

Embracing Innovation in the Animal Drug Approval Process



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Four Critical Standards

- Safety
 - Human Food
 - Target Animal
 - Environmental
 - User Safety
- Effectiveness - Substantial Evidence
- Quality Manufactured Product
- Properly Labeled Product



Our Challenge

- To engage in the development and evaluation of new animal drugs, especially new innovative technologies
 - Non-traditional therapeutic indications
 - Increased safe, affordable and abundant food production
- Meet the changing, innovative regulatory needs of industry

Traditional Approval Model

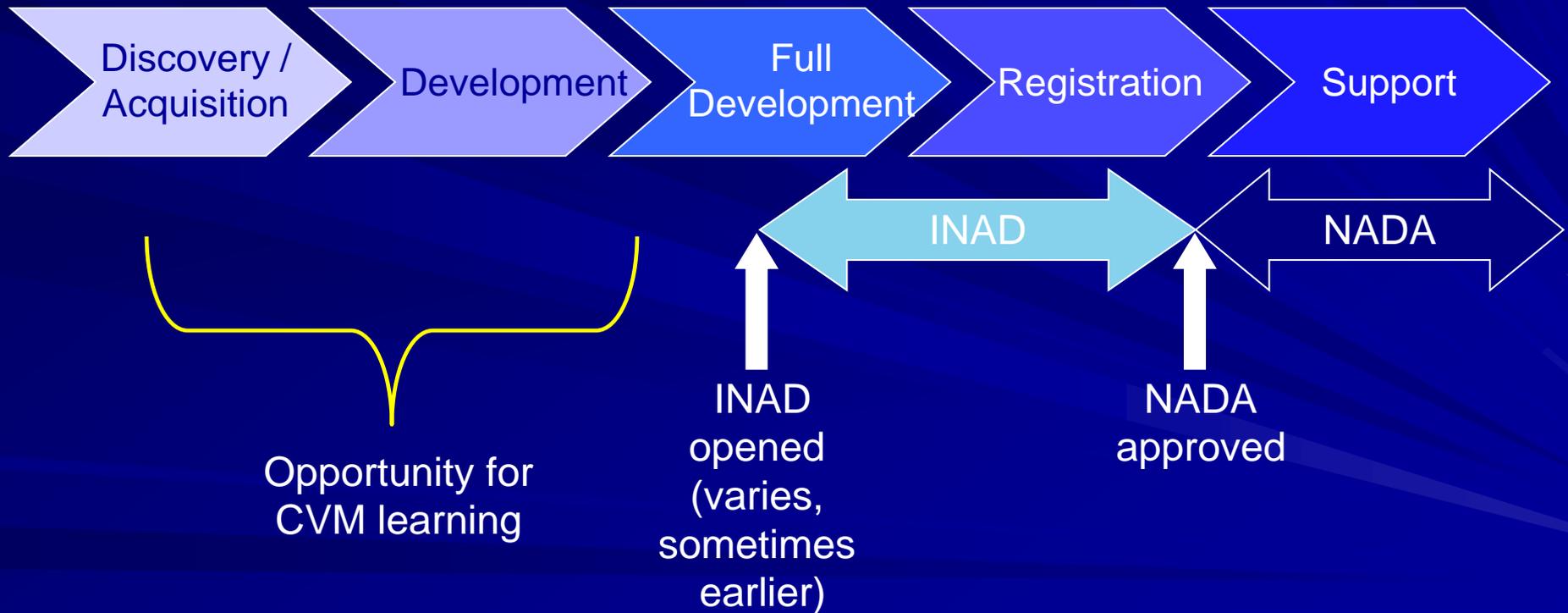
- Time-tested
- Efficient for *traditional* chemical entities
- Inefficient at addressing issues associated with new technologies
- ONADE needs to be agile in a dynamic environment



Perceptions of The Animal Drug Approval Process

- Don't be the first one through the process
- Current Guidance doesn't fit
- Processes are unpredictable for new innovation
- Inconsistencies between divisions and reviewers
- Fixing problems only after one or more cycles of review
- Ineffective and not timely communication

Drug Development Process



New Approach

- Use novel approaches to demonstrate our critical standards
- Increase predictability
- Gain enough scientific expertise to understand what is critical and what is not
- Become comfortable with ambiguity



Six Steps for Innovation within CVM

1. Create a cross-divisional advisory group to imaginatively and creatively develop new ways of embracing innovation- IVET
2. Visit pharmaceutical companies and consultants to discuss bringing new innovation to CVM
3. Establish an innovation working group with the Animal Health Institute
4. Animal Drug User Fee Act (ADUFA) 3– Embracing innovation/filling the pipeline
5. Work with sponsors before the pre-submission conference
6. Establish technology teams

Accomplishments

- Innovation Exploration Team- IVET
- Focus Groups
- Tech Teams
- Pre-INAD SOP
- International Collaboration

Innovation Exploration Team (IVET)

- Facilitate the introduction of innovative products and processes into ONADE by:
 - communicating with sponsors
 - proposing ways to adapt internal processes
 - providing training to ONADE reviewers to increase scientific and technical knowledge among reviewers
 - utilizing the existing knowledge within the Office, Center, and Agency
 - collaborating with International drug approval agencies

Focus Groups

- “Big Picture” novel technology issues for discussion, training, etc.
- Not necessarily tied to a specific submission or product
- Example: biomarkers

Technology Teams

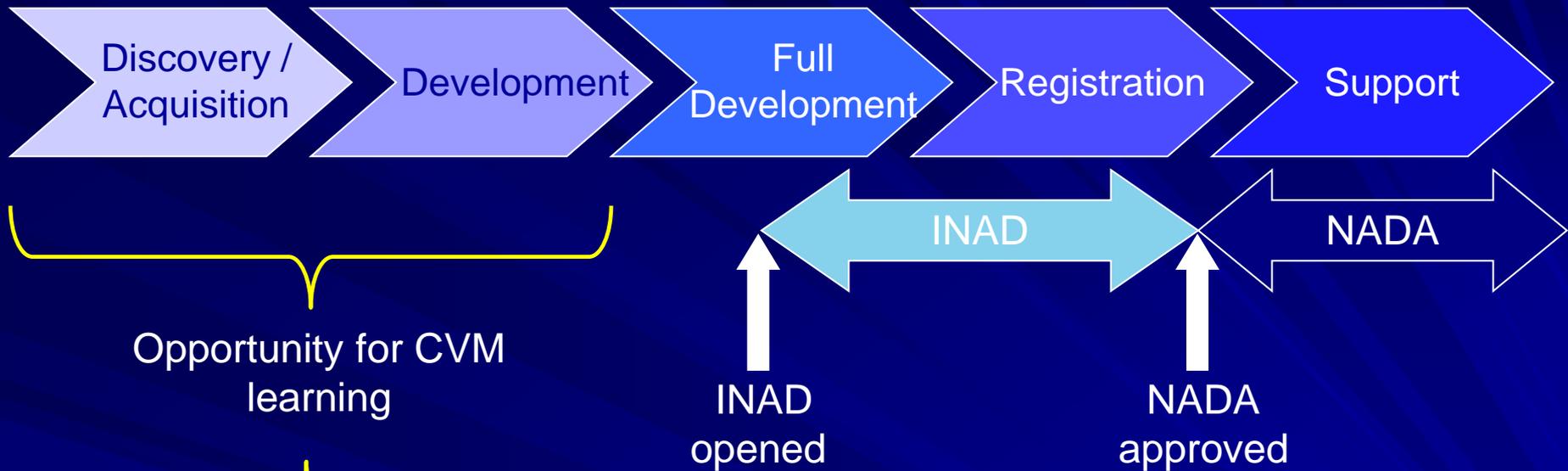
- A specific novel product, technology or platform to be reviewed
- Informally meet with sponsors in advance to establishing an INAD
- Develop potential review methods to handle novel products that may not fit under our current guidance

Pre-INAD Process

- Collaborator/Sponsor fills out questionnaire for innovative product/process
- Possible Tech Team formed - SOP in place
- Pre-INAD VMF file opened
- Interactions with CVM- informal, science-focused
- Greater focus on non-sponsor information sources
- Ideal - 2 years before pre-submission conference

Pre-INAD Process

- Gather information
 - Researchers and scientists developing the innovative technologies (including Collaborator/Sponsor)
 - Other Agencies (domestic and international)
 - Use of published literature, preliminary data, etc.
 - Epidemiologic tools
- Issue identification/risk analysis
- Transition to INAD and review team



Identify Product
Questionnaire
Form Tech Team
Open VMF



Gather Information



Issue Identification
and Risk Analysis



Transition to Review Team

↑ scientific knowledge
=
↑ regulatory certainty

**Systematic process to identify knowledge needs,
knowledge gaps, and regulatory strategy**

International Collaboration

- Current discussions
 - European Medicines Agency (EMA)
 - Veterinary Drug Directorate (VDD)
- Collaborate on ways to evaluate innovative technologies (*e.g.* stem cells)
- Regulatory Cooperation Council (RCC)

International Collaboration

Topics for Discussion

- How can the regulatory bodies in different countries share data on products?
- Single set of studies for EMA and CVM?
- Increasing the consistency of labeling across countries
- How do we better engage researchers from universities and other facilities around the world?

What Do We Need From Our Collaborators?

- **Increased collaboration** with CVM to work on issues earlier
- New lines of **communication and interaction** amongst scientists
- **Innovative and creative thinking**
- Higher level of **scientific engagement**
- **High quality** submissions

What's the Win?

- Maximize use of all forms of available information:
 - Increased use of preliminary data
 - Novel use of literature and other information
 - Collaborative data sharing
 - Within CVM divisions
 - Across international regulatory groups
- Early decisions and consultations with CVM
- Increased predictability
- And ultimately, increased availability of safe and effective novel technologies in the marketplace

Questions?



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