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

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Working Group Members

IQ Consortium Members

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CRO Partners

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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

    or
  - ❑ Rework program based on feedback, repeat pilot run

Outcome:

Pilot program outcome pending

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