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

Protocol no go decision can be made at any step of evaluation

Step 1

Sponsor sends invitation for trial participation.

Step 2

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

SPONSOR-INITIATED PROTOCOLS

Sponsor's site evaluation timeline can be short and deciding factor for site selection

Step 3

Confidential Disclosure Agreement is executed.

Step 4

Full Protocol is provided to the site.

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.

SPONSOR-INITIATED PROTOCOLS

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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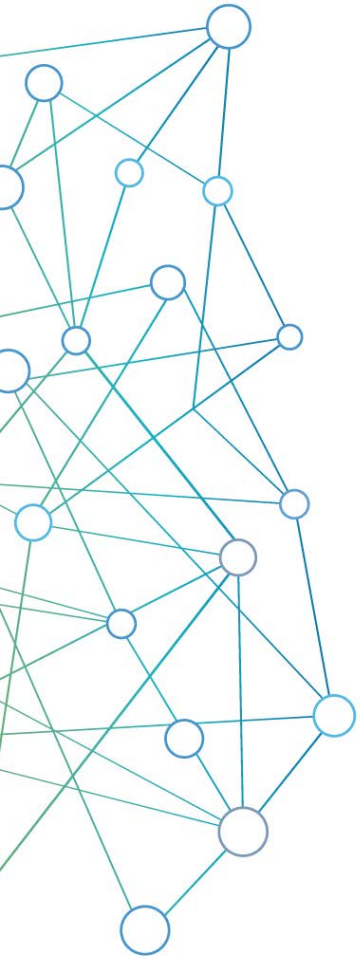
Considerations

- ✓ Science and Protocol
- ✓ Population/Enrollment
- ✓ Resources
  - PI and staff
  - Facilities
  - Regulatory
  - Budget and Contract
- ✓ Other considerations

CASE STUDY #1

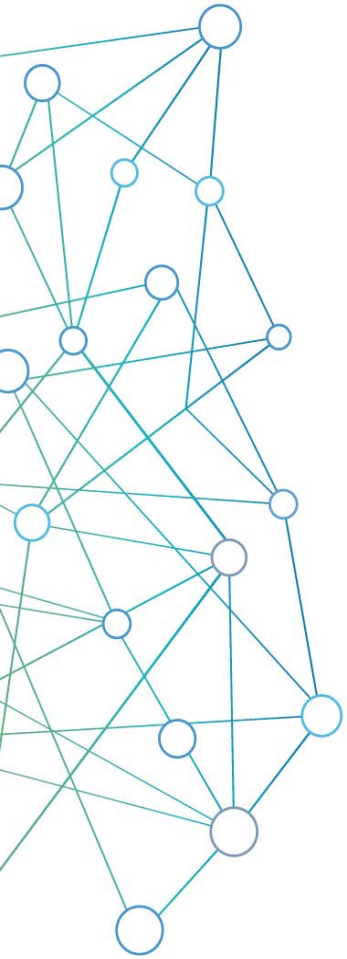


A phase 1 study of S01 in patients with advanced relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Sponsor: Zpharma

CASE STUDY #1

Science/Protocol Design



Preclinical studies support the study hypothesis and goals

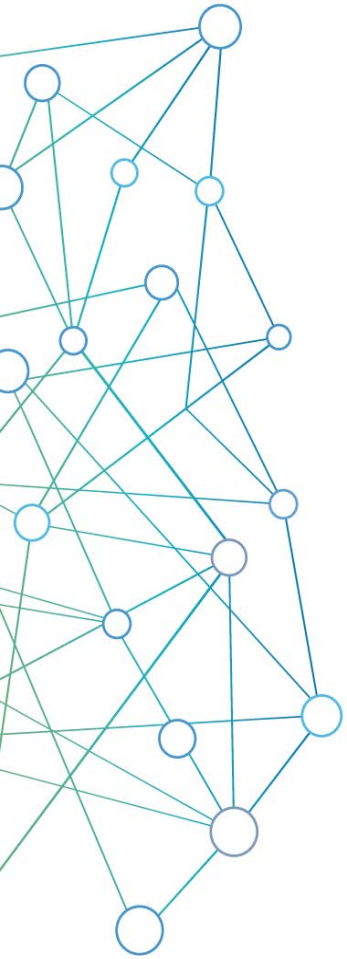
Standard 3+3 dose escalation study design

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

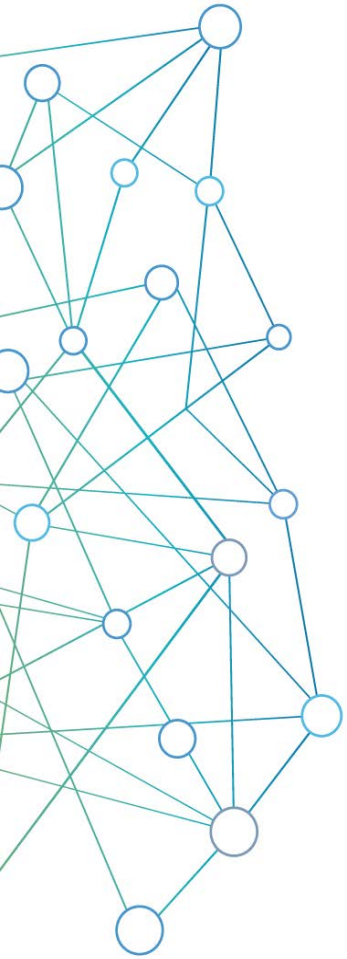
Standard CT/MRI every 8 weeks

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

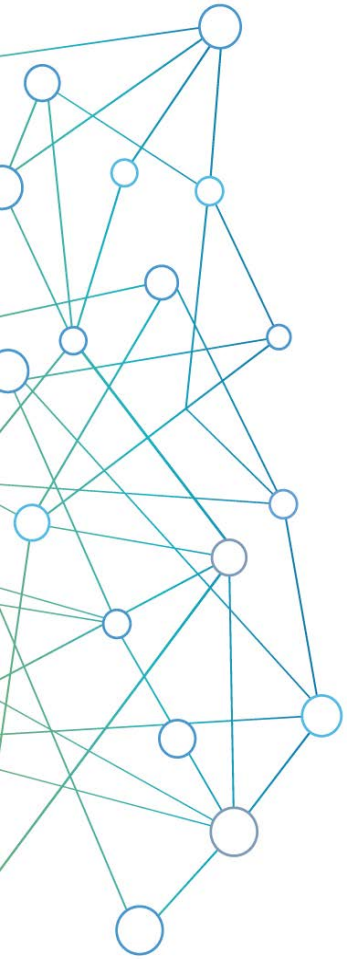
3 study sites, N=30 patients (10 slots/site)

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)



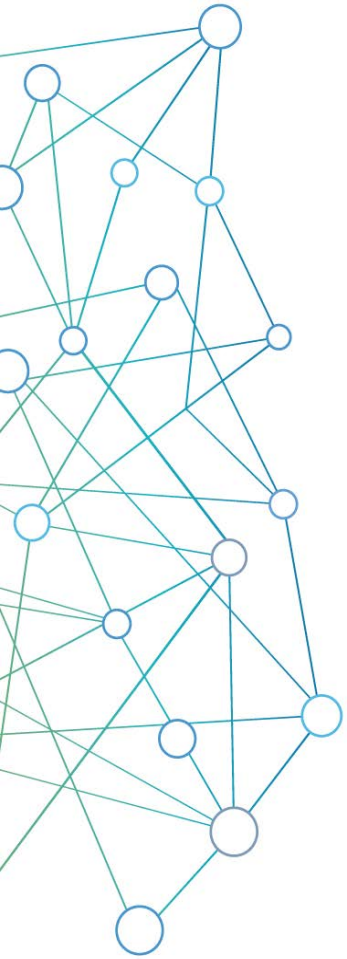
Infusion area issues:

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)

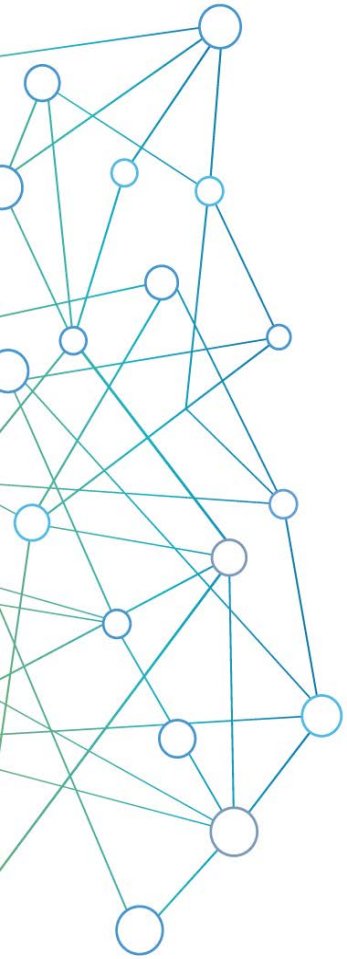


Staff and PI have capacity to take on the trial

There is no coverage for after hours pk processing

CASE STUDY #1

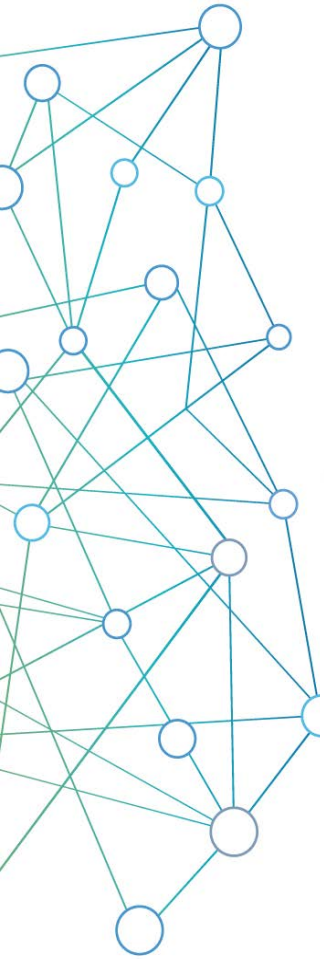
Resources (budget and contract)



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?

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