

# Submitting a PET Drug Investigational New Drug (IND) Application

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**Center for Drug Evaluation and Research**  
**U.S. Food and Drug Administration**

# *Outline*

- **Introduction**
- **When IND Submission Is Not Required**
- **When IND Submission Is Appropriate**
- **IND For Clinical Trial vs. Expanded Access**
- **IND Content**
- **IND Process**

# *Uses of PET Drugs*

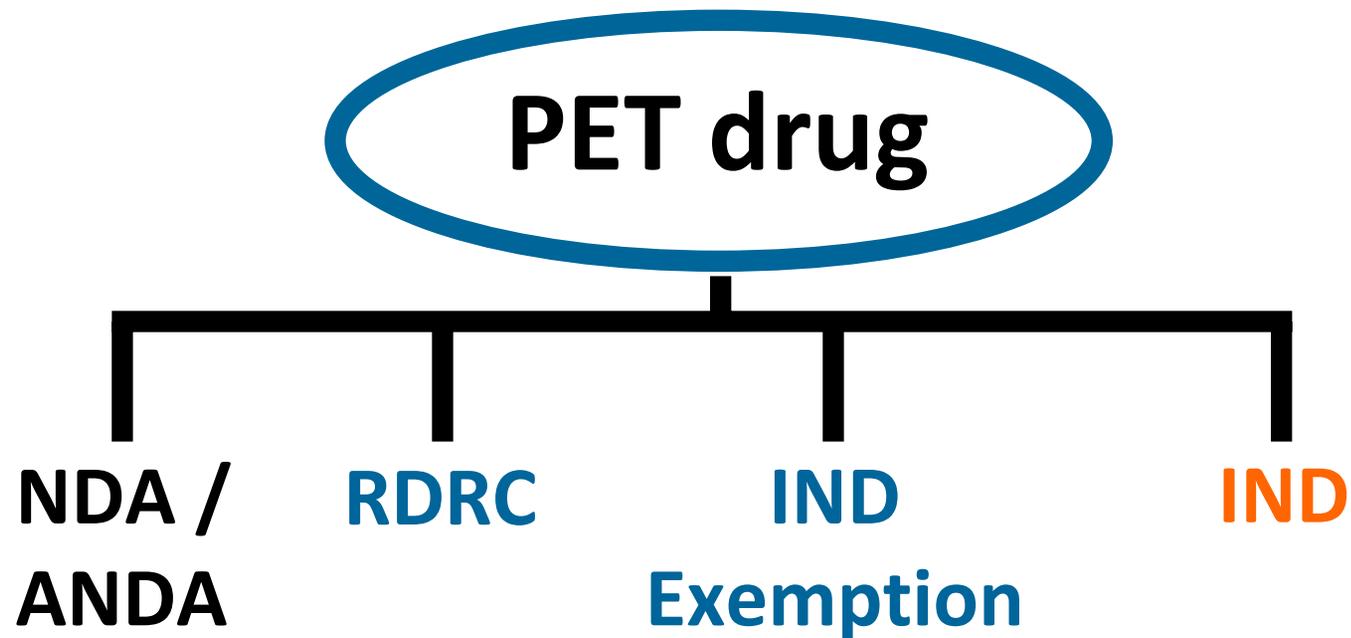
- **“investigational use” ...**
  - Drug administered within a clinical trial/study or other research project
  - IND or RDRC or exempt from IND
- **“clinical use” ...**
  - Drug administered as part of clinical care
  - Drug approved under NDA/ANDA or otherwise legally marketed

# *PET Drug Regulation*

**by Dec 12, 2011**

**NDA or ANDA must be submitted for any PET drug marketed for clinical use in the U.S.**

# *Which submission is most appropriate?*



# RDRC

*IND not needed if study is approved by a Radioactive Drug Research Committee (RDRC)*

*RDRC research limited to:*

- **Basic science**
- **Not for diagnostic or therapeutic purpose**
- **Not an evaluation of drug's safety/efficacy**
- **Dose known not to cause any pharm effect**
- **Radiation dose within specific limits**

# RDRC Info

[www.fda.gov](http://www.fda.gov)

In search box, “RDRC”

The screenshot shows the FDA website interface. At the top, there is a navigation bar for the U.S. Department of Health & Human Services with the URL www.hhs.gov. Below this is the FDA logo and the text 'U.S. Food and Drug Administration'. A search bar contains the text 'RDRC' and a 'go' button. A navigation menu includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled 'Drugs' and includes links for Share, Email this Page, Print this page, and Change Font Size. The breadcrumb trail reads 'Home > Drugs > Science & Research (Drugs) > Research Areas'. A sidebar on the left shows a menu with 'Science & Research (Drugs)', 'Research Areas', and 'Oncology'. The main heading is 'Radioactive Drug Research Committee (RDRC) Program'. Below the heading is a list of links: 'What is the RDRC Program?', 'What are the Qualifications and Requirements of RDRC Membership?', 'How Does an RDRC Obtain FDA Approval?', 'What are the Responsibilities of the RDRC?', 'What Information Does the RDRC Review?', 'Federal Regulations (21 CFR 361.1)', 'RDRC Forms and Checklist', 'Guidances for Industry', 'Historical Information for RDRC Program', and 'Contact Us'. The first link, 'What is the RDRC Program?', is highlighted.

# IND Exemption

*Sponsor or Sponsor Investigator (SI)  
determines whether study/trial is exempt*

## CRITERIA

- Drug used has approved NDA or ANDA
- No intent to support new indication, labeling change, or advertising change
- No intent to promote/commercialize the drug
- No significant risk increase (e.g. dose, route of administration, patient population)
- Compliant with IRB/consent process

# IND Exemption Info

www.fda.gov

In search box, “21 CFR 312.2”

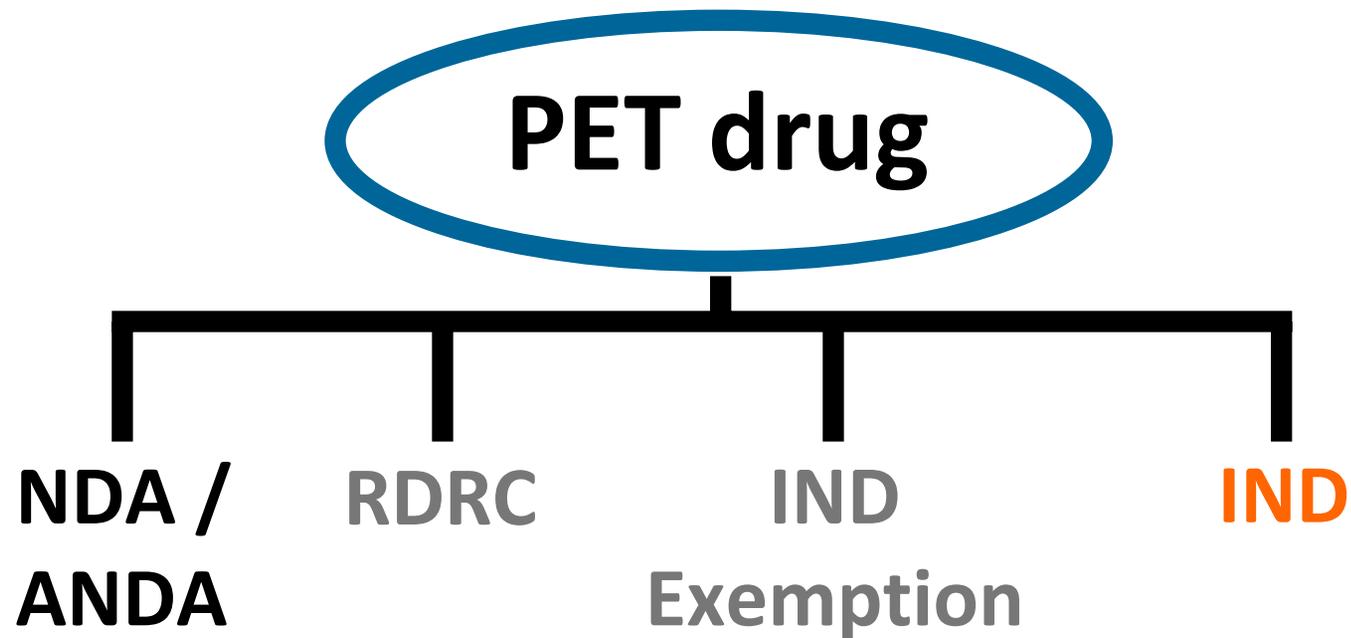
The screenshot shows the FDA website search interface. At the top, it says "U.S. Department of Health & Human Services" and "www.hhs.gov". Below that is the "FDA U.S. Food and Drug Administration" logo and a search bar with a "go" button. A navigation menu includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. There are also links for "Print this page" and "Change font size".

The search results section shows "Results 1 - 1 of about 1 for 21CFR312.2. Search took 0.02 seconds." Below this, there is a search box containing "21CFR312.2" and a "Search" button. To the right of the search box are links for "Advanced Search" and "Sort by date / Sort by relevance". Below the search box, it says "Results for '21CFR312.2' in All of FDA".

The search result is a link to "CFR - Code of Federal Regulations Title 21". Below the link, there is a snippet of text: "... [Code of Federal Regulations]. [Title 21, Volume 5]. [Revised as of April 1, 2010]. [CITE: 21CFR312.2]. TITLE 21--FOOD AND DRUGS. CHAPTER ...". At the bottom of the snippet, it says "www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.2 - 20k - Cached".

An orange arrow points from the text "In search box, '21 CFR 312.2'" to the search box in the screenshot.

# *Should I Be Submitting An IND?*



# Outline

- Introduction
- When IND Submission Is Not Required
- **When IND Submission Is Appropriate**
- IND For Clinical Trial vs. Expanded Access
- IND Content
- IND Process

# What is an **IND**?

*An IND Application is a request for authorization from FDA to:*

- **Administer an investigational drug to humans**
- **Be exempt from premarket approval requirements**
- **Ship lawfully**

# *Why is the **IND** Process Important for PET drugs?*

- Drug development & clinical research
- Patient access to:
  - Investigational PET drugs
  - PET drugs already in clinical use and uncommon usage does not justify submission of NDA/ANDA
- IND process active now and continues beyond Dec 12, 2011

# IND Information

www.fda.gov

In search box, “IND”

The screenshot shows the FDA website interface. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the text 'U.S. Department of Health & Human Services' and 'www.hhs.gov'. Below this is the FDA logo and 'U.S. Food and Drug Administration'. A search bar is visible with the text 'A-Z Index' and 'Search' followed by a 'go' button. A breadcrumb trail reads: 'Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products'. There are also links for 'Share', 'Email this Page', 'Print this page', and 'Change Font Size'. The main content area is titled 'Drugs' and shows a breadcrumb trail: 'Home > Drugs > Development & Approval Process (Drugs) > How Drugs are Developed and Approved'. The main heading is 'Investigational New Drug (IND) Application'. A sidebar on the left lists 'Development & Approval Process (Drugs)', 'How Drugs are Developed and Approved', and 'Types of Applications', with 'Investigational New Drug (IND) Application' selected. The main content area lists several topics: 'Introduction', 'Pre-IND Consultation Program', 'Guidance Documents for INDs', 'Laws, Regulations, Policies and Procedures' (including 'Code of Federal Regulations' and 'Manual of Policies and Procedures (MaPPs)'), and 'Emergency Use of an Investigational Drug or Biologic'. A 'Spotlight' box on the right highlights the 'Final Rule: IND Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans (9/28/2010)'.

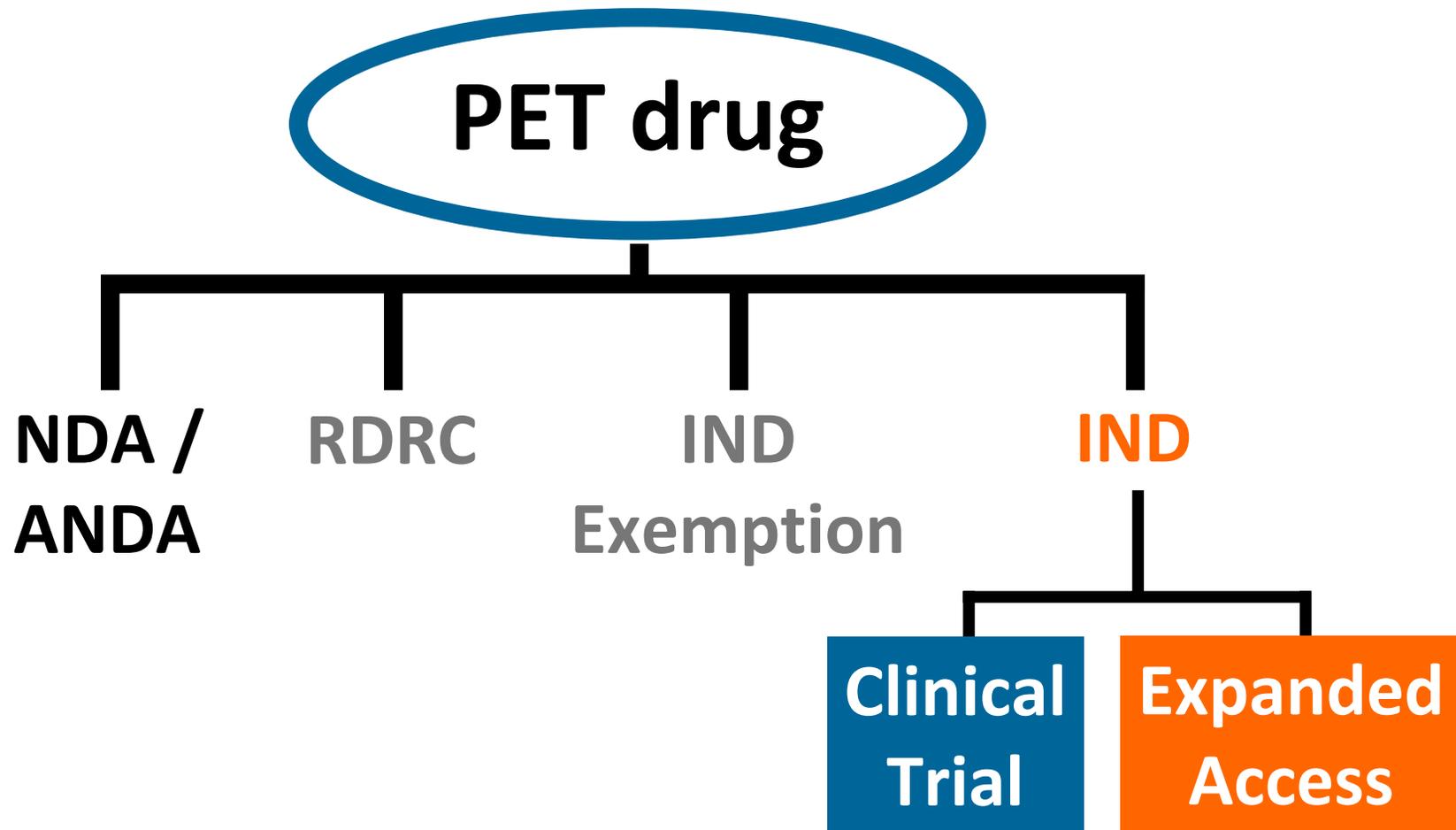
# **IND** *Webpage Information*

- **Pre-IND consultation/meeting program**
- **Guidance documents**
- **Emergency IND options**
- **Multiple related aspects (forms, contacts)**
- **Content and format of IND submissions**

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# IND Options



# *Why is the **IND** Process Important for PET drugs?*

- Drug development **Clinical Trial**
- Patient access to: **Expanded Access**
  - Investigational PET drugs
  - PET drugs already in clinical use and uncommon usage does not justify submission of NDA/ANDA
- IND process active now and continues beyond Dec 12, 2011

# ***“Access” to Investigational PET Drugs Via:***

## **Clinical Trial**

**Primary purpose is to study the drug**

## **Expanded Access**

**Primary purpose is to diagnose or  
monitor patient’s disease / condition**

# Expanded Access

[www.fda.gov](http://www.fda.gov)

In search box, “expanded access”

The screenshot shows the FDA website interface. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below this is the FDA logo and the text 'U.S. Food and Drug Administration'. A search bar is visible with the text 'A-Z Index' and 'Search' followed by a search input field and a 'go' button. Below the search bar, there is a horizontal menu with links: Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products. Below the menu, there are social media and utility icons: Share, Email this Page, Print this page, and Change Font Size. The main content area is titled 'For Consumers' and includes a breadcrumb trail: Home > For Consumers > Consumer Information by Audience > For Patients and Patient Advocates. On the left, there is a sidebar with a blue header 'Consumer Information by Audience' and a sub-header 'For Patients and Patient Advocates'. Under this, there is a link 'Access to Investigational Drugs' with a right-pointing arrow. Below this link, there is a snippet of text: 'Deciding Whether to Seek Access to an Investigational Drug'. The main content area features a section titled 'Access to Investigational Drugs' with a sub-header 'Investigational or experimental drugs are new drugs that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and are in the process of being tested for safety and effectiveness.' Below this, there is a paragraph: 'Patients may decide to seek access to investigational drugs for different reasons. Some patients with serious or life-threatening illnesses seek treatment with investigational drugs if FDA-approved therapies are not'. On the right, there is a 'Contact Us' section with a sub-header 'Office of Special Health Issues' and contact information: Phone: 301-796-8460, Email: OSHI@fda.hhs.gov, Address: 10903 New Hampshire Avenue, Bldg. 32, Room 5367, Silver Spring, MD 20993.

# *Expanded Access*

## **C R I T E R I A**

- Patient(s) with serious or immediately life-threatening disease / condition
- No satisfactory alternative “therapy”
- Potential patient benefit justifies potential risks of “treatment” use
- Provision of drug will not interfere with drug development

# Expanded Access Criteria

[www.fda.gov](http://www.fda.gov)

In search box, “21 CFR 312.305”

The screenshot shows the FDA website search interface. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the text 'U.S. Department of Health & Human Services' on the left, and 'www.hhs.gov' on the right. Below this is the FDA logo and 'U.S. Food and Drug Administration'. A search bar is located on the right side of the header, with a 'Search' button and a 'go' button. Below the search bar is a navigation menu with links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area shows the search results for '21CFR312.305'. The search bar contains the text '21CFR312.305' and a 'Search' button. The results show 'Results 1 - 1 of about 1 for 21CFR312.305. Search took 0.03 seconds.' Below the search bar, there is a link to 'CFR - Code of Federal Regulations Title 21' and a link to 'www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.305 - 23k - Cached'. An orange arrow points from the search bar to the search results.

# *Expanded Access*

## *Good Clinical Practice*

- **Informed consent**
- **IRB approval**
- **Safety reports & annual reports**
- **Provide Investigator's Brochure if exists**
- **Adherence to expanded access protocol**
  - Criteria for patient selection
  - Safety monitoring

# *Drugs That May Qualify For Expanded Access*

**Low usage may not justify submission of NDA**

***Modernization Act (comply with USP monograph):***

- Carbon monoxide C11
- Fluorodopa F18 injection
- Flumazaniol C11 injection
- Mespiperone C11 injection
- Methionine C11 injection
- Raclopride C11 injection
- Sodium acetate C11 injection
- Water O15 injection

**But other PET drugs could potentially qualify.**

# *Drugs That **DO NOT** Qualify For Expanded Access*

## *Approved PET drugs*

- Ammonia N13
- Sodium fluoride F18
- Fludeoxyglucose F18
- Rubidium chloride Rb82

## **SUBMIT**

- **ANDA** using the NDA product as the reference product
- OR**
- **505(b)(2)**

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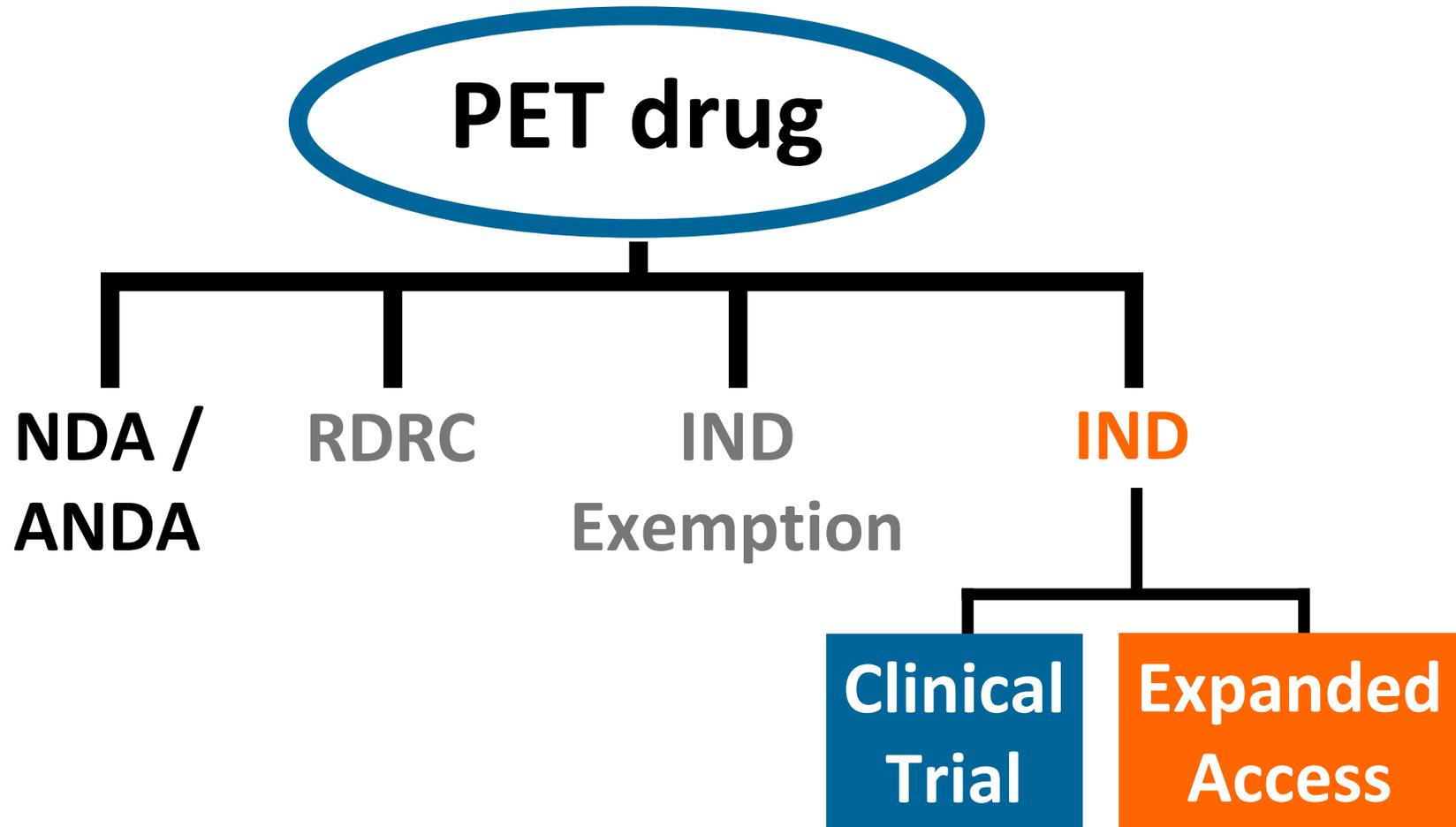
# *IND Sponsor, Investigator, Spon.-Invest. (SI)*

Sponsor	Investigator
Submits IND	
Responsible for and initiates clinical investigation	Conducts clinical investigation
Individual, institution, or company	Individual

“**Sponsor-investigator**” is an individual who immediately directs the investigational drug administration

21CFR312 (sections 3, 50 – 70)

# IND Options



# Trial IND Content

www.fda.gov

In search box, “21 CFR 312.23”

Click on 2<sup>nd</sup> link

The screenshot shows the FDA website search interface. At the top, it says "U.S. Department of Health & Human Services" and "www.hhs.gov". Below that is the "FDA U.S. Food and Drug Administration" logo and a search bar with "A-Z Index" and "go" buttons. A navigation menu includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The search results section shows "Results 1 - 3 of about 3 for 21CFR312.23. Search took 0.03 seconds." The search input field contains "21CFR312.23" and the "Search" button is highlighted. Below the search bar, there are two search results. The first result is a PDF document titled "AddMortalreformation[21CFR312.23(a)(10)J... W PART OF THE CLINICAL STUDY TO BE CONDUCEO SY A CONTRXT RESEAR...@Nf.ZATION? uYES ~ S=VES. ...". The second result is "CFR - Code of Federal Regulations Title 21". An orange arrow points to the second result link.

# **IND Content (p1/2)**

- 1. Form FDA-1571 (cover sheet)**
- 2. Form FDA-3674 (Clinical trials.gov info)**
- 3. Table of contents**
- 4. Introductory statement, including description of clinical investigation**
- 5. Investigator brochure... *not needed for SI***
- 6. Clinical protocol**
- 7. Informed Consent**
- 8. Background information... *see next slide***

# **IND Content (p2/2)**

## **7. Background information... *(continued)***

- a. Chemistry, manufacturing & control (CMC) info**
- b. Animal and/or clinical pharmacology-toxicology information that supports safety of study/trial**
- c. Summary of previous PET drug clinical experience**
- d. Estimate of radiation-absorbed dose to body and critical organs, with justification**

# Expanded Access IND Content

www.fda.gov

In search box, “21 CFR 312.305”

The screenshot shows the FDA website search interface. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below this is the FDA logo and the text 'U.S. Food and Drug Administration'. A search bar is located on the right side of the navigation bar, with a 'go' button. Below the navigation bar is a menu with links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled 'FDA Home' and features a search section. The search box contains the text '21CFR312.305' and has a 'Search' button. To the right of the search box are links for 'A-Z Index', 'Advanced Search', and 'Sort by date / Sort by relevance'. Below the search box, the results are displayed: 'Results 1 - 1 of about 1 for 21CFR312.305. Search took 0.03 seconds.' The first result is a link to 'CFR - Code of Federal Regulations Title 21' with a dotted border around the text. Below the link is a snippet of text: '... [Code of Federal Regulations]. [Title 21, Volume 5]. [Revised as of April 1, 2010]. [CITE: 21CFR312.305]. TITLE 21--FOOD AND DRUGS. CHAPTER ...' and a URL: 'www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.305 - 23k - Cached'. An orange arrow points from the search box to the first result link.

# Expanded Access

## IND Content (p1/4)

*Identify category in IND submission:*

- Individual patient
- **Intermediate-size patient population**
- Widespread use (treatment IND)
  - Actively pursuing marketing approval
  - Has on-going or completed clinical trials

# *Expanded Access*

## *IND Content (p2/4)*

- 1. Form FDA-1571 (cover sheet)**
- 2. “Protocol”**
  - Title, protocol #
  - Rationale for intended use
  - Criteria for patient selection
  - Drug dose, # of doses, route of administration
  - Safety monitoring
  - Drug production site
- 3. Estimate of radiation-absorbed dose to body and critical organs, with justification**

# *Expanded Access*

## *IND Content (p3/4)*

- 4. Chemistry, manufacturing & control (CMC)**
- 5. Pharmacology & toxicology to justify dose and duration of use**
- 6. Satisfaction of Expanded Access criteria**
  - Serious, life threatening condition
  - No alternative diagnostic agent
  - Potential benefit justifies risks
  - Use will not interfere with trials for marketing approval

# Expanded Access

## IND Content (p4/4)

### *Additional Information Required If*

### *Intermediate-size Population:*

- **Is drug under development for marketing approval?**
  - Explain why drug cannot be developed OR
  - Explain why patients cannot be enrolled in clinical study
- **Planned size of patient population**
- **Sufficient evidence for safety of drug at proposed dose and duration to justify # of patients**
- **Preliminary evidence of effectiveness**

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# **IND Submission Logistics**

- Paper or electronic
- If paper, supply 3 copies
- Electronic submission similar to pathway for NDA / ANDA
- Contact (email) [esub@fda.hhs.gov](mailto:esub@fda.hhs.gov) for questions re: electronic submission

# Electronic Submission Info

[www.fda.gov](http://www.fda.gov)

In search box, “CDER Electronic Submission”

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# **IND Submission Logistics**

***Mail paper submission to:***

**US Food and Drug Administration  
Central Document Room  
5901-B Ammendale Rd.  
Beltsville, MD 20705-1266**

***For more info, telephone: 301-796-2050  
(Division of Medical Imaging Products)***

# IND Process

- Submission of IND application to FDA by sponsor or Sponsor-Investigator (SI)  
↓
- FDA assigns IND number and issues acknowledgement letter  
↓
- Clinical trial/study cannot be initiated until 30 days after date of IND receipt, unless otherwise notified by FDA  
↓
- FDA will notify sponsor or SI of any deficiencies within the 30 day review period

# *Can I Administer The PET Drug While My IND Is Being Reviewed?*

- **Yes, if can provide documentation about current clinical use AND adequate drug quality (e.g. reference USP monograph)**
- **No, if not in current clinical use**
- **If unsure, ask FDA**

# **IND Review and Maintenance**

- **IND is reviewed by multiple disciplines**
  - Project manager, chemistry, pharmacology / toxicology, microbiology, clinical pharmacology, clinical, statistics if appropriate
- **Discussion of IND submissions weekly**

## **ONCE THE STUDY MAY PROCEED...**

- **Submit protocol revisions and new protocols BEFORE initiating them**
- **Report serious and unexpected adverse events**
- **Submit annual progress reports**

# *Questions after SNM???*

***Dr. Kaye Kang***

***kyong.kang@fda.hhs.gov***

***telephone: 301-796-2050***

***Division of Medical Imaging Products***

# *Specific Websites (p1/3)*

## **Electronic Submission:**

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/default.htm>

## **IND Overview:**

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm>

# *Specific Websites (p2/3)*

## **IND Exemption:**

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.2>

## **Expanded Access:**

<http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/AccessToInvestigationalDrugs/default.htm>

# *Specific Websites (p3/3)*

## **Clinical Trial IND Content:**

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=312.23>

## **Expanded Access IND Content:**

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.305>

# *Register With FDA*

## **Required for:**

- **Domestic and foreign establishments that produce, repack, or re-label drug products in U.S. (or import / offer import drug products)**

## **New since Jun 1, 2009:**

- **Must register electronically (next slide)**

## **When must I register?**

- **Now!**

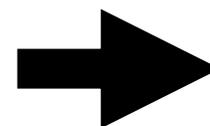
# Drug Registration and Listing System

[www.fda.gov](http://www.fda.gov)

In search box, “DRLS”

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**Business Operation Code  
(PET Drug Production)**



**C91403**

# Structured Product Labeling

[www.fda.gov](http://www.fda.gov)

In search box, “PET SPL”

The screenshot shows the FDA website interface. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below this is the FDA logo and the text 'U.S. Food and Drug Administration'. A search bar contains the text 'PET SPL' and a 'go' button. A navigation menu includes links for Home, Food, Drugs, Medical Devices, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, Radiation-Emitting Products, and Tobacco Products. The main content area is titled 'For Industry' and includes a breadcrumb trail: Home > For Industry > Data Standards > Structured Product Labeling. On the left, there is a sidebar menu for 'Data Standards' with 'Structured Product Labeling' selected. The main content area features a heading for 'Positron Emission Tomography (PET) Drug SPL SPL Training Session - Positron Emission Tomography (PET) Drug SPL'. Below the heading, it provides the date (Tuesday, March 8, 2011) and time (1:00 - 2:30 p.m., ET). A section titled 'Registration Information' states that there is no registration fee but pre-registration is required, and provides an email address (spl@fda.hhs.gov) for registration. A list of two items is provided: 1. Attendee's first and last name, and 2. Name of your organization.

