Goals:

Additional Tools

- On-going communication
 - Regular site calls (e.g., weekly, bi-weekly)
 - Scripted and non-scripted dialogue
 - Site teleconferences
 - Enrollment metrics
 - Screened, enrolled completers
 - Projected
 - Actual
 - Total active / eligible sites



Conclusions

- Proactive approach
 - Thorough site feasibility and qualification
- Enrollment plan
 - Introduction, development of study-specific template; implementation of individualized plans
- On-going review of plan and tracking
- Maximize knowledge and creativity
- Contingency planning

