

CROs Perspectives on Effective Relationships with Sponsors

Chris Chase

RTI LLC Brookings SD
Dept Vet & Biomed Sci
South Dakota State University

Credits

- Weinberg Group-**Pros & Cons of Working with Contract Research Organizations**
<https://weinberggroup.com/blog/pros-cons-working-with-cro/>
- BioPharm- **Establishing a Successful CRO–Client Relationship**
<http://www.biopharminternational.com/establishing-successful-cro-client-relationship>
- **25 Years in CRO business**

Background

- Sisseton
- Pre-Vet SDSU
- Iowa State DVM 1980
- Practiced 5 years in Viborg
- Graduate School- University of Wisconsin-Madison-
MS & PhD
- Relief and consulting practice work 1985-2009

Background

- ARS Laramie WY 1990-1992
 - Bluetongue and Arbovirus research
- SDSU 1992
- Flandreau Veterinary Clinic
 - 1992-2009
- Rural Technologies Inc
 - Contract Research Organization
 - Founded 1994

Background

- Chase Consulting
 - Pfizer/Zoetis Animal Health
 - Merial Animal Health/Boehringer Ingelheim Vetmedica
 - Schering Plough/Intervet/Merck
 - Novartis/Elanco Animal Health
 - Boehringer Ingelheim Vetmedica
 - Hipra
 - Pharmgate
 - Speak on immunology, virology and vaccinology
 - State and national associations
 - Internationally

Serendipity

- Serendip, the old Persian name for Sri Lanka
- is the effect by which one accidentally discovers something fortunate

Collaborations

- National Animal Disease Center
 - Julia Ridpath
 - John Neill
- SDSU
 - Arnold Hippen, Johan Osorio-Dairy Science
 - Jeff Clapper, Zach Smith, Amanda Weaver-Animal Science
 - Adam Hoppe- Bio/Chem
 - Alan Young-Vet Science

Rural Technologies, Inc.



RTI was founded to develop and market products or services from basic science discoveries through industry, university, and government partnerships. Since its inception in 1994, RTI has funded this effort through grants and contract research.

Co-founded with David Hurley

RTI, LLC

Research Technology Innovation



Changed Corporate Structure 2013

Contract Research

- RTI has conducted over 300 contract studies including bacterial, viral, immunological, and nutritional studies in the last 6 years.
- RTI has developed 6 new challenge models within the last three years.

Services and Products

- Contract Research Organization
 - Basic and Applied Research:
 - Focus
 - Virology
 - Microbiology
 - Immunology
 - Nutrition
 - Research Grants
 - Diagnostic Reagents

RTI Core Species

- **Porcine**

Farrow to finish, gilts, gnotobiotic, and seronegative sources



- **Bovine**

Heifers, cows, cow-calf, seronegative calves, and colostrum-deprived calves



- **Poultry**

SPF chicks, broilers, laying hens



- **Canine**

Contract Research

Types of Trials

Biologicals – Vaccine

Efficacy trials – USDA

Safety- USDA

Backpassage – USDA

Pharmaceutical – Antimicrobial

General health – morbidity/mortality

Safety-FDA

Phase 1 – Proof of concept/marketing

Nutrition

Feed and Weigh

GI Morphology – Morphometrics

Immunological Responses

RTI, LLC

Executive Leadership



Rollie Nevins
Chief Executive and
Financial Officer
35 years Experience in the
food animal industry



Kipp Erickson, PhD
Chief Operating Officer
25 years Experience in the
human and animal health
industry



Chris Chase, DVM, PhD
Chief Scientific Officer
30 years Clinical
Veterinary Medicine and
Research Experience



Carol Rinehart, PhD
Regulatory Affairs
35 years Clinical Research
and Vaccine Licensing
Experience (Licensed 27
products USDA)



Why use CRO-Advantages?

- ***Sponsors can delegate all their duties and functions to a CRO***
- *CROs have the necessary resources already in place*
- *CROs are prepared to move forward*
- *Better idea upfront about how much a project may cost*

Providing a comprehensive approach to research....



Why use CRO-Advantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- ***CROs have the necessary resources already in place***
- *CROs are prepared to move forward*
- *Better idea upfront about how much a project may cost*

Clinical Facilities at a Glance

- 21,000 sq. foot, BSL2 Clinical Building, Brookings, SD opened in 2016
 - Climate controlled, Bio-filtered rooms
- 12,000 sq. foot, BSL2 Clinical Building, Hudson, SD
 - Climate controlled, Bio-filtered rooms
- 6 additional BSL2 & BSL1 cattle and swine facility near Brookings, SD
- Poultry research site, Stilwell, KS



RTI's New Animal Research Facility

RTI, LLC

Clinical Leadership



Michelle Blaha, DVM
Clinical Research
Veterinarian and
Principal Investigator
8 years Experience animal
health and clinical
research



Brittany DiVerde, DVM
Clinical Research
Veterinarian, Investigator
8 years Experience in animal
and public health, and clinical
research.



Sara Vander Wal, BS
Clinical Research Project Manager
IACUC Coordinator
7 years Experience animal health
and clinical research



Eduardo Vivas, MS, PhD, DVM
Veterinarian, Investigator
Kansas City Facility Manager
20+ years Experience animal health
and clinical research



Why use CRO-Advantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- *CROs have the necessary resources already in place*
- ***CROs are prepared to move forward***
- *Better idea upfront about how much a project may cost*

RTI Expertise



- 2013
- 8 Full-time staff
- 4 Part-time staff

- 2019
- 25 Full-time staff
- 8 Part-time staff



Animal Research Models

Bovine

- Bovine Coronavirus Challenge Model
- BHV Type 1 Respiratory Challenge Model
- BHV Type 1 Fetal Protection Model
- Bovine Rotavirus Challenge Model
- BRSV Challenge Model
- BVDV Type I and II Challenge Models
- BVDV Fetal Protection Model
- Leptospirosis Challenge Model

Porcine

- E. coli PWD Model (F18, K88)
- Erysipelothrix rhusiopathiae
- Mycotoxin (ZEA)
- Porcine Parvovirus
- PRRSV Nursery Model
- PRRSV Fetal Persistence Model
- Mycoplasma hyopneumoniae Model
- Porcine Circovirus 2
- Porcine Epidemic diarrhea virus

Poultry

- Salmonella typimurium
- Salmonella enteritidis
- Coccidia (Eimeria spp)
- Marek's Disease Virus

General

- Field Safety Studies

Customized research models

Why use CRO-Advantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- *CROs have the necessary resources already in place*
- *CROs are prepared to move forward*
- **Better idea upfront about how much a project may cost**

Why use CRO-Advantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- *CROs have the necessary resources already in place*
- *CROs are prepared to move forward*
- **Better idea upfront about how much a project may cost**
 - Extensive budget development that often includes items that the client may include as overhead in internal studies- wake up call to Client on costs

Why use CRO- Disadvantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- *It can be difficult to maintain oversight*
- *Multiple audits are necessary*

Why use CRO- Disadvantages?

- ***Sponsors can delegate all their duties and functions to a CRO***
 - While delegation can mean that program tasks get completed, there is no automatic assurance that those tasks will be completed properly.
 - The Sponsor retains ultimate responsibility for the program regardless of the duties and functions delegated to the CRO.
 - Any problem with anything related to the CRO's actions, the Sponsor must deal with the consequences.
- *It can be difficult to maintain oversight*
- *Multiple audits are necessary*

Why use CRO- Disadvantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- ***It can be difficult to maintain oversight***
- *Multiple audits are necessary*

Why use CRO- Disadvantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- ***It can be difficult to maintain oversight***
 - Sponsors are not involved with the day-to-day operations of the CRO.
 - The line of communication is not always clear.
 - The larger and more complex the trial, the more difficult it is to maintain oversight.
- *Multiple audits are necessary*

Why use CRO- Disadvantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- *It can be difficult to maintain oversight*
- ***Multiple audits are necessary***

Why use CRO- Disadvantages?

- *Sponsors can delegate all their duties and functions to a CRO*
- *It can be difficult to maintain oversight*
- ***Multiple audits are necessary***
 - Sponsor must conduct multiple audits to protect their interests.
 - Conduct a prequalification trial to ensure that the CRO can provide the services that the Sponsor needs with the necessary quality.
 - Conduct routine audits at points during the trial to ensure the quality of the program, and conducting an audit near the end of the program to make sure that the program is closed properly.
 - Audits are less of a con than they are “must-haves.”

Keys to Successful CRO-Client Relationships

- Requirement of Project Stated
 - Pitfall- Ambiguous project aims-
 - Type of study-Developmental, pilot, pivotal, marketing
 - Aim of Study-Clear and defined
 - Negative Outcomes- many changes made, time wasted and project off-track
 - Solutions
 - Agree on roles and scope of project
 - Ensure technical, confidential agreements in place
 - Agree and sign off on technical documents- understand “high risk” technical studies

Contract Research

Types of Trials

Biologicals – Vaccine

Developmental

Efficacy trials – USDA

Safety

Backpassage – USDA

Pharmaceutical – Antimicrobial

FDA label

General health – morbidity/mortality

Phase 1 – Proof of concept/marketing

Nutrition

Feed and Weigh

GI Morphology – Morphometrics

Immunological Responses

Keys to Successful CRO-Client Relationships

- Agreed timelines
 - Pitfall- False expectation of project delivery
 - Is Clients Product ready to test?- potency, import testing, manufacturing failure
 - Inadequate scheduling at CRO
 - Negative Outcomes- unhappy client
 - Solutions
 - Feasibility (pilot) study may give more accurate estimate of outcomes and timelines
 - Provide feedback on any delays or problems as soon as possible

Keys to Successful CRO-Client Relationships

- Regular communication
 - Pitfall- Project progress not monitored
 - Negative Outcomes- client loses confidence in CRO
 - Solutions
 - Set up regular update times by email, tele- or video-conferencing

Keys to Successful CRO-Client Relationships

- Changes are required
 - Potential Pitfall- Too much time spent on agreeing to changes
 - Negative Outcomes- changes put the project behind schedule
 - Solutions
 - CRO flexibility to react quickly to implement changes including the documentation

Keys to Successful CRO-Client Relationships

- Test article availability
 - Potential Pitfall- Cannot perform testing on time
 - Negative Outcome- CRO may need to reschedule trial
 - Solutions
 - Provide current information to CRO on test article timeline
 - Prepare an alternate timeline if the test article release is delayed

Keys to Successful CRO-Client Relationships

- Review of Documentation
 - Potential Pitfall- Documents awaiting review lead to project delay
 - Solutions
 - Have dedicated teams ready in place at both sides to ensure timely review

Keys to Successful CRO-Client Relationships

- Delivery of Final Report
 - Potential Pitfall- Delay in Final Report leads to delay for agency submission
 - Solutions
 - CRO puts together outline for assembling Final Report at the initiation of the study
 - CRO communicates regularly on progress of Final Report

Keys to Successful CRO-Client Relationships

- Financial Considerations
 - Protocol Development and Budgeting
 - Client receives the budget in a timely manner
 - Client needs to be prepared to pay for protocol development and budgeting to the CRO when the CRO does not do the study
 - Study Payments
 - Financial Terms and payment schedule need to be clearly stated and executed
 - Delays in disbursement need to be communicated
 - Delayed payments affect the goodwill between the CRO and client

CRO SWOT Analysis

- Strengths
 - Respond rapidly
 - Resources and Expertise available
- Weakness
 - Cyclic business and AHI acquisitions
 - Control for Client
- Opportunities
 - AHI acquisitions and Startups
 - VFD and alternatives to antimicrobials
 - Define mechanisms not just efficacy
- Threats
 - Cyclic business and AHI acquisitions

Summary

- Best Opportunity for Improvement -Communication
 - Communication between CRO-client on your needs and expectations and CRO's expertise
 - Communication between CRO-client budget, protocol, study
 - Communication between CRO-client during the study
 - Communication between CRO-client- final report, publications and post-study debrief (the good, the bad and the ugly)

Thank You!



**SOUTH DAKOTA
STATE UNIVERSITY**
*College of Agriculture, Food
and Environmental Sciences*



