Collaboration between Sponsors and CROs: Understanding the Impact of Timeline Pressure on the 3Rs

9 October 2014
IQ Symposium 2014 – “Pre-competitive Collaboration for Innovation”
Working Group Members

IQ Consortium Members
• Donna Clemons, DVM, MS, DACLAM- Global Director, Comparative Medicine- AbbVie Inc.
• Khary A. Adams, MS, MBA- Head of Laboratory Animal Sciences US-AstraZeneca

CRO Partners
• Marilyn J. Brown, DVM, MS, DACLAM, ECLAM-Corporate Vice-President, Global Animal Welfare- Charles River Laboratories
• Gwendalyn M. Maginnis, DVM- Senior Clinical Veterinarian- WilResearch
• Stanley Dannemiller, DVM, MS, DACLAM- Director, Comparative Medicine Unit, Northeast Ohio Medical University (Director, Animal Laboratories, Ricerca Biosciences)
Background:

• Outsourcing to CROs constitutes a major part of pharmaceutical research (and animal use), but was overlooked in most 3Rs discussions

• A major “pain point” for 3Rs considerations in contracted studies is abbreviated timelines for onboarding and design

• Abbreviated timelines and rapid study changes can lead to communication errors, negative impact on study integrity and quality, and animal welfare concerns

• Decisions maybe in the hands of individuals in CROs and Sponsor organizations who don’t have a full background in animal study conduct and/or don’t recognize the implications of some study decisions
Goal:
Create a quick training tool for CRO and Sponsor

- Establish a common language and clear terminology to support 3Rs discussions
- Irrespective of individual background, develop basic knowledge of various scientific, regulatory, and animal welfare impacts of study timeline factors relative to major research animal species
- Facilitate communication and partnership toward enhancing the focus on 3Rs during study design and scheduling
- **Focus on the ultimate goal of refinement of study techniques/animal use to minimize negative impact on animals AND reduction of animal numbers through improved data and avoidance of study/group repetition**
Program excerpt:

Timeline Impact on Animal Health and Welfare

* Inappropriate (or missing) animal welfare endpoints
  * Lack of complete information on prior compound history, adverse events, comparison to previous study conditions
* Quarantine
  * Repercussions of reduced quarantine (disease risk, risk of losing the entire study => delay)
* Stress and/or distress
* Vulnerability to injury
  * Lack of acclimation to study procedure
  * Fight wounds due to social incompatibility
* Surgical technique/inadequate recovery
  * Training, surgeon fatigue, recovery time
* Increased technician procedural error
  * Inadequate training time
  * Health and welfare complications in the animals
Process:

- Develop Training
- Approval by the 3Rs LG and the IQ Consortium BOD
- Pilot training
- Review efficacy of program
- Determine future steps
  - Expand training and seek venues for promulgation
  - Rework program based on feedback, repeat pilot run
Outcome:

Pilot program outcome pending
Acknowledgments and Appreciation

• 3Rs Leadership Group
• The entire CRO Outreach Working Group
• CRO Partners
• Pilot Program volunteers
• Advisors and reviewers who gave us guidance and insight on the training, the surveys, and assistance in recruiting volunteers