PROTOCOL OPTIMIZATION: How to Select Trials for Success

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PHASE 1 CLINICAL TRIALS PROGRAM AT SCCA

• Program was established in 2008
• 23 Research staff grouped in regulatory, research, and finance teams
• Over 70 completed or open Phase 1 studies

• Ave # Phase 1 protocols under consideration:
  • 1-2 industry-sponsored proposals/week
  • 3-5 IIT proposals/year
WHAT IS THE CLINICAL TRIAL FEASIBILITY ASSESSMENT?

✓ Process of comprehensive analysis and planning including risk assessment and contingency planning to determine best course of action when considering a new trial.

✓ Clinical Trials Feasibility Assessment should be conducted during the study start-up process, and throughout the study opening.
SPONSOR-INITIATED PROTOCOLS

CRITICAL STEPS IN EVALUATION OF NEW TRIAL PROPOSALS

Step 1
Sponsor sends invitation for trial participation.

Step 2
Sponsor provides protocol synopsis and requests completion of a study questionnaire.

Protocol no go decision can be made at any step of evaluation.
SPONSOR-INITIATED PROTOCOLS

Step 3
Confidential Disclosure Agreement is executed.

Step 4
Full Protocol is provided to the site.

Sponsor’s site evaluation timeline can be short and deciding factor for site selection
SPONSOR-INITIATED PROTOCOLS

Step 5
Site qualification visit is followed by site selection.

Step 6
If selected, the site receives regulatory, budget, and contract package and proceeds with start-up activities.
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Considerations

✓ Science and Protocol
SPONSOR-INITIATED PROTOCOLS

Considerations

✓ Science and Protocol
✓ Population/Enrollment
SPONSOR-INITIATED PROTOCOLS

Considerations

✓ Science and Protocol
✓ Population/Enrollment
✓ Resources
  • PI and staff
  • Facilities
  • Regulatory
  • Budget and Contract
✓ Other considerations
INVESTIGATOR-INITIATED (II) PROTOCOLS

- II Trials are labor intensive and require experience and knowledge of clinical trials.

- The protocol feedback should be obtained from multiple senior Investigators and experienced staff.

- Even with best vetting process, unanticipated problems may arise.
INVESTIGATOR-INITIATED PROTOCOLS

CRITICAL STEPS IN EVALUATION OF NEW TRIAL PROPOSALS

Step 1
Development of protocol and budget and submission to a funding agency.

Step 2
Regulatory and Funding approval.
INVESTIGATOR-INITIATED PROTOCOLS

Step 3
Design of Electronic CRFs in Electronic Data Capture System.

Step 4
Site initiation visit and protocol training. Regulatory and contractual approvals for external sites.
INVESTIGATOR-INITIATED PROTOCOLS

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  • Budget and Contract
✓ Other considerations
CASE STUDY #1

A phase 1 study of S01 in patients with advanced relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Sponsor: Zpharma
Science/Protocol Design

Preclinical studies support the study hypothesis and goals

Standard 3+3 dose escalation study design

Reasonable frequency of visits and windows

Patents may benefit from participation
CASE STUDY #1

Science/Protocol Design

4QW IV drug administration with physical exam, and standard clinical labs

Standard CT/MRI every 8 weeks

C1D1 requires hourly pks, vitals, and neurological exam up to 12 hours post dosing

Eye exams every 8 weeks
CASE STUDY #1

Enrollment/Population

Enrollment period 9/1/2016-2/2018

3 study sites, N=30 patients (10 slots/site)

2-3 target patients/month
1-2 patients/month after inclusion/exclusion

1 competing Investigator–Initiated Trial
6/2017 (N=30 patients over 3 years)
CASE STUDY #1

Resources (facilities and operations)

Infusion area issues:

- Neurological exams too complex and frequent for clinic staff
- Infusion can’t accommodate long C1D1 due to restricted hours of operation
CASE STUDY #1

Resources (staffing)

Staff and PI have capacity to take on the trial

There is no coverage for after hours pk processing
CASE STUDY #1

Resources (budget and contract)

Master Contract Agreement in place

Sponsor budget is reasonable
CASE STUDY #1
Conclusions

Successful study conduct depends on careful feasibility assessment by Research and Regulatory Coordinators.

Continuous communication and clarification of issues with the sponsor and internal departments before committing to a trial is crucial.

Coaching and Mentoring of new staff and Investigators by experienced Coordinators is key to growing successful clinical trials program.
Thank You
Questions?