

Ensuring Timely Recruitment of Appropriate Subjects

Susan Chrolavicius

Timely Recruitment

Why does it matter?

How do we Ensure Timely Recruitment?

Study Protocol Design

Site Selection and Site Activation Process – Site Personnel

Monitoring Recruitment

Encouraging Recruitment

Other suggestions

Why does it matter?

Timeline for the answer to the research question depends on achieving recruitment target goal.

The sooner we finish recruitment, the sooner we can complete patient follow-up. The sooner the close-out and presentation of results, the sooner the preferred treatment is available to patients.

Other factors:

- *Study results will be relevant only if they reflect current practice*
- *Measure of study discipline (and therefore quality)*
- *Efficiencies leads to economic benefits*

How to Ensure Timely Recruitment

Start with Identifying Appropriate Subjects (Protocol)

1. Does the Research Question address important health outcomes and is it feasible to try to answer the question?
Are others also interested in the question?
2. Do you expect the results to have wide applicability?
How many people could benefit from the study?
3. Do your eligibility criteria permit enrollment of typical subjects or are they too restrictive?
4. Is your study protocol reflective of practice or do you insist on additional procedures not routinely performed?

Study Protocol Design

Start by Identifying Appropriate Subjects (Protocol)

- Does the Research Question address important health outcomes?
Is it feasible to try to answer the question?
Are others also interested in the question?
- Do you expect the results to have wide applicability?
How many people could benefit from the study?
- Do your eligibility criteria permit enrollment of typical subjects or are they too restrictive?

Keep it Simple

- Is your study protocol reflective of practice or do you insist on additional procedures not routinely performed.

Site Selection

- Determine # sites needed to achieve a given sample size based on suggested target (e.g. 2 patients/per site/month).

Is this the best approach? Can some sites do much better?

- Fact: < 50% of sites provide 98% of patients in most trials
- Improve site selection process by targetting “good sites”
Resources can then also be targetted to these sites.
- Choose investigators with interest and commitment to research (historical performance, feasibility questionnaires)
- Investigator per Patient Fees (reasonable vs expectation)

Site Personnel

Importance of a Good Study Coordinator

Knows how to identify potential patients
(clinic lists/database, referrals, other)



Screening and selection of patients

Develops relationships with patients over
long-term follow-up

Committed to research

Knowledge of the study protocol and
procedures

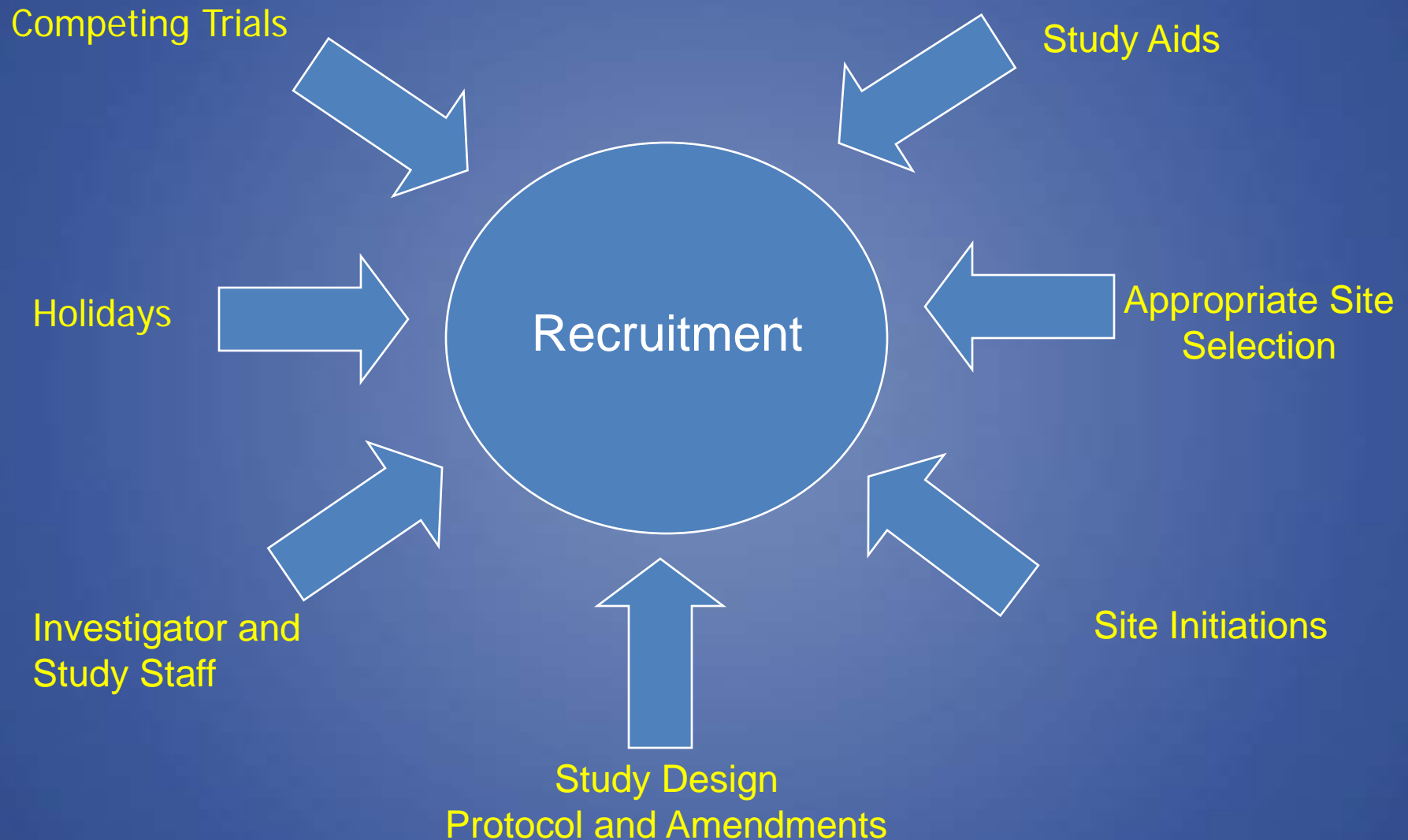
Site Activation

- Recruitment affected by site activation schedule
- Rate Limiting Factors for Site Initiations
 - Who is performing site initiations (*are there built-in incentives to delay initiations*)?
 - Site Contracts/Hospital Contracts
 - Health Authority/REB Submissions and Approvals
 - Translation of documents
 - IP (study drug) Importation delays in some countries
 - Export Licenses for Biological Samples

Recruitment Strategies

- Sharing successful patient recruitment strategies
- Maintain a ranking (best PI, best country) and distribute it to all sites with the monthly newsletter
- Establish the authorship policy for the trials and base it on patient recruitment
- Establish criteria for attendance at final investigators' meeting
- Screening Logs

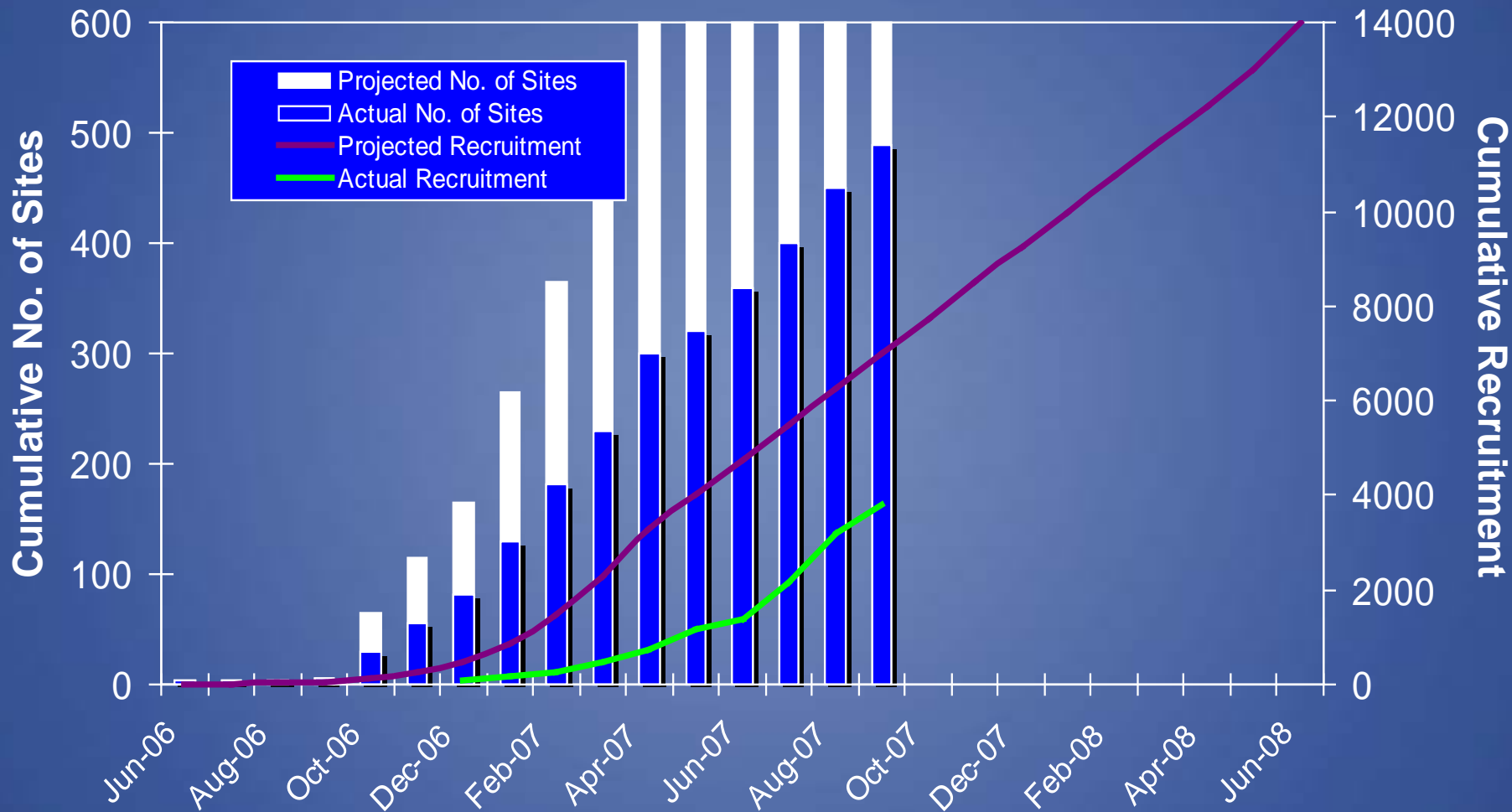
Factors Influencing Recruitment



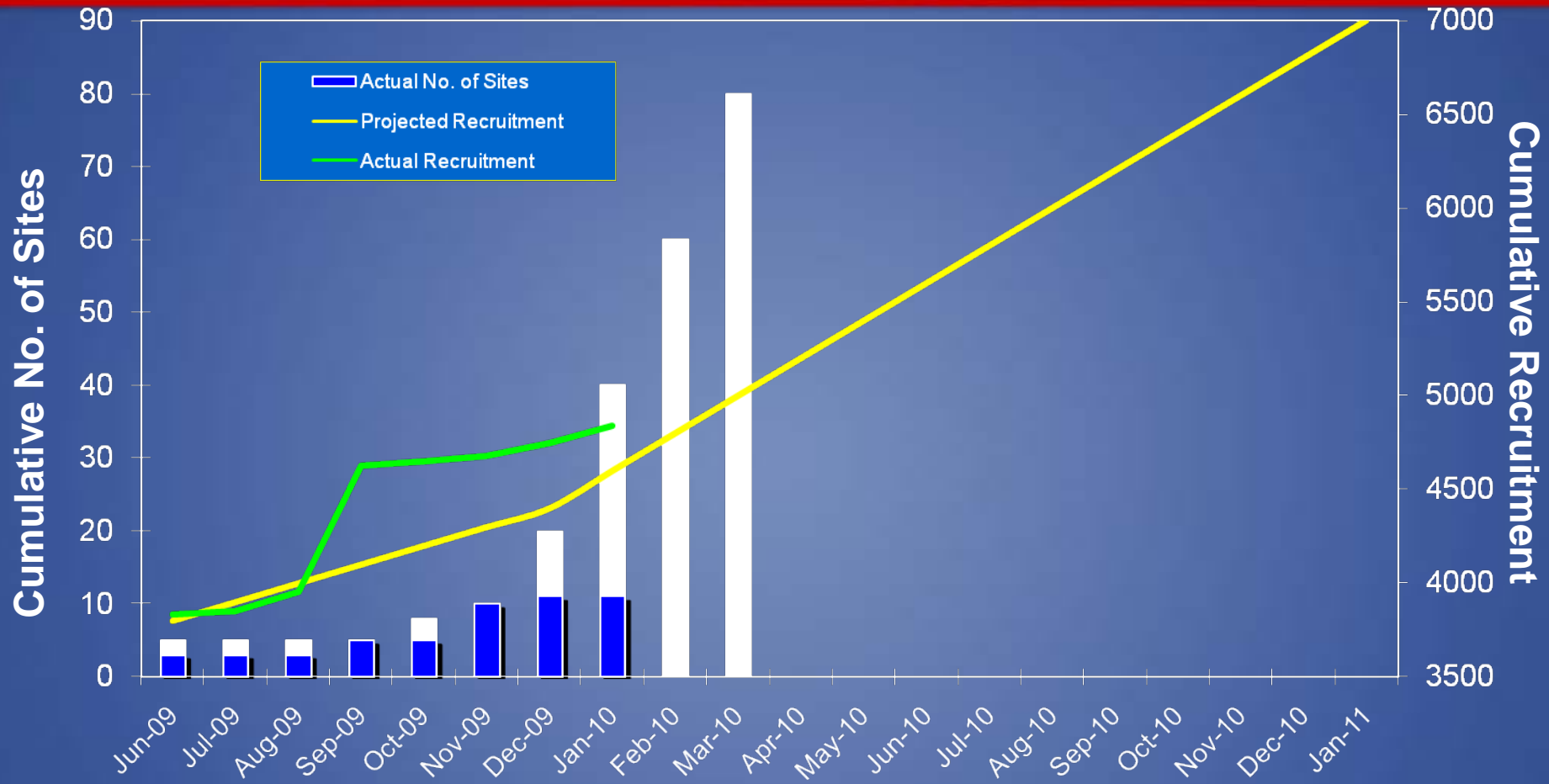
Recruitment Phase

- Provide support to sites to capture the targeted population (e.g. abbreviated ICF for STEMI pts)
- Regular communication to sites from National Leaders and Coordinating Centre
- Monitor Recruitment Closely
 - Screening Logs
 - Projected vs. actual recruitment curves/tables
 - Monitoring of site activity and recruitment rates
 - Weekly/monthly recruitment– global, country, sites

Projected vs Actual Recruitment



Projected vs Actual Recruitment as of JANUARY 06, 2010



Recruitment by Country

Country	Total No. of Sites	No. of Inactive Sites*	Total No. of Pts up to Dec 27	Recruitment during week of:				Total No. of Pts
				Dec 28	Jan 4	Jan 11	Jan 18	
Canada	9	3	68	0	6	3	2	79
France	10	2	113	1	6	1	6	127
India	14	1	467	10	7	7	13	504
OVERALL	33	6	648	11	19	11	21	710

**Inactive sites which have not randomized a patient in the last 30 days*

Study Aids

- Newsletters
- Recruitment kits:
 - Mini protocols, Inclusion/Exclusion cards
 - Subject Medical Chart Sticker
 - Dr. Referral cards
 - Investigative Site Poster
 - Pens, Post-it notes, Magnets
- Recruitment Funding:
 - Staff lunch and learn
 - Database searches of potential participants
 - Other appropriate activities

Best Laid Plans....

What if despite all of these plans recruitment continues to lag across the study?

NEED TO BE FLEXIBLE

and consider all options
e.g., loosen eligibility criteria

Actions if Poor Recruitment

Site Specific:

Identify barriers to recruitment (may have legitimate reason – how can we help?_

Screening logs

May need to close and replace non recruiting sites

Recruitment Motivation

- Site Encouragement
 - Congratulatory emails or letters for 1st patient or other recruitment milestones
- Regular teleconferences to discuss any recruitment issues
- Keep investigators updated on current study recruitment
- Local investigator meetings
- Country-specific newsletters

Conclusion

- Know why timely recruitment is so important
- Design protocol to facilitate recruitment
- Choose sites with proven track records
- Appreciate efforts of study site personnel
- Continually monitor recruitment and provide feedback
- Prepare to be flexible to achieve your goals