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## Lean Times for Your Animal Research Programs: A Slugfest or a Snugfest with AAALAC Accreditation?

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# Objectives for Today's Presentation

- To provide a quick background on AAALAC facts pertinent to our discussion
- To review the pressures, cautions and possible approaches for creative solutions
- To answer any questions you may have on AAALAC or the its accreditation process: A town hall exchange



# Brief Notes on AAALAC International

- Governance by a BOT comprised of scientific organizations and scientific support organizations valuing the importance of animal health and welfare to science
- Voluntary, peer review of animal care and use programs
- 772 animal care and use programs in 30 countries are accredited.
- AAALAC International is nonpolitical and non-regulatory



# Who Are the AAALAC BOT Members?

- 69 Organizations
  - Approximately 40 represent research disciplines
  - 17 Represent veterinary or animal sciences specialty groups
  - Patient advocacy, science advocacy and industry/academic interest groups comprise the balance
  - An international dimension: EFPIA, ESLAV, FELASA, IAT, ICLAS



# AAALAC Mission

AAALAC International is a voluntary accrediting organization that enhances the quality of research, teaching, and testing by promoting humane, responsible animal care and use. It provides advice and independent assessments to participating institutions and accredits those that meet or exceed applicable standards.

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# Accreditation Internationally

- Sensitive to legal and cultural issues of the country
- National requirements as baseline
  - National laws, regulations, policies, guidelines
  - Supranational standards (86/609/EEC, 89/391/EEC, et al.)
- No national requirements → *Guide*\* provisions applied
- AAALAC Reference Resources as applicable
- Expert professional judgment
- Peer review process

\*ALL PRINCIPLES OF *GUIDE* MUST BE MET



# Players in AAALAC's Adoption of Standards

- Council on Accreditation
  - Committee on Reference Resources
    - 22 U.S. Documents
    - 2 Canadian Documents
    - 26 European Documents
    - Reorganized according to topic
    - Used as a basis for program evaluation: “Typically, a Reference Resource would serve as the basis for a [suggestion for improvement](#), though not a [mandatory](#) item for correction.”
  - Letter to the “*Guide*” Update Committee



# Globalization and Outsourcing of Animal Research

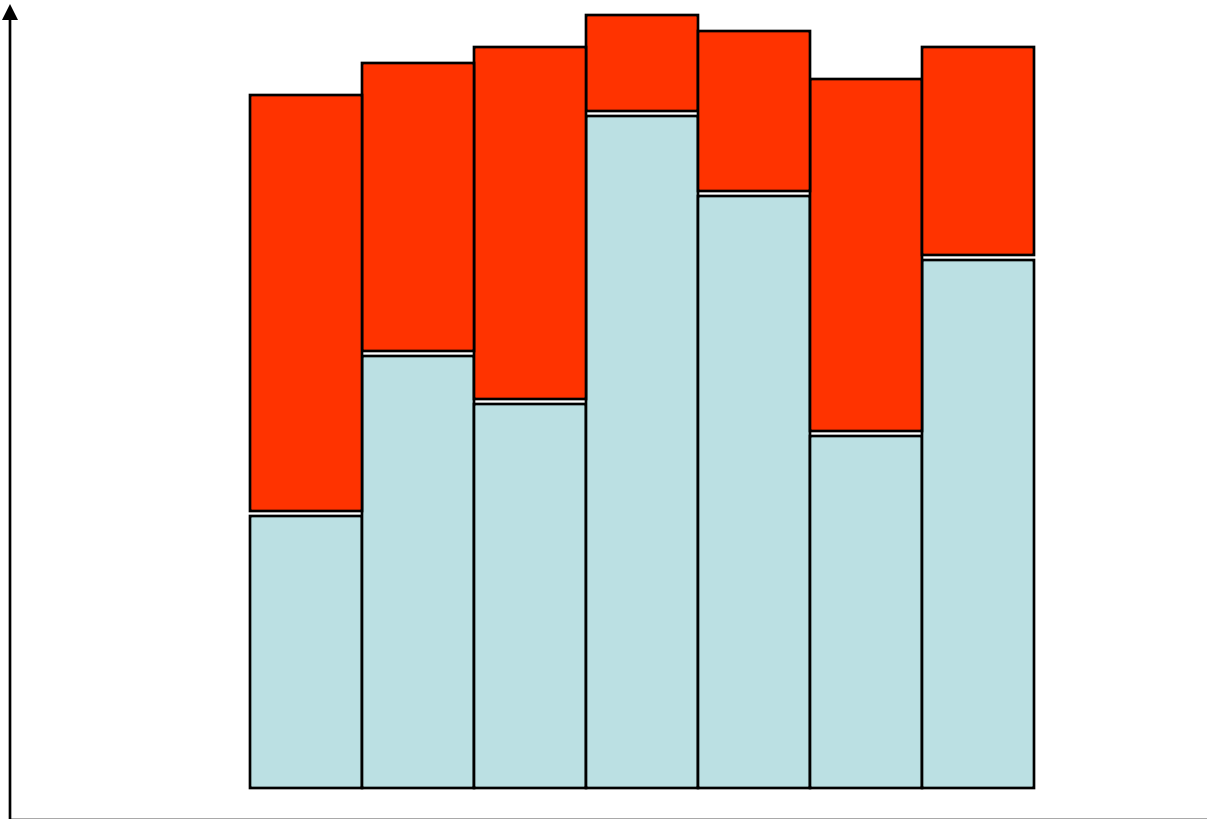
- There are obvious theoretical merits to harmonization and standardization if achievable
- To account for regional differences in standards, AAALAC accredits globally by using the “Guide” or by using local standards that produce performance outcomes compatible with the “Guide”



# International Accreditation



Quality level



Countries

Legal requirements...



# Non-U.S. Accreditation History

- First non-U.S. site accredited by AAALAC in 1981
- First European site accredited by AAALAC in 1986
- First Pacific Rim site accredited by AAALAC in 1995
- 772 institutions now accredited in 30 countries
  - US 674
  - Europe 50
  - Pacific Rim 48



# Factors Potentially Influencing the Conduct of Animal Research

- Flat or declining funding for biomedical research?
- Flat or declining funding for research infrastructure?
- Flat funding for federal oversight programs for animal research?
- No commensurate decrement in federal regulatory expectations



## Lean Times Are With Us?

- Funding source and mission dependent
- Possibly some insulation on the horizon for institutions that are federally-funded
- Health care costs and consolidation in the pharmaceutical industry a factor?
- What about small pharmaceutical and biotech start-up organizations?
- Outsourcing to low cost competitors
- In-sourcing to low cost competitors



# Factors Influencing the Conduct of Animal Research

- European movements towards reduced nonhuman primate use
- Migration of non-human primate studies offshore?
- The EU's REACH Legislation
  - 30,000 chemicals
  - Limits on animal testing
  - Non-compliance: the new protectionism?



## Flat Federal Funding for Regulatory Oversight

- Does it impact AAALAC International?
  - Significant findings first detected by AAALAC
  - AAALAC's "boots on the ground" are highly visible to the institutional members
  - AAALAC is obliged to examine institution-regulatory agency interactions
  - AAALAC "Inspectors"?



# The Essence of AAALAC's Critical Approach

- What's the problem? The facts.
- Why is it a problem? The observed deficiency.
- What must or should be done about the problem?
  - Non-prescriptive directions on the solution through relevant literature, regulatory or third party (non-AAALAC) consultative guidance.
- Remember: Recognize your role in the design and implementation of performance standards.



# Factors Potentially Influencing the Conduct of Animal Research

- The value of the U.S. dollar and institutional behavior-attempting to do more with less
  - More prudent animal use?
  - Efficiency measures for cost reduction in animal husbandry
  - Fewer FTE, fewer specialists, more generalists
  - Animal model selection by cost/benefit ratio
    - Storing germ-lines: embryo and sperm cryopreservation
    - Off shore activities-colony management
    - “Class B” dog and cat use



# Factors Potentially Influencing the Conduct of Animal Research

- More prudent animal use?
  - Numbers of animals used decreases
  - Operational impact
    - Fewer animals at dispersed sites
    - Inefficiency in operations
    - Less oversight
  - Outsourcing to other facilities (AAALAC implications)



# Factors Potentially Influencing the Conduct of Animal Research

- Efficiency measures for cost reduction in animal husbandry
  - Remember your role in performance standards
  - Assimilate and analyze the current literature
  - Focus on critical operations in quality and welfare
    - Sanitation/sterilization examples
    - Cage population density standards



# Factors Potentially Influencing the Conduct of Animal Research

- Fewer FTEs with decreased funding
  - Fewer specialists?
  - More generalists?
  - Competence must prevail
  - Who owns the process of evaluating competence?
  - Is that process rigorous?
- A driving force for satellite housing?



# Factors Potentially Influencing the Conduct of Animal Research

- Animal model selection by cost/benefit ratio
  - Storing germ-lines: embryo and sperm cryopreservation
  - Off shore (or contract lab) activities-colony management
  - “Class B” dog and cat use vis-à-vis colony bred animals



# Impact of Declining Funding for Infrastructure

- Veterinary scientist workforce issues
- Leaner management and/or supervision teams
- Increased deferred maintenance
- Reluctance to build for the future
- Less expensive options for maintaining models may be pursued
- Increased oversight may be necessary
  - IACUC implications
  - Staff implications



# Town Hall Time

Your questions and comments on  
AAALAC International please!

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