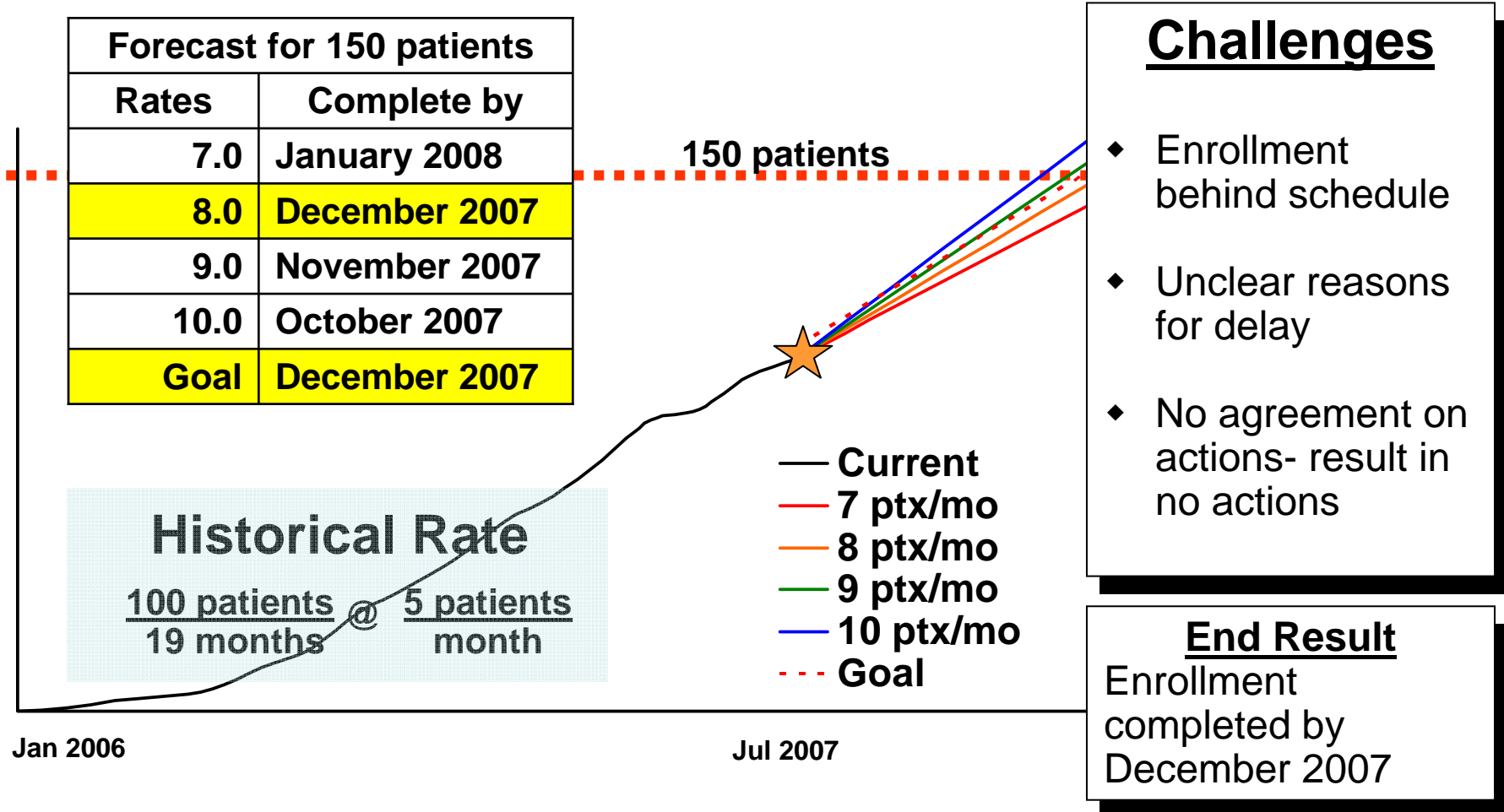


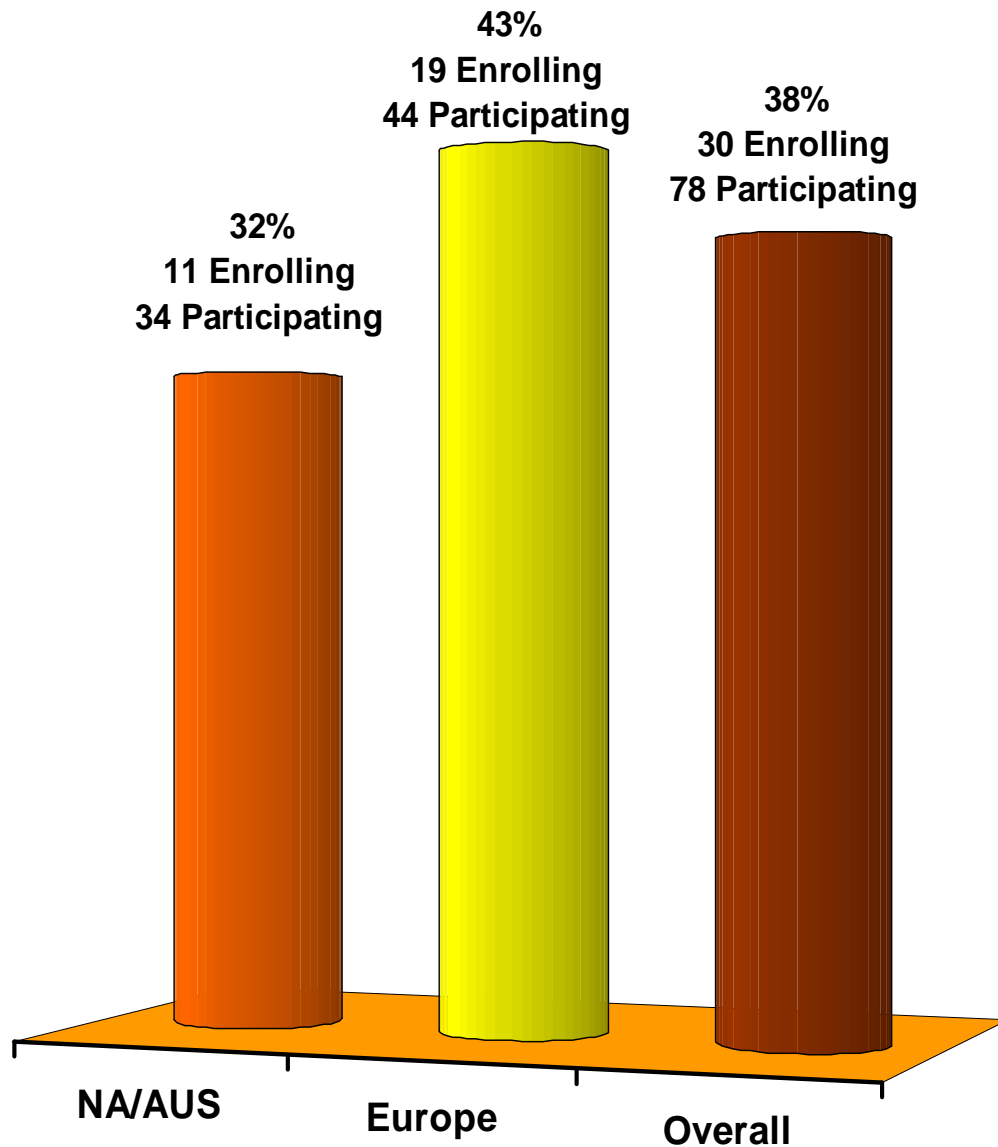
Sample Patient Enrollment Analyses



Project Summary

Challenges	Enrollment on important clinical trial was behind schedule <ul style="list-style-type: none">◆ Disagreement on reasons for slow enrollment◆ No clear accountability for enrollment◆ Past attempts to accelerate enrollment failed
Goal	Enroll 50 more patients by December (four months)
Critical Success Factors	<ol style="list-style-type: none">1. Identify root causes for slow enrollment; assess gaps and causes2. Target best options to improve enrollment; align team on solution3. Implement best options immediately
Project Team	<ol style="list-style-type: none">1. Medical monitor2. Clinical operations3. Contract Research Organization (CRO)
Analyses	<ol style="list-style-type: none">1. Identify barriers to enrollment and address possible root causes2. Identify best tactical options to enroll remaining patients in time
Outcomes	<ol style="list-style-type: none">1. Identified barriers to enrollment by country, site and study2. Focused on highest enrolling sites to enroll last 50 patients3. Enrolled 50 in 4 months

Not Enough Enrolling Sites



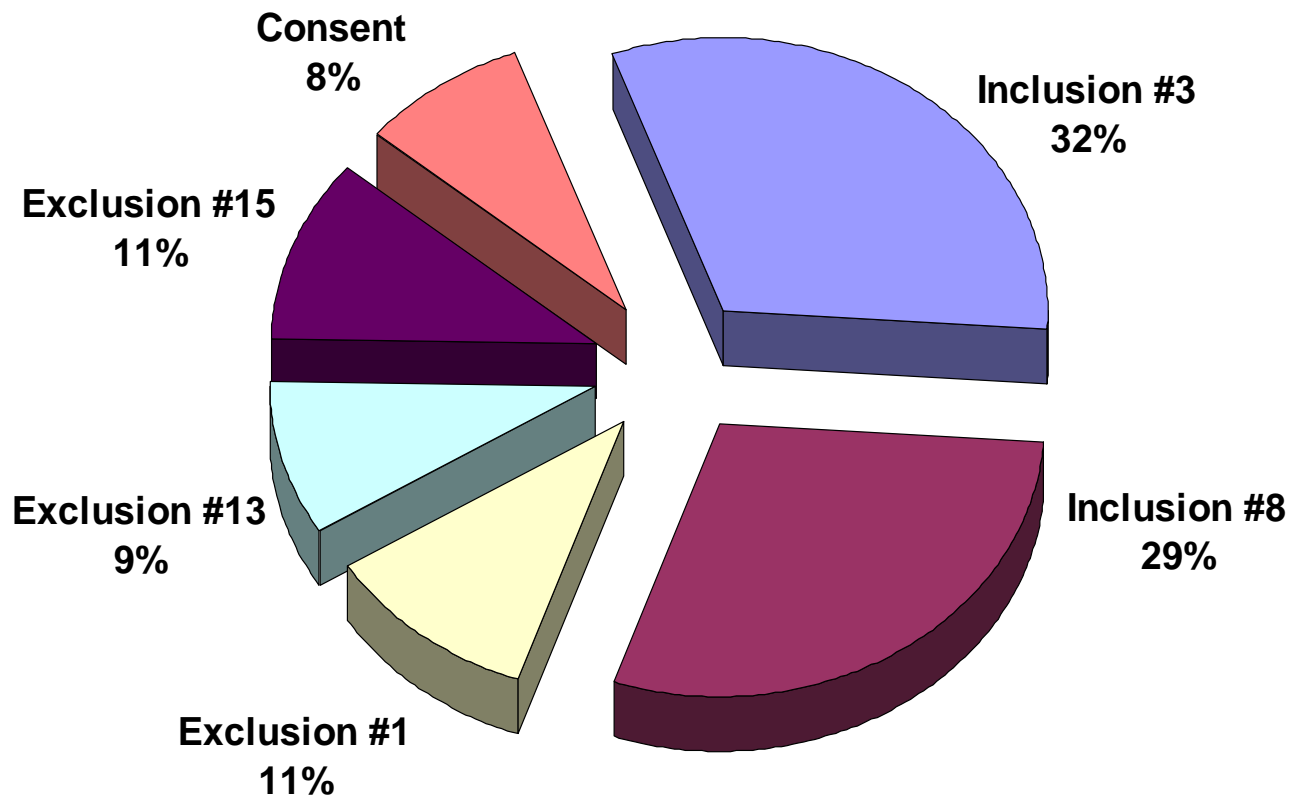
After 1 year, less than half of sites are enrolling patients

Next Steps

Identify barriers to sites enrolling patients

Identify options to accelerate enrollment at enrolling sites

Patient Selection Barriers



Patient Screening

- ◆ Two criteria are blocking out 60% of patients
- ◆ Almost 10% of patients decline participation in study

Considerations

- ◆ Relax selection criteria
- ◆ Improve consent process

Country Specific Trends

Czech Republic

1. Selection criterion #1 is main barrier (gold bar)
2. Obtaining consent is next greatest barrier (green bar)

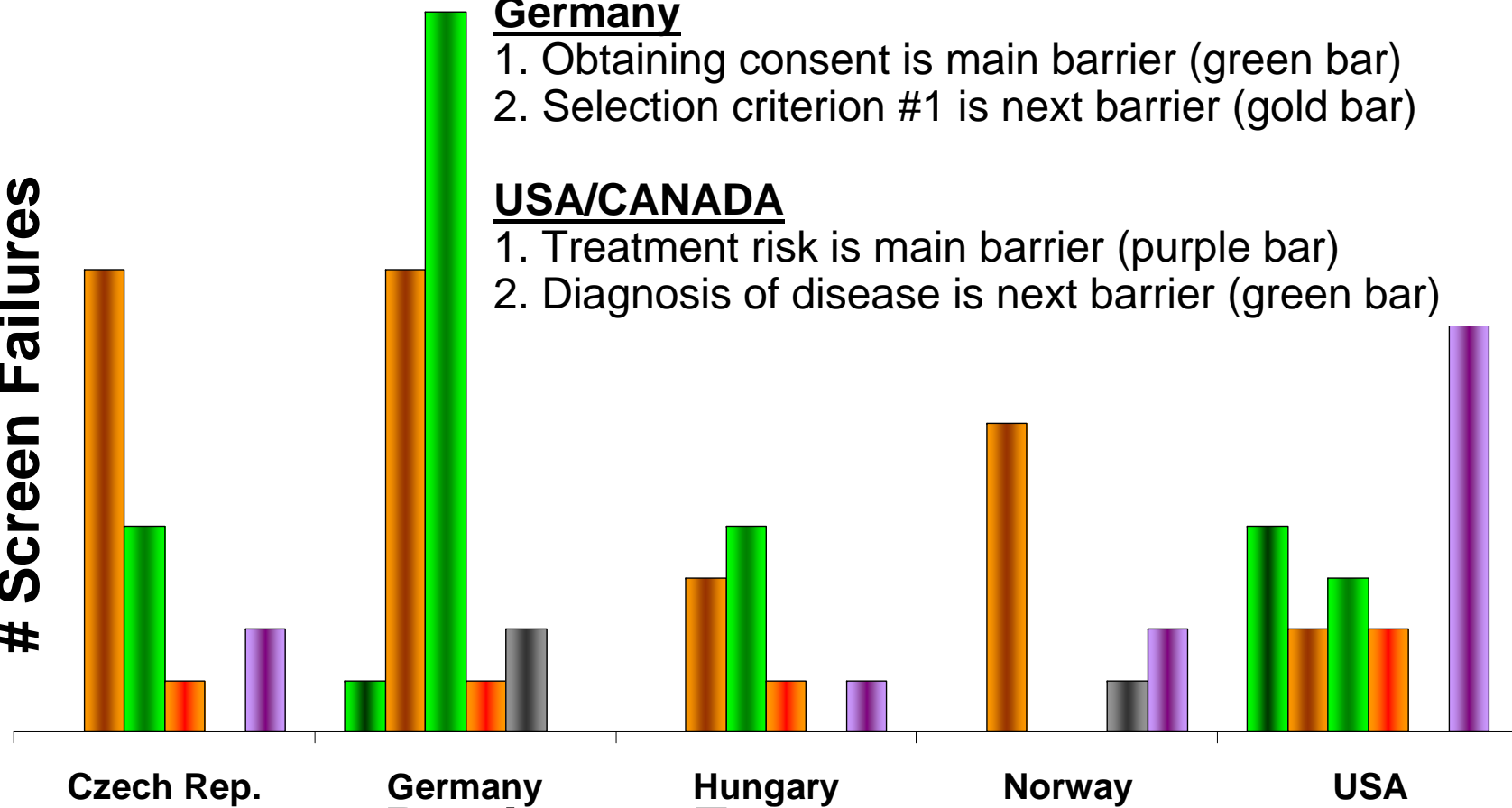
Germany

1. Obtaining consent is main barrier (green bar)
2. Selection criterion #1 is next barrier (gold bar)

USA/CANADA

1. Treatment risk is main barrier (purple bar)
2. Diagnosis of disease is next barrier (green bar)

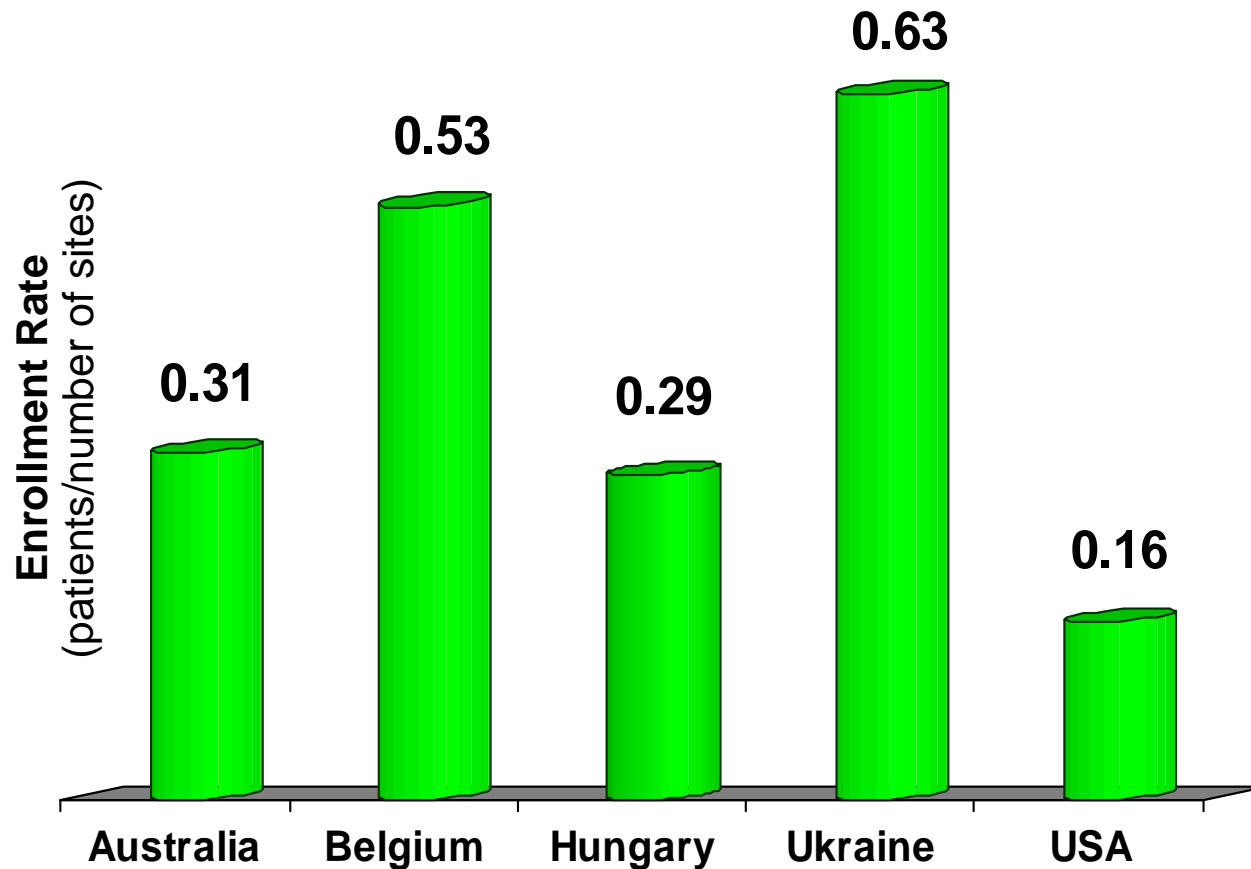
Screen Failures



Barriers to Enrollment

Kenneth Wu and Associates, LLC

Maximize Enrollment at Top Sites



Enrollment Focus

- ◆ Focus on enrollment at top enrolling sites
- ◆ 17 top enrolling sites can enroll 50 patients by December
- ◆ Focus on 17 top sites

Project Timeline

Milestones	Date	Accomplishments
Collect Metrics	Before May	<ul style="list-style-type: none"> ◆ Reviewed CRO study metrics ◆ Discuss possible root causes with study team
Analysis Phase	June	<ul style="list-style-type: none"> ◆ Analyze performance metrics ◆ Discuss findings with clinical trial management ◆ Discuss corrective actions
Present Findings		<ul style="list-style-type: none"> ◆ Discussed opportunities and desired outcomes ◆ Consensus on best options ◆ Assignment of action items with due dates
Monitor Results	July to December	<ul style="list-style-type: none"> ◆ Follow up on action items each week ◆ Report on success of interventions ◆ Identify new options and follow up

Should Haves, Could Haves, Misses

What Happened

Set Study Goals

Forecast Enrollment

Design Protocol

Select CRO

Collect Metrics

Select Sites

Report Progress

Activate Sites

Enrollment Breakdown

Indecision / Inaction
Confusion on Roles
Apathy / Dissent
Unclear Commitments
Unclear Accountability

Confusion
Blame
Mistrust/Turn over
Crisis Management

Planning

Enrollment Phase

Sponsor commitments:
Recruit experienced team
Define roles and responsibilities
Set goals; weekly, monthly
Make decisions quickly
Gain commitments from team
Define accountability for all

Align strategy and tactics
Make commitments on decisions and actions
Refine and redeploy tactics based on new data
Recommit to new plan; who does what when
Maintain transparency; truthful status updates
Continuously improve on processes and metrics
Hold individuals accountable for deliverables

CRO commitments:
Provide experienced team
Report metrics
Propose actions
Implement plans

Should Haves