U.S. FDA Regulatory Framework: Animal Rule

Susan McDermott, MD
Lead Medical Officer
Counter-Terrorism and Emergency Coordination Staff
Office of the Center Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Non-Clinical Data for Regulatory Decision-Making on the Efficacy of Medical Countermeasures
European Medicines Agency
Hybrid workshop
24-25 Nov. 2025

FDA supports the 3Rs

FDA endorses the principles of replacement, reduction, and refinement of the use of animals in biomedical research.

Financial disclosures

I do not have any relevant financial disclosures for this presentation and attest that the clinical recommendations are evidence-based and free of commercial bias.

THE REGULATIONS COMMONLY KNOWN AS THE *ANIMAL RULE*

The Animal Rule

Drugs

Subpart I –

Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

21 CFR Parts 314.600-650

Biologics

Subpart H –

Approval of Biological Products When Human Efficacy Studies Are Not Ethical or Feasible

21 CFR Parts 601.90-95

Federal Register Vol. 67, No. 105, 37988-37998, May 31, 2002

New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies are Not Ethical or Feasible

The Animal Rule

- Effectiveness is established based on adequate and well-controlled studies in animals
  - "…when the results of those animal studies establish that the drug *[or biological]* product is reasonably likely to produce clinical benefit in humans."

Quote from 21 CFR 314.610(a) for drugs and 21 CFR 601.91(a) for biological products

Effectiveness

- Safety is established "under preexisting requirements for establishing the safety of new drug and biological products."

Quote from 67 FR 37988 at 37989, May 31, 2002

Safety

The Animal Rule

Scope: The Animal Rule can be used only when all of these circumstances are met

The product is intended to ameliorate or prevent a serious or life-threatening condition caused by exposure to a lethal or permanently disabling toxic chemical, biological, radiological or nuclear (CBRN) substance	Definitive human efficacy studies cannot be conducted because deliberate exposure of healthy volunteers to the lethal or permanently disabling toxic CBRN substance would be unethical	Field trials to study effectiveness of the product after an accidental or hostile exposure to the CBRN substance have not been feasible	The product cannot be approved or licensed for the proposed indication based on efficacy standards described in other parts of the regulations

The product has been studied for safety

From 21 CFR 314.600 for drugs; 21 CFR 601.90 for biologics

The Animal Rule

1. There is a reasonably well-understood pathophysiological mechanism of the toxicity of the substance and its prevention or substantial reduction by the product

2. The effect is demonstrated in more than one animal species expected to react with a response predictive for humans, unless the effect is demonstrated in a single animal species that represents a sufficiently well-characterized animal model for predicting the response in humans

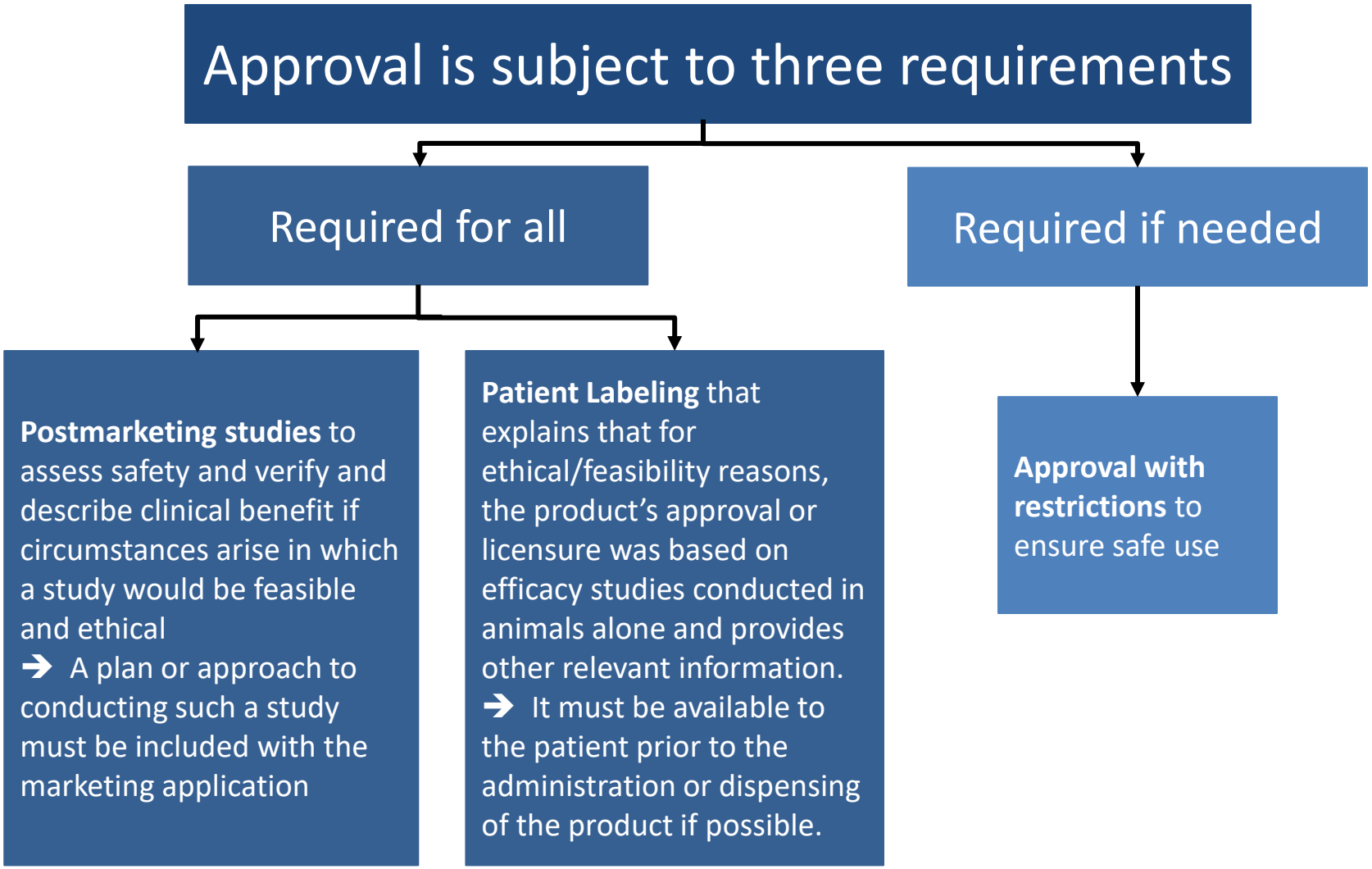
All four criteria must be met

3. The animal study endpoint is clearly related to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity

4. The data or information on the kinetics and pharmacodynamics of the product or other relevant data or information, in animals and humans, allows selection of an effective dose in humans

Quoted from 21 CFR 314.610(a) for drugs; 21 CFR 601.91(a) for biologics

The Animal Rule



From 21 CFR 314.610(b) for drugs; 21 CFR 601.91(b) for biologics

Product Development Under the Animal Rule

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

or

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71, Room 3128
Silver Spring, MD 20993-0002
Phone: 800-835-4709 or 240-402-8010
Email: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2015
Animal Rule

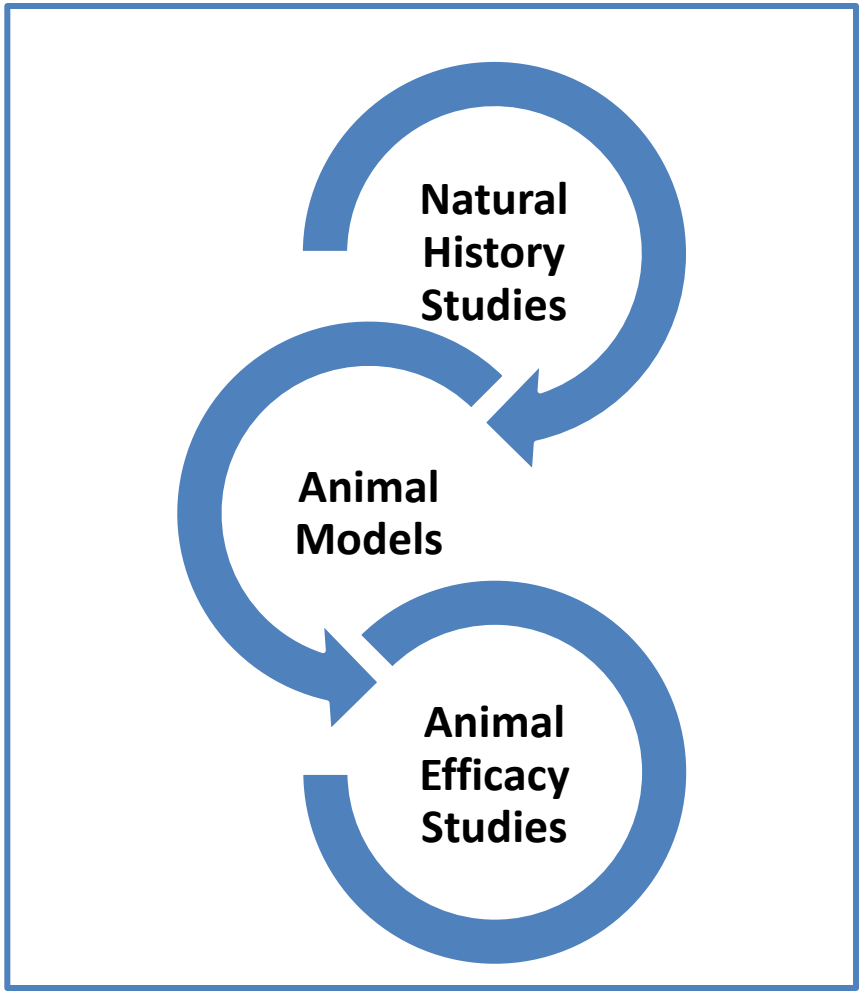
See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/product-development-under-animal-rule

THE CRITICAL IMPORTANCE OF ANIMAL MODELS

Establishing effectiveness

Effectiveness is established based on adequate and well-controlled studies in animals

- **"…when the results of those animal studies establish that the drug *[or biological]* product is reasonably likely to produce clinical benefit in humans."**



Quoted from 21 CFR 314.610(a) for drugs and 21 CFR 601.91(a) for biological products

Animal models

Selection of an Animal Model

Adequacy as a model of key elements of the human disease or condition

AND

Suitability with regard to the investigational drug or biological product

Product Development Under the Animal Rule

V. ESSENTIAL ELEMENTS OF AN ANIMAL MODEL

A. Elements Related to the Etiologic or Challenge Agent-Induced Disease or Condition

1. *Characteristics of the Etiologic or Challenge Agent That Influence the Disease or Condition*
2. *Host Susceptibility and Response*
3. *Natural History of the Disease or Condition – Pathophysiological Comparability*
4. *Trigger for Intervention*

B. Elements Related to the Investigational Drug and the Selection of an Effective Dose in Humans

1. *The Investigational Drug*
2. *Selection of an Effective Dose in Humans*

➔ **See also checklist in section IX**

Data elements to be compared between the selected animal species and humans

IX. CHECKLIST OF ESSENTIAL ELEMENTS OF AN ANIMAL MODEL

The following checklist provides a list of data elements (and the corresponding sections within this guidance) for consideration when developing an animal model. The purpose of this checklist is to remind sponsors of the need to compare the data elements for the selected animal species to what is known about the human disease or condition in their submissions to FDA. Sponsors should note and explain any differences and indicate whether they expect these differences to have an impact on the interpretability of the data.

DATA ELEMENTS (Corresponding Sections Within the Guidance)	Animal(s)	Human
ELEMENTS RELATED TO THE ETIOLOGIC OR CHALLENGE AGENT-INDUCED DISEASE OR CONDITION		
CHARACTERISTICS OF THE ETIOLOGIC OR CHALLENGE AGENT		
• The Challenge Agent (V.A.1.a)		
• Pathophysiological Mechanisms of Toxicity or Virulence (V.A.1.b)		
• Route of Exposure (V.A.1.c)		
• Dose and Quantification of Exposure (V.A.1.d)		
HOST SUSCEPTIBILITY AND RESPONSE (V.A.2)		
NATURAL HISTORY OF THE DISEASE OR CONDITION - PATHOPHYSIOLOGICAL COMPARABILITY		
• Time to Onset (V.A.3.a)		
• Progression (V.A.3.b)		
• Manifestations (V.A.3.c)		
TRIGGER FOR INTERVENTION (V.A.4)		
ELEMENTS RELATED TO THE INVESTIGATIONAL DRUG AND THE SELECTION OF AN EFFECTIVE DOSE IN HUMANS		
THE INVESTIGATIONAL DRUG		
• Mechanism of Action (V.B.1.a)		
• Drug Class (V.B.1.b)		
• Dosage Form and Route of Administration (V.B.1.c)		
SELECTION OF AN EFFECTIVE DOSE IN HUMANS (‡)		
• PK and PD Information to Be Obtained in Animals and Humans (V.B.2.a)		
• PK/PD Considerations for Human Dose Selection (V.B.2.b)		
(‡) For information on vaccine dose selection, see section VII.A.		

DEMONSTRATING EFFICACY

Statutory standard for effectiveness

Substantial evidence

" . . . evidence consisting of **adequate and well-controlled investigations**, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

(Section 505(d) of FD&C Act (21 U.S.C. 355(d))

Efficacy studies

Design and Conduct of Efficacy Studies

Adequate and well-controlled animal efficacy studies substitute for human efficacy trials

Product Development Under the Animal Rule

VI. DESIGN CONSIDERATIONS FOR THE ADEQUATE AND WELL-CONTROLLED EFFICACY STUDIES IN ANIMALS

A. General Principles

B. Dose Selection in Animals

➔ See also checklist in section X

Adequate and well-controlled studies

21 CFR 314.126(b)

- Describes the characteristics of an adequate and well-controlled study, such as:
  - Study objectives
  - Methods of analysis
  - Use of control groups
  - Method of selection of subjects
  - Method for assigning subjects to treatment/control groups
  - Measures taken to minimize bias (e.g., blinding)
  - Methods of assessment of subjects' responses
  - Analysis of results

Study design elements that should be described and justified in the protocol

X. CHECKLIST OF ELEMENTS OF AN ADEQUATE AND WELL-CONTROLLED ANIMAL EFFICACY STUDY PROTOCOL

This checklist is included to remind sponsors of the information that should be included in their adequate and well-controlled animal efficacy study protocols. For further information, refer to section VI.

PROTOCOL CONSIDERATIONS
• Indication to Be Studied
• Agency Concurrence on the Details of the Animal Model
• Comparability of the Study Design to the Clinical Scenario

STUDY DESIGN ELEMENTS	Described	Justified
• Controls		
• Size of Study Groups and Male/Female Composition of Groups		
• Animal Characteristics (†) (e.g., species, age, weight, source of animals)		
• Inclusion and Exclusion Criteria for Acceptance Into Study		
• Dose, Route of Exposure, and Preparation of the Challenge Agent		
• Trigger for Intervention		
• Dose, Regimen, and Route of Administration of the Investigational Drug		
• Randomization		
• Blinding		
• Statistical Plan		
• Endpoints		
• Euthanasia Criteria		
• Observation Frequency and Schedule		
• Animal Care Interventions		
• Plan for Ensuring the Quality and Integrity of the Data		

(†) See section IV.D for further description.

Communication is key

Obtain Agency concurrence on:

- Animal models in which efficacy will be tested
- Design of the adequate and well-controlled animal efficacy studies

Animal Rule approvals/licensures

Soman Nerve Agent Poisoning – Prophylaxis Against Lethal Effects

- PYRIDOSTIGMINE BROMIDE (pyridostigmine bromide tablet (30 mg)) (CDER, 2003)
- PYRIDOSTIGMINE BROMIDE (pyridostigmine bromide extended-release tablets (105 mg)) (CDER, 2024)

Anthrax – Inhalational

- RAXIBACUMAB (raxibacumab injection) (CDER, 2012)
- ANTHRASIL (Anthrax Immune Globulin Intravenous (Human)) (CBER, 2015)
- BIOTHRAX (Anthrax Vaccine Adsorbed) (CBER, 2015)
  - Only the post-exposure prophylaxis indication was an Animal Rule approval
- ANTHIM (obiltoxaximab injection) (CDER, 2016)
- CYFENDUS (Anthrax Vaccine Adsorbed, Adjuvanted) suspension for intramuscular injection (CBER, 2023)

Cyanide Poisoning

- CYANOKIT (hydroxocobalamin injection, powder, lyophilized, for solution) (CDER, 2006)

Symptomatic Botulism

- BAT (Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) - (Equine)) (CBER, 2013)

Hematopoietic Syndrome of Acute Radiation Syndrome

- NEUPOGEN (filgrastim injection) (CDER, 2015)
- NEULASTA (pegfilgrastim injection) (CDER, 2015)
- LEUKINE (sargramostim solution and lyophilized powder, for injection) (CDER, 2018)
- NPLATE (romiplostim for injection for subcutaneous use) (CDER, 2021)

Plague – Including Pneumonic and Septicemic Plague

- LEVAQUIN (levofloxacin tablet, oral solution & injection) (CDER, 2012)
- CIPRO (ciprofloxacin hydrochloride tablet & oral suspension, ciprofloxacin IV infusion) (CDER, 2015)
- AVELOX (moxifloxacin hydrochloride tablet & moxifloxacin injection) (CDER, 2015)

Smallpox Disease

- TPOXX (tecovirimat)
  - TPOXX (tecovirimat capsule for oral use) (CDER, 2018)
    - TPOXX (tecovirimat capsule for oral use) (*expanded patient population*) (CDER, 2022)
  - TPOXX (tecovirimat injection for intravenous use) (CDER, 2022)
- TEMBEXA (brincidofovir oral suspension & tablet) (CDER, 2021)

For more information see FDA's Animal Rule Information webpage and FDA's Animal Rule Approvals webpage.


FDA
U.S. FOOD & DRUG
ADMINISTRATION

ADDITIONAL RESOURCE SLIDES

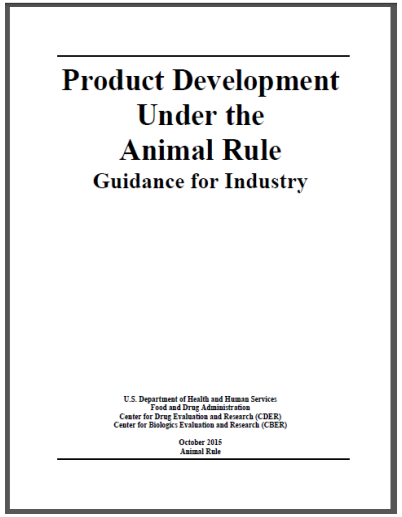
THE ANIMAL RULE FROM A PRACTICAL STANDPOINT

Communication is key

FDA encourages early and ongoing communication

Guidances for developing products under the Animal Rule

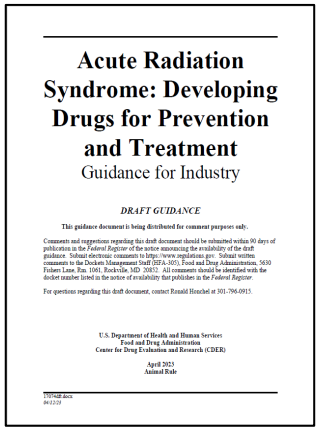
Overarching guidance


Product Development Under the Animal Rule
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

October 2015
Animal Rule

Indication-specific guidances

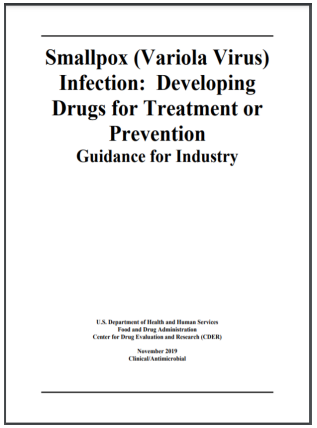

Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

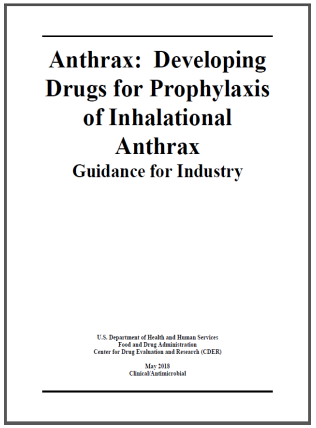
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2023
Animal Rule


Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention
Guidance for Industry

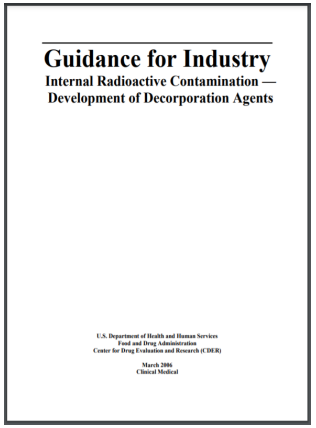
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

November 2019
Clinical/Antimicrobial


Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax
Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

May 2018
Clinical/Antimicrobial


Guidance for Industry
Internal Radioactive Contamination — Development of Decorporation Agents

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2006
Clinical Medical

Regulation versus guidance

Regulation

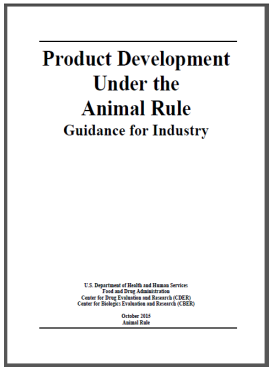
Code of Federal Regulations
A point in time eCFR system
NATIONAL ARCHIVES
eCFR

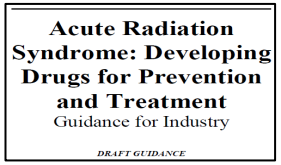
21 CFR 314
Subpart I

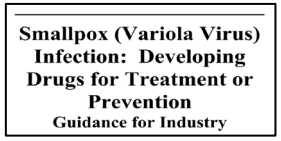
21 CFR 601
Subpart H

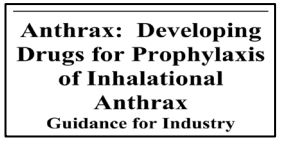
Standards for approval or licensure

Guidance


Product Development
Under the
Animal Rule
Guidance for Industry


Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment
Guidance for Industry
DRAFT GUIDANCE

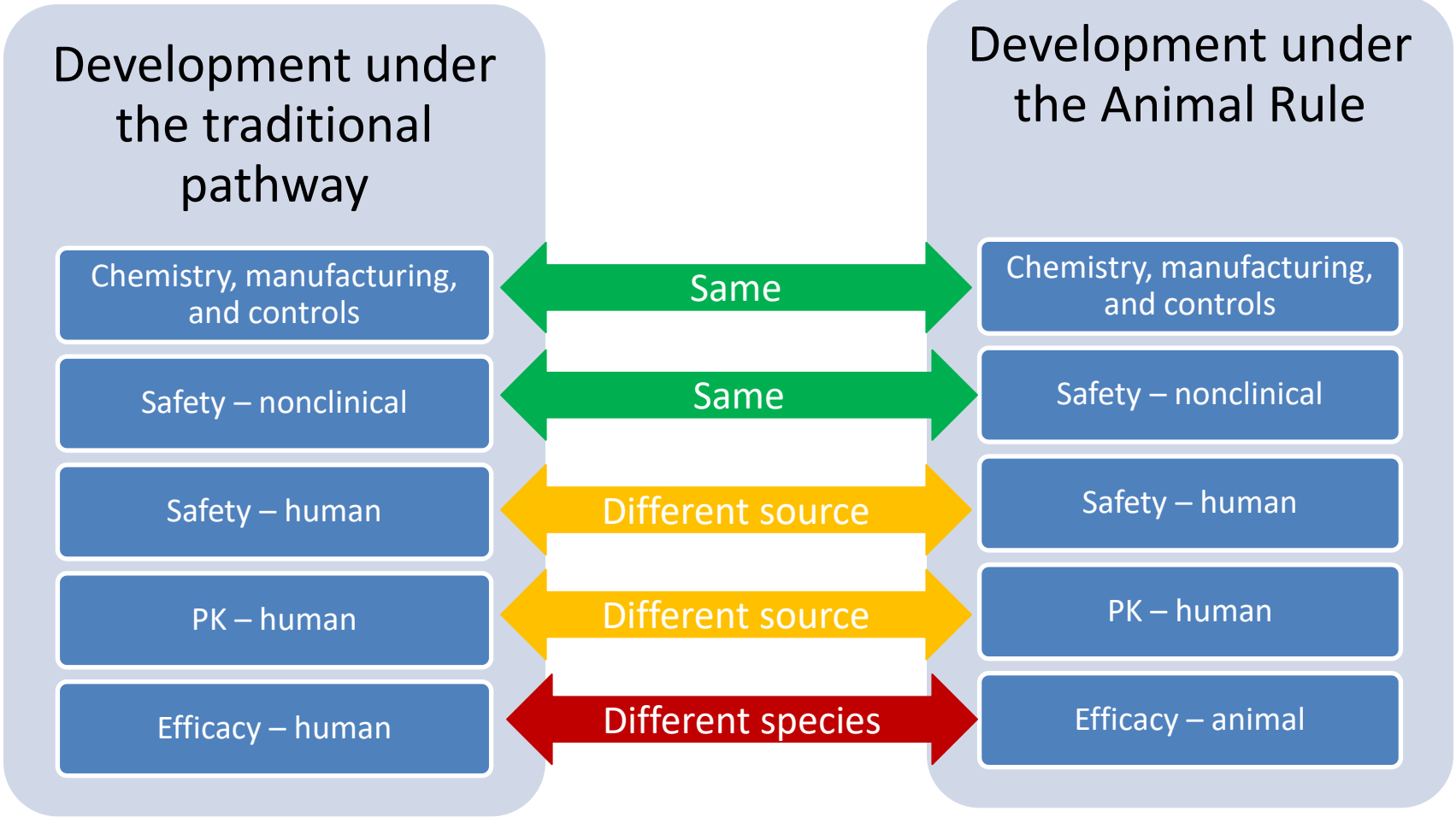

Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention
Guidance for Industry


Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax
Guidance for Industry


Guidance for Industry
Internal Radioactive Contamination — Development of Decorporation Agents

Nonbinding recommendations - FDA's current thinking on the topic

Key differences in product development



DATA QUALITY AND INTEGRITY

Confidence in the data is critical

There are no regulations that specifically address data quality and integrity issues for Animal Rule-specific studies

FDA recommends the use of the good laboratory practice (GLP) regulations, to the extent practicable

From FDA's guidance of *Product Development Under the Animal Rule* – section IV. B

Confidence in the data is critical

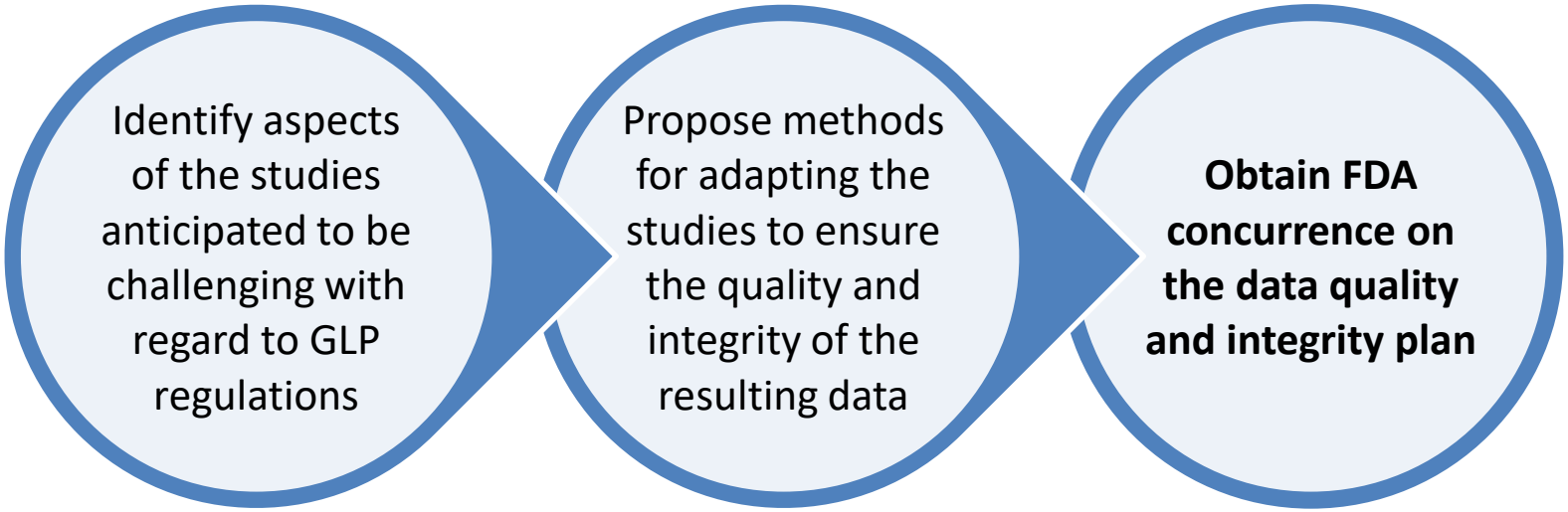
FDA recommends the use of the GLP regulations, to the extent practicable

- For the adequate and well-controlled animal efficacy studies that serve as substantial evidence of the effectiveness necessary for approval of drugs or licensure of biological products under the Animal Rule
- For the pharmacokinetic and/or pharmacodynamic studies in animals used to select a dose and regimen in humans

From FDA's guidance *Product Development Under the Animal Rule* – section IV.B

Confidence in the data is critical

Before initiating these studies



From FDA's guidance of *Product Development Under the Animal Rule* – section IV. B

Different concepts – equally important

Data quality and integrity

Adequate and well-controlled study

Different concepts – equally important

Ensuring data quality and integrity does not compensate for problems with study design

Data quality and integrity

Adequate and well-controlled study

Different concepts – equally important

Ensuring data quality and integrity does not compensate for problems with study design

Data quality and integrity

Adequate and well-controlled study

Good study design does not compensate for problems with data quality and integrity

ANIMAL RULE APPROVALS/LICENSURES

Animal Rule approvals/licensures

Soman Nerve Agent Poisoning – Prophylaxis Against Lethal Effects

- PYRIDOSTIGMINE BROMIDE (pyridostigmine bromide tablet (30 mg)) (CDER, 2003)
- PYRIDOSTIGMINE BROMIDE (pyridostigmine bromide extended-release tablets (105 mg)) (CDER, 2024)

Anthrax – Inhalational

- RAXIBACUMAB (raxibacumab injection) (CDER, 2012)
- ANTHRASIL (Anthrax Immune Globulin Intravenous (Human)) (CBER, 2015)
- BIOTHRAX (Anthrax Vaccine Adsorbed) (CBER, 2015)
  - Only the post-exposure prophylaxis indication was an Animal Rule approval
- ANTHIM (obiltoxaximab injection) (CDER, 2016)
- CYFENDUS (Anthrax Vaccine Adsorbed, Adjuvanted) suspension for intramuscular injection (CBER, 2023)

Cyanide Poisoning

- CYANOKIT (hydroxocobalamin injection, powder, lyophilized, for solution) (CDER, 2006)

Symptomatic Botulism

- BAT (Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) - (Equine)) (CBER, 2013)

Hematopoietic Syndrome of Acute Radiation Syndrome

- NEUPOGEN (filgrastim injection) (CDER, 2015)
- NEULASTA (pegfilgrastim injection) (CDER, 2015)
- LEUKINE (sargramostim solution and lyophilized powder, for injection) (CDER, 2018)
- NPLATE (romiplostim for injection for subcutaneous use) (CDER, 2021)

Plague – Including Pneumonic and Septicemic Plague

- LEVAQUIN (levofloxacin tablet, oral solution & injection) (CDER, 2012)
- CIPRO (ciprofloxacin hydrochloride tablet & oral suspension, ciprofloxacin IV infusion) (CDER, 2015)
- AVELOX (moxifloxacin hydrochloride tablet & moxifloxacin injection) (CDER, 2015)

Smallpox Disease

- TPOXX (tecovirimat)
  - TPOXX (tecovirimat capsule for oral use) (CDER, 2018)
    - TPOXX (tecovirimat capsule for oral use) (*expanded patient population*) (CDER, 2022)
  - TPOXX (tecovirimat injection for intravenous use) (CDER, 2022)
- TEMBEXA (brincidofovir oral suspension & tablet) (CDER, 2021)

For more information see FDA's Animal Rule Information webpage and FDA's Animal Rule Approvals web page.

FDA'S ANIMAL MODEL QUALIFICATION PROGRAM

Animal Model Qualification Program (AMQP)

Purpose	To support the development of product-independent animal models that can be used for efficacy testing of multiple products under the Animal Rule
	Qualified animal models are made publicly available
Voluntary	Seeking qualification of an animal model through the AMQP is voluntary
Expert feedback	Provides an avenue to obtain FDA subject matter expert feedback on early animal model development
	There is also value to qualifying animal models that have been used in Animal Rule approvals
Additional information	See the Animal Model Qualification Program web page Contact information: AnimalModelQualification@FDA.HHS.gov

Qualification of an animal model - a two-part regulatory conclusion

- FDA has concluded that a specific animal species, given a specific challenge agent by a specific route, produces a disease process or condition that in multiple important aspects corresponds to the human disease or condition of interest

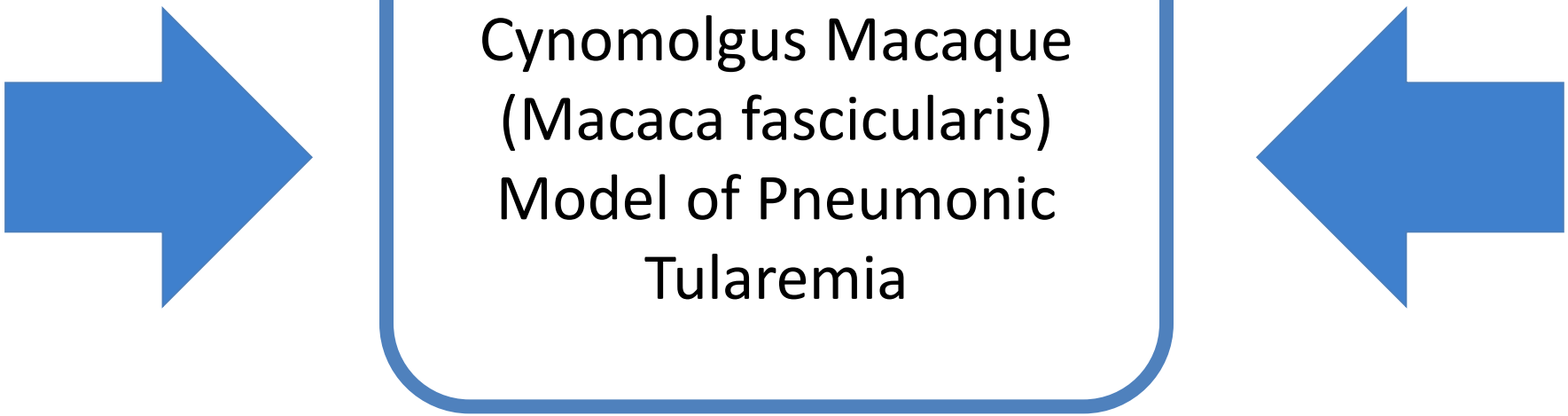
1. Model of the disease or condition

- FDA has accepted the description of the model's appropriate use *[e.g., treatment of pneumonic plague]* in regulatory applications, including the definition of the parameters of the disease or condition that will be used as measures of quality control and quality assurance when the model is used

2. Description of use in regulatory applications

From FDA's guidance *Product Development Under the Animal Rule* – section III.D

First animal model qualified

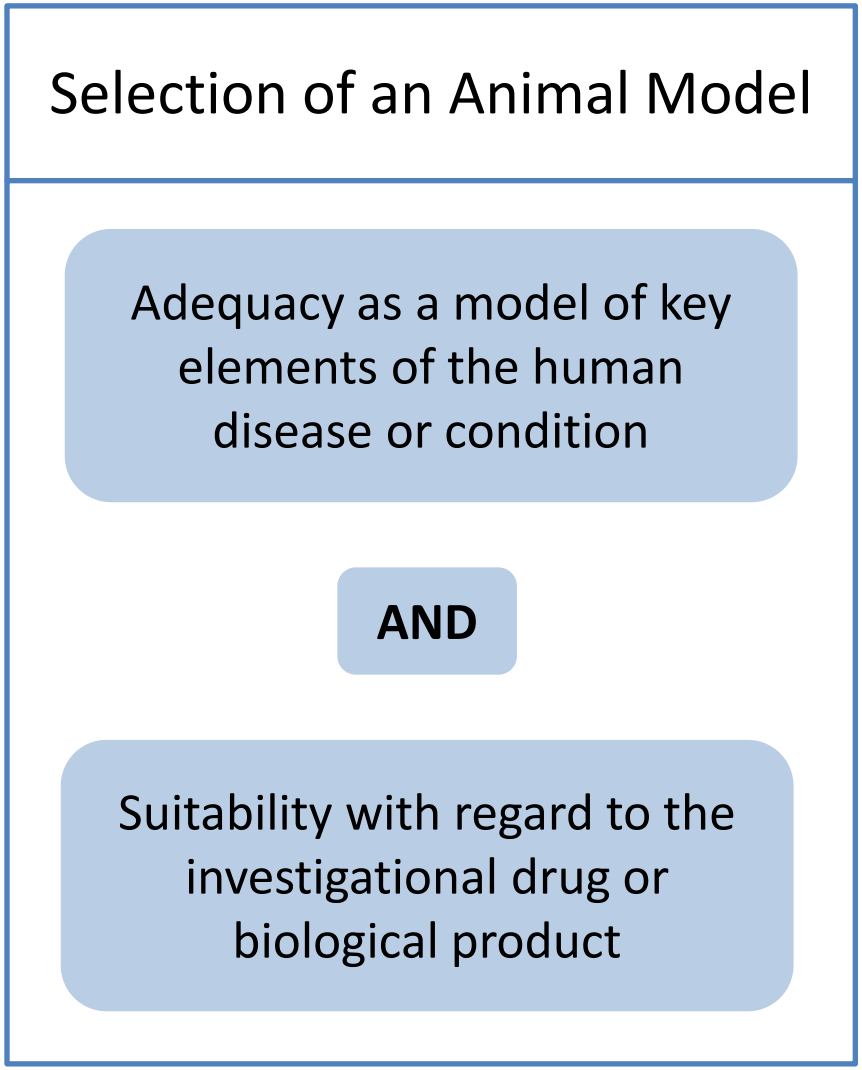


NIH/NIAID

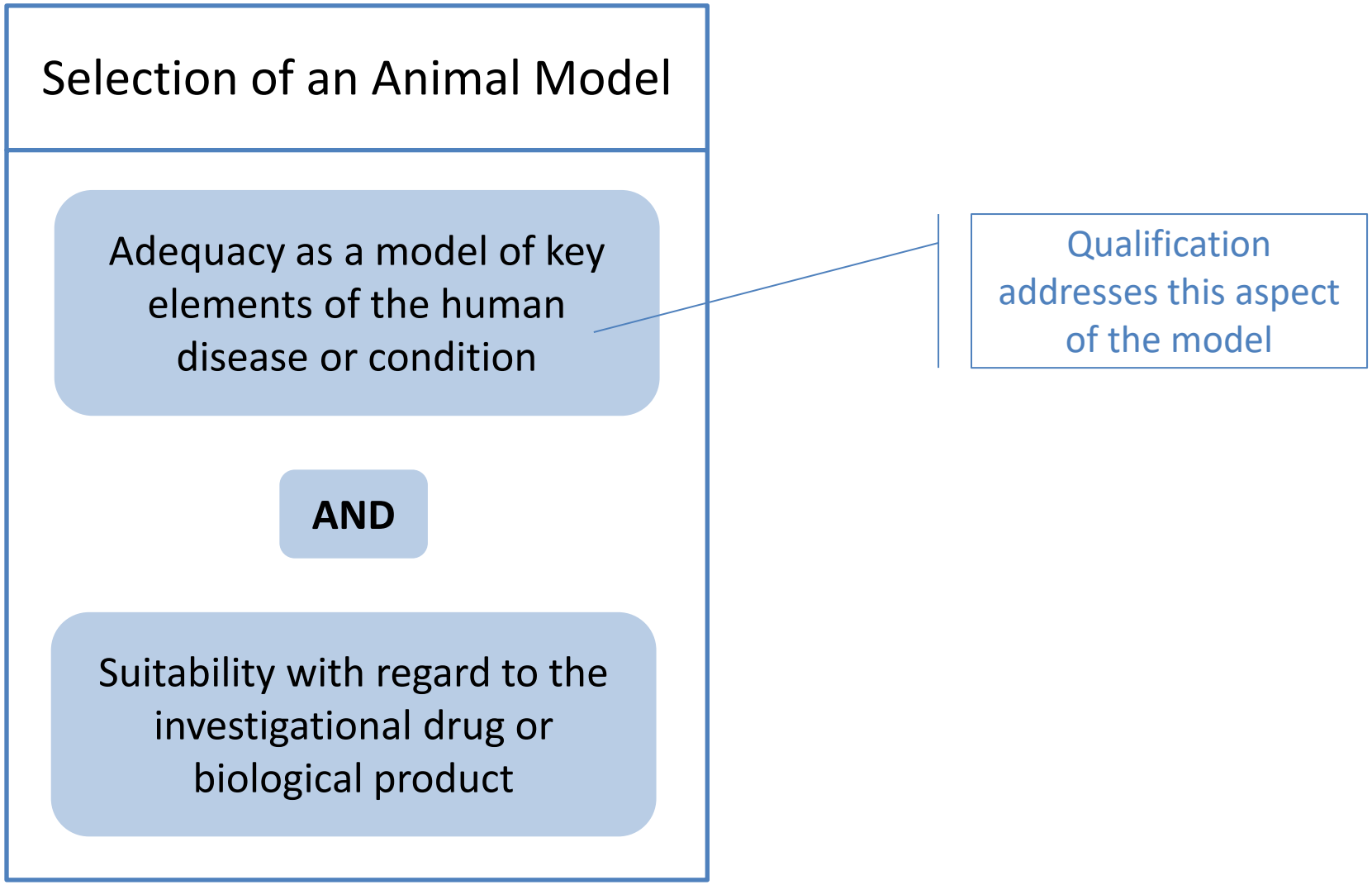
Oct. 12, 2021

DDT-AMQ-000006

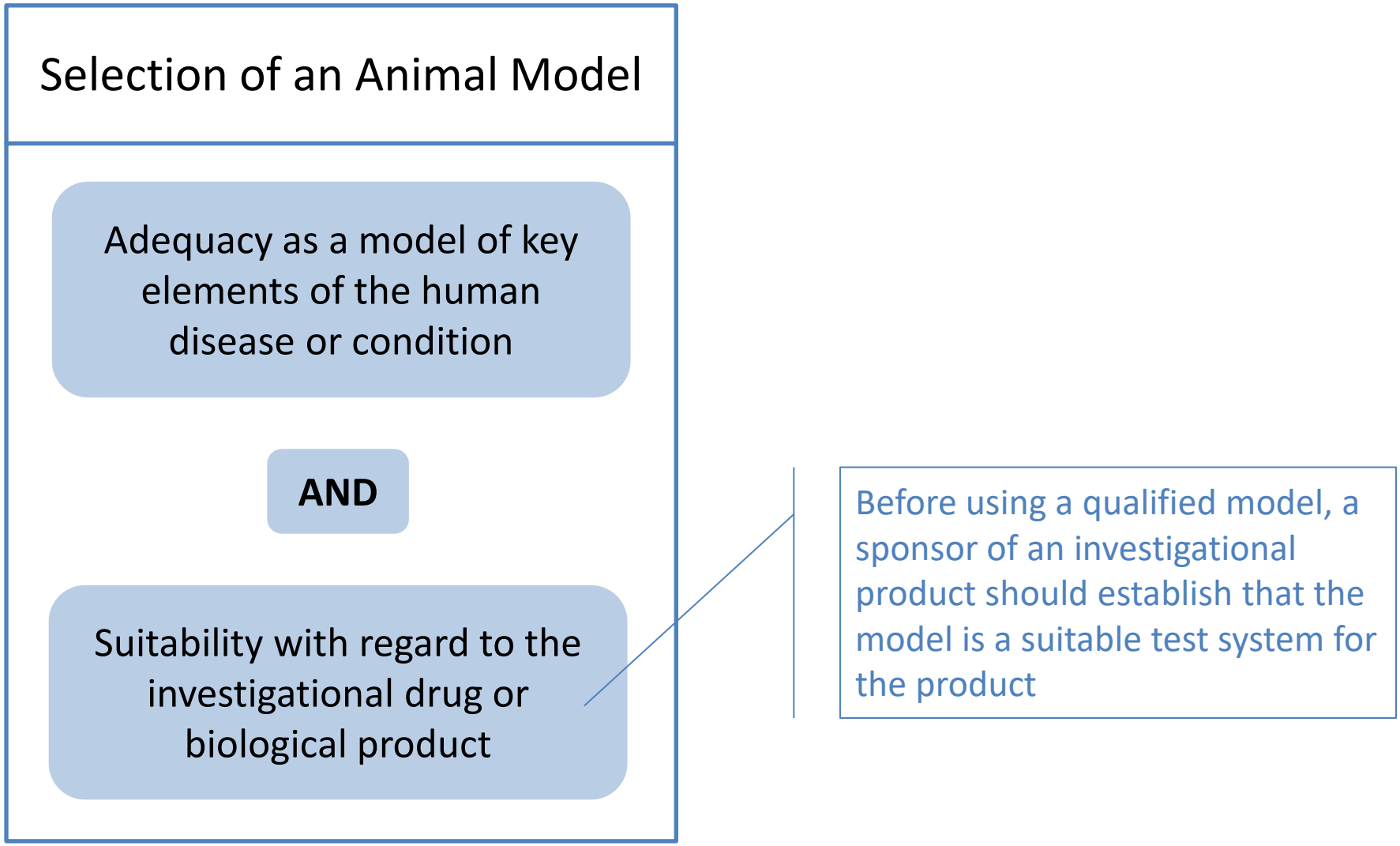
An important caveat for the use of a qualified model



An important caveat for the use of a qualified model



An important caveat for the use of a qualified model



ALTERNATIVE METHODS

Alternative methods

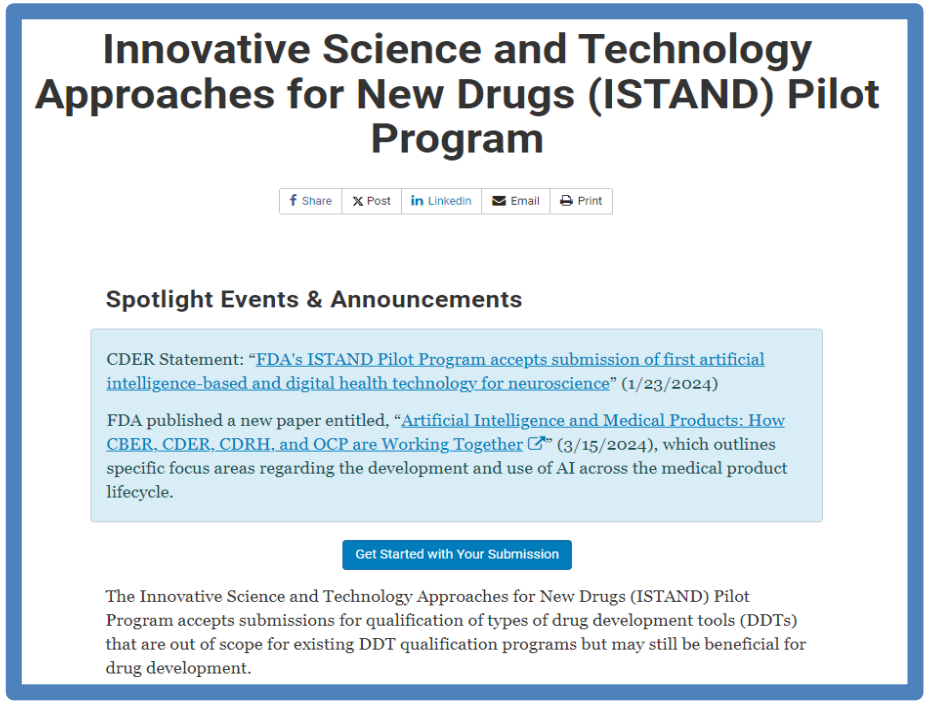
Approval under the Animal Rule requires adequate and well-controlled animal efficacy studies. Nonanimal methods may be supportive.

FDA supports the principles of the *3Rs*, to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with the FDA if they wish to use a nonanimal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

Advancing Alternative Methods at FDA

Share | Post | Linkedin | Email | Print

FDA is working to advance alternative methods for regulatory use. Alternative Methods have the potential to provide more timely and more predictive information to assess certain aspects of FDA-regulated products while also replacing, reducing and/or refining animal testing (the 3Rs).



Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program

Share | Post | Linkedin | Email | Print

Spotlight Events & Announcements

CDER Statement: "FDA's ISTAND Pilot Program accepts submission of first artificial intelligence-based and digital health technology for neuroscience" (1/23/2024)

FDA published a new paper entitled, "Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together" (3/15/2024), which outlines specific focus areas regarding the development and use of AI across the medical product lifecycle.

Get Started with Your Submission

The Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program accepts submissions for qualification of types of drug development tools (DDTs) that are out of scope for existing DDT qualification programs but may still be beneficial for drug development.

CONTACT INFORMATION FOR QUESTIONS

Contact information

Questions related to medical countermeasure development in CDER and CBER

- **If you know the regulatory review division for your product**
  - Consult the review division
- **If you are unsure of the regulatory review division for your product**
  - Consult the CDER contact: Susan McDermott, MD
    - 301-796-1121 or Susan.McDermott@FDA.HHS.gov
  - Consult the CBER contact: David Cho, PhD, MPH
    - 240-402-8036 or David.Cho@FDA.HHS.gov

REFERENCES

Some relevant regulations

Regulations

(found in the Code of Federal Regulations)

- Animal Rule: 21 CFR 314.600-650 (drugs); 21 CFR 601.90-95 (biologics)
- Good laboratory practice for nonclinical laboratory studies: 21 CFR part 58
- Adequate and well-controlled studies: 21 CFR 314.126

Publication of the final rule

(see introduction/preamble)

- New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible (Federal Register Vol. 67, No. 105, 37988-37998, May 31, 2002)

Animal Rule-related guidances

Animal Rule - product development guidances

- ***Product Development Under the Animal Rule*** (CDER/CBER, October 2015)
- ***Acute Radiation Syndrome: Developing Drugs for Prevention and Treatment*** (Draft) (CDER, April 2023)
- ***Smallpox (Variola Virus) Infection: Developing Drugs for Treatment or Prevention*** (CDER, November 2019)
- ***Anthrax: Developing Drugs for Prophylaxis of Inhalational Anthrax*** (CDER, May 2018)
- ***Internal Radioactive Contamination – Development of Decorporation Agents*** (CDER, March 2006)

Animal Model Qualification Program-related guidance

- ***Qualification Process for Drug Development Tools*** (CDER/CBER November 2020)

Animal Rule-related documents (other than guidance)

Other Animal Rule-related documents

- Compliance Program
  - ***Inspection of Nonclinical Laboratories Conducting Animal Rule-Specific Studies*** (Program 7348.007) (March 2019)
- Data standards implementation guide
  - ***CDISC Standard for Exchange of Nonclinical Data Implementation Guide: Animal Rule*** (version 1.0) (SENDIG-AR) (September 2019)

Some product development guidances

Special protocol assessment (SPA) guidance

- ***Special Protocol Assessment*** (Revision 1) (CDER/CBER, April 2018)

Communications guidance

- ***Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*** (DRAFT, CDER/CBER, September 2023)

Product classification guidance

- ***Classification of Products as Drugs and Devices & Additional Product Classification Issues*** (OC/OSMP/OCP, September 2017)

Some relevant FDA web pages

Animal Rule-related

- Animal Rule Approvals
- Animal Rule Information
- Animal Model Qualification Program

Guidance-related

- Search For FDA Guidance Documents (FDA's overarching guidance web page)
- Vaccine and Related Biological Product Guidances (topic-focused guidance web page)

Alternative methods

- Advancing Alternative Methods at FDA
- Innovative Science and Technology Approaches for New Drugs (ISTAND) Program

Medical countermeasure-related

- Medical Countermeasures Initiative (MCMi)
  - MCMi Program Update

If the hyperlink fails, go to www.fda.gov and search on the topic

Publicly available information

Animal Rule approvals/licensures

CDER

- Refer to CDER's Animal Rule Approvals web page
  - Use the information from that web page to search in Drugs@FDA

CBER

- Refer to CBER's web page: CBER-Regulated Products with Supporting Documents
  - Alphabetical listing of products with links to publicly available documents

Meetings*

- Public meetings and workshops
- FDA advisory committee meetings

* Receive FDA email alerts on emergency preparedness and response topics from FDA, including medical countermeasures and emerging infectious diseases – subscribe using link at the bottom of the Medical Countermeasures Initiative (MCMi) webpage


FDA
U.S. FOOD & DRUG
ADMINISTRATION