Kyong “Kaye” Kang

Chief Project Manager for the Division of Imaging and Radiation Medicine in the Office of Specialty Medicine.

Kaye has been with the FDA since 1996 where she started as a Consumer Safety Officer in the Division of Medical Imaging and Radiopharmaceutical Drug Products (DMIRDP) and worked in the same division (currently DIRM) as Regulatory Project Manager and Chief Project Manager.

She has a Pharm.D. from University of Maryland at Baltimore (UMAB) School of Pharmacy.
IMPACT OF COVID-19:
FDA-SNMMI WEBINAR

REGULATORY SUBMISSIONS
DURING COVID-19

Kyong “Kaye” Kang, Pharm.D.
Chief, Project Management Staff
Division of Imaging and Radiation Medicine (DIRM)
Office of Specialty Medicine (OSM)
Office of Regulatory Operations (ORO)
Outline of Presentation

• Current State of CDER
• Prioritization of Workload during COVID-19
• Submission of Drug Development Request for COVID-19
• Clinical Trials Conduct
• Electronic Submissions
• New Working Paradigm
• Conclusion
Current State of CDER

• Responsible for regulation of drug therapies

• CDER’s key priorities
  – Making safe and effective drugs to treat COVID-19 patients as soon as possible
  – Monitoring nation’s supply and taking action to mitigate drug shortages
  – Working to help ensure health of all patients

• Continues to manage non COVID-19 submissions
Workload Prioritization during Public Health Emergency (COVID-19)

• Making safe and effective drugs to treat COVID-19 patients as soon as possible
  – Expedite the regulatory review process for therapeutics in clinical trials for COVID-19 including review of clinical trial protocols and development programs
  – More than 140 active trials of therapeutic agents are in progress
  – Issuing more than 12 guidance documents for industry related to therapeutic development since the start of the COVID-19 outbreak
Workload Prioritization during Public Health Emergency (COVID-19)

• Monitoring nation’s supply of medicine and taking action to mitigate drug shortages
  – Hand sanitizers and ethanol for use in hand sanitizers: about 3,000 new hand sanitizers manufacturers have registered with FDA
  – Fielded more than 23,000 inquiries (from Jan.1 to Apr. 30, 2020) regarding medications
Workload Prioritization during Public Health Emergency (COVID-19)

• Working to help ensure health of all patients
  – Safeguarding against unsafe drugs
  – Maintaining surveillance of the safety of all prescription and over-the-counter drugs
  – Reviewing applications to investigate or market new and generic drugs
  – Engaging with industry in numerous ways to ensure clinical research for a range of diseases continues
Prioritization of Non-COVID-19 Workload

- COVID-19 related work varies in all review divisions.
- Prioritizing non-COVID-19 related work
- Communication with sponsor for goal date change
Submissions related to COVID-19 Drug Development

• [COVID19-productdevelopment@fda.hhs.gov](mailto:COVID19-productdevelopment@fda.hhs.gov)

• Track submissions exclusively for COVID19 related drug product development; some inquiries forwarded to CBER, CDRH and CFSAN (dietary supplements)

• COVID Scientific Technical Triage Team (CSTTT) manages the COVID submissions
Product Jurisdiction Process

• All submissions related to COVID-19 go to CSTTT.

• CSTTT will review the submission and completeness and sufficiency and forward it to appropriate review division.
COVID-19 Drug Development Proposal

- Recommend seeking initial advice under pre-IND.
  - COVID-19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products.
  - https://www.fda.gov/media/137927/download

- For approved product seeking a new use or products in development under an IND for another use, recommend a new pre-IND for the proposed COVID-19 use. Cross-reference any other NDA, BLA, or IND for the product.
  - COVID-19: Developing Drugs and Biological Products for Treatment or Prevention
  - https://www.fda.gov/media/137926/download
Clinical Trials Conduct

- For **general questions** (not specific to a particular IND), refer to [FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Pandemic](https://www.fda.gov/).  

- For **general questions that are not covered by the guidance**, submit questions to the [clinicaltrialconduct-COVID19@fda.hhs.gov](mailto:clinicaltrialconduct-COVID19@fda.hhs.gov)

- For **specific questions related to potential impacts or potential changes in conduct of a particular trial under IND related to COVID-19**, you can reach out to the Division’s RPM, refer to the guidance, and/or submit questions to the [clinicaltrialconduct-COVID19@fda.hhs.gov](mailto:clinicaltrialconduct-COVID19@fda.hhs.gov)
Electronic Submission

- Gateway
  - NDAs
  - BLAs
  - Commercial INDs

- CDER NextGen Portal
  - Pre-IND
  - Research INDs
CDER NextGen Portal

• **Benefits of submitting via the Portal**
  – Efficiency
  – Timeliness
  – Ease of Use
  – Automated Confirmation
  – Historical Record

• **How to Gain Access**
  – **New Users**
    To register for an account with the CDER NextGen Portal, navigate to [https://edm.fda.gov](https://edm.fda.gov) and follow the signup instructions.
  – **Existing Portal Users**
    Research IND tab was added to your account automatically – click on it when you are ready to submit a request.

• **What File Types Are Accepted**
  – **CDER Currently accepts the following file types as part of an original IND or amendment:** PDF, SAS, MS Word, Text, MS Excel, MP4, XPT and Simcyp Simulator

• **Need Support?**
  – In order to get assistance on registering for the CDER NextGen Portal, please reference the [user guides and FAQ’s](https://edm.fda.gov). For additional support, please contact CDER Platform Support at edmsupport@fda.hhs.gov.

• **LINK:** [CDER NextGen Portal](https://edm.fda.gov)
Research Investigational New Drug (IND) Reference Guide

Click here to access the portal
Research Investigational New Drug (IND)

Introduction
A Research IND (also called a non-commercial IND) is one for which the sponsor (generally an individual investigator, academic institution or non-profit entity) does not intend to later commercialize the product. These studies are strictly for research, are usually shorter in duration and may result in publications in peer. This guide is to show submitters how to submit a request for a Research IND. For technical assistance, the CDER Platform Support Team (EDMSupport@fda.hhs.gov) is available to help.

Step 1. Once you land on the Portal homepage, click Research IND.
Research Investigational New Drug (IND)

Creating a Research IND Submission

Step 1. Click Create New Submission.

Step 2. Select "Yes" or "No" to whether you have an IND Number for this submission.

If you selected "Yes" in question 2, provide the IND Number provided by the FDA for this Research IND, otherwise move to Step 4.

Step 3. Provide the IND Number provided by the FDA for this Research IND.

Step 4. Click Next.
Submitting Research IND Documents

Step 1. From the dropdown, select the document type you would like to be uploaded for this submission.

Step 2. Click Choose File.

Step 3. Search and select the document you would like to be uploaded.

- The allowable formats for uploading a document are PDF, MS Word, MS Excel, SAS, XPT, Text, Simcyp Simulator, and MP4. The maximum file size upload is 45 MB per file. Macros are not allowed.

Step 4. (Optional) Provide a brief description of the document.

- There is a 300 character limit.

Step 5. Click Confirm Attachment.
Research Investigational New Drug (IND)

Submitting Research IND Documents

Step 6. Click Review.

Under Saved Documents, you are able to do the following:
- Click Attach Document if you would like to attach additional documents
- Click View Saved Document to view document uploaded
- Click Remove Document to delete document uploaded.
- Click Save as Draft to save your submission and have the ability to complete it at a later time
- Click Delete Submission to delete the request altogether
- Click Back will navigate back to enter Research IND Page

⚠️ Please note that you will be prompted to select a document in order to proceed.
### Research Investigational New Drug (IND)

#### Review Research IND

**Step 1.** Review all information in tabs entered.

**Step 2.** Click the checkbox that this information transmitted through email or portal is confidential and intended solely for the use of the FDA CDER.

**Step 3.** Click Submit to FDA.

---

#### Research IND Documents

In this submission, please attach “Form 1571” or “2052” or any “Other” document applicable to this submission.

- **Attach Document**

#### Saved Document(s)

<table>
<thead>
<tr>
<th>File Name</th>
<th>Document Type</th>
<th>Note Description</th>
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<tbody>
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<td>Form 1571 or 2052</td>
<td>SEC Form Research IND</td>
</tr>
</tbody>
</table>

- **View Saved Document**

- **Review Document**

#### Research IND Information

- **Postcode:**
  - **Do you have an IND Number for this submission?**
    - **Yes**
  - **Please provide the IND Number provided by the FDA for this Research IND:**
    - **001-123456**

- **Edit Responses**

#### Contact Information

**Submitter’s Information**

<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Phone</th>
<th>Fax</th>
<th>Address Line 1</th>
<th>Address Line 2</th>
<th>City</th>
<th>County</th>
<th>Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td><a href="mailto:john.doe@example.com">john.doe@example.com</a></td>
<td>1234567890</td>
<td></td>
<td>123 Main St</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Research Investigational New Drug (IND)

Review Research IND

Step 4. A confirmation message will appear and you will receive an email from CDER NexGen Portal alerting that you have a new notification from the FDA regarding your submission.

Step 5. Click Return to Home to return to the Home page.

Research IND Submitted to the FDA

Thank you for submitting your Research IND. Your Event ID is RI-00102.

For technical support, contact the CDER Platform Support Team at EDMSupport@fda.hhs.gov.

Research IND Summary:

Do you have an IND Number for this Submission? Yes
Please provide the IND Number provided by the FDA for this Research IND: IND-123456
Number of Submitted Documents: 1

Submitter's Contact Information:

<table>
<thead>
<tr>
<th>Name</th>
<th>Email</th>
<th>Country/Phone Number/Extension</th>
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</thead>
<tbody>
<tr>
<td>John Smith</td>
<td><a href="mailto:John.Johnson@Example.com">John.Johnson@Example.com</a></td>
<td>USA 312123456</td>
</tr>
</tbody>
</table>

Please note that no further action is needed at this time on your end. We will review this information and follow up accordingly. If you identify changes or corrections are needed, contact the Division of Drug Information at druginfo@fda.hhs.gov.

For technical support, contact the CDER Platform Support Team at EDMSupport@fda.hhs.gov.
Review Submitted Research IND

Step 6. Highlight the submitted Event ID you want to view.

Step 7. Click View Submission.
Technical Support and Resources
CDER NextGen Portal Support & Resources

The CDER NextGen Portal ([https://edm.fda.gov/](https://edm.fda.gov/)) has many resources for support.

**Portal Announcements**
Your Portal home page contains portal announcements so users are always in the know.

**Learn More Information**
Everything related to the portal events can be found on the "Learn More" link. On the event home page, users can find the "Learn More" link to Reference Guides and FAQs.

**Technical Support**
For all technical support, contact CDER Platform Support Team at EDMSupport@fda.hhs.gov.

**Portal Video Tutorial**
The "Video Tutorial" contains 1-4 minute video clips on how to complete submissions for events on the portal.
New Working Paradigm

• Working remotely

• Virtual meetings

• Work with review divisions’ RPMS directly
Conclusion

• Continuity of important public health mission

• Addressing the changing needs
  – Prioritization of Workload during COVID-19
  – Submission of Drug Development Request for COVID-19
  – Clinical Trials Conduct
  – Electronic Submission
Speaker Bio

• LCDR Ramanadham is currently the Associate Director for Scientific Operations for the Office of Pharmaceutical Manufacturing Assessment, within the Office of Pharmaceutical Quality. He joined the Agency in November 2009 after graduating with his Doctor of Pharmacy degree from the University of Maryland and his M.B.A. from the University of Baltimore. Prior to joining FDA, LCDR Ramanadham had experience in solid oral dosage manufacturing ranging from OTC products to schedule II narcotics. Outside of FDA, LCDR Ramanadham continues to practice pharmacy in the community setting to maintain perspective on the clinical relevancy and impact of our efforts in pharmaceutical quality.
Pre-Approval Inspections and Use of Alternative Approaches to Facility Assessment

LCDR Mahesh Ramanadham, Pharm.D./MBA, R.Ph.
Associate Director for Scientific Operations
Office of Pharmaceutical Manufacturing Assessment
Office of Pharmaceutical Quality
FDA/CDER

17-June-2020
Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.
Pharmaceutical Quality

A quality product of any kind consistently meets the expectations of the user.

Drugs are no different.
Patients expect safe and effective medicine with every dose they take.
Pharmaceutical quality is assuring every dose is safe and effective, free of contamination and defects.
It is what gives patients confidence in their *next* dose of medicine.
Team-based Integrated Quality Assessment (IQA)

Inclusive of drug substance, drug product, manufacturing, and facilities, and maximizes each team member’s expertise

Science- and Risk-Based approach that is patient-focused
Manufacturing Risk Assessment

- **General**
  - Risk factors to all facilities
    - E.g., CGMP status, data integrity concerns, etc.

- **Unit Operation Specific**
  - Risk factors for all unit operations
    - E.g., Drug load, BCS class, prior facility experience, scale-up, microbiology risks, etc.
  - Risk factors on specific unit operations
    - E.g., Blending, granulation, compression, etc.

Initial unit operation risk determines the extent of assessment needed including pre-approval inspection decisions.

- Assessment
  - Unit operations assessment (abbreviated or full)
    - E.g., Risk mitigation strategies added to each unit operation
Pre-Approval Inspection Goals

• Focus Areas
  – Readiness to Commercial Manufacturing
    • Incoming Materials
    • Process, CPPs
    • Equipment / facilities / Cleaning
    • Personnel Training & Competence
  – Conformance to Application
  – Data Integrity
Manufacturing Facility Assessment during COVID-19

• Mission critical pre-approval and for-cause inspections prioritized in light of travel restrictions

• Mission critical assessment:
  – weighs concerns about the safety of all those involved in inspections against the public health benefits
  – considers factors such as clinical benefit and medical necessity

• Alternative approaches of gathering information to support facility assessment
  – Records Request under § 704(a)(4) of the FD&C Act
  – Using information shared by other regulatory agencies (e.g. mutual recognition, confidentiality agreements)
  – Additional information from applicants
Statutory Authority under § 704(a)(4)

• (a) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records requested.

• (c) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this chapter in order to ensure compliance with this chapter.
In other words...

• FDA may request records from a facility in advance or in lieu of an on-site inspection

• For pre-approval inspections, applicability will depend upon the risk factors driving the inspection needs

• Records requested will be used to assess capability of the facility and its quality systems to perform the manufacturing operations

• If we determine that risks have not been mitigated, an on-site inspection may still be required
Information from Other Regulatory Agencies

• Mutual Recognition Agreement (MRA) between FDA and EU:
  – Allows drug inspectors to rely upon information from drug inspections conducted within each other’s borders.
  – Generally applicable to surveillance inspections
  – Not formally established for pre-approval inspections

• Though MRA has not been established for pre-approval inspections, information from MRA partner inspections may be used to determine if the risks indicating a pre-approval inspection are mitigated.

• Confidentiality agreements allow FDA and other Agencies to share information about facility inspections.
Manufacturing Facility Assessment during COVID-19

• FDA has utilized the various resources described and has gained useful information about manufacturing facilities, operations, and CGMPs.

• FDA has been able to make decisions on facilities and act on associated applications.
What Can You Do?

• As a sponsor, be in close communication with staff at your manufacturing and testing facilities

• Ensure they commit to timely response to any request

• Treat the records request as you would an inspection, providing complete, specific and accurate documents

• If Agency requests, be ready to provide information about other regulatory inspections at your facilities should it be requested

• While it may not be feasible for PET DP manufacturing facilities, consider alternate facilities where possible for increased flexibility (e.g. testing facilities)
Don’t Forget We are Patients too!
Libero (Louis) Marzella

Director, Division of Imaging and Radiation Medicine (DIRM)  
Center for Drug Evaluation and Research (CDER)  
Food and Drug Administration (FDA)

DIRM regulates imaging drugs including contrast agents and radiopharmaceuticals as well as therapeutic drugs for use in radiation injury
Effects of the current public health emergency on FDA application review activities

Libero (Louis) Marzella MD, PhD
Division of Imaging and Radiation Medicine
CDER/FDA
Overall Session Objectives

• give overview of FDA activities to address the public health emergency, describe activities related to radiopharmaceutical development

• hear from SNMMI, industry and sponsor/investigators about the challenges encountered and their unmet needs

• consider best practices that might enhance efficiency during this period and future preparedness
COVID 19-specific Review Activities

- major new focus in clinical research on development of COVID-19 diagnostics and therapeutics, disease characterization, and natural history studies
- major areas include: medical devices such as in vitro diagnostics, personal protective equipment; drugs such as antiviral and immunomodulators; biologics such as vaccines and blood products
  - corresponding increases in therapeutics INDs seen by e.g. Infectious Diseases and Pulmonary Divisions at FDA. Little new IND activity for imaging agents
  - example of this activity: as of April 16, 2020, FDA received 950 inquiries and proposals concerning COVID-19 related drug development
COVID-19 Specific Review Activities

coronavirus treatment acceleration program
  • tracking and accelerated review of new studies
  • expedited sponsor meeting timelines
    – pre-IND consultation program
  • earlier involvement of senior leadership
  • establishing review priorities
  • redeployed medical, operations, and policy staff to support the overall effort
  • results: as of May 11, 2020, there were 144 active trials of therapeutics and 457 development programs for therapeutic agents in the planning stages
Increasing Availability of Products to Address Public Health Emergencies

- investigational agents made available for clinical use through expanded access protocols and INDs
- emergency requests to use investigational products for patients with COVID-19 infections
- emergency use authorizations (EUA) for unapproved medical products
  - e.g. remdesivir
Effect of Emergency on General Product Development

• major delays in conduct of clinical studies in many diagnostic and therapeutic areas publicly reported
• annual IND reports expected to show an important decrease in enrollment in clinical trials during this period
  – severe effects on studies of imaging agents that rely on elective procedures that are currently suspended
  – major trials have been interrupted and the start of other trials has been delayed
Clinical Trial Guidances

• adaptive changes in trial conduct have been necessary for the duration of the public health emergency
  – tele-trials evolving along with tele-medicine
• FDA guidance on trial conduct issued to assist sponsors to
  – assure the safety of trial participants
  – maintain compliance with good clinical practice
  – minimize risks to trial integrity
• other FDA guidances on drug development specific to COVID-19
Product Marketing

• FDA continues to monitor drug supply and demand and to facilitate responses
  – with regard to radiopharmaceuticals we are not aware of major disruption to supply chains or drug shortages
  – examples of delays or deferral of product launches have been reported

• report shortages to DRUGSHORTAGES@fda.hhs.gov
  we will review and swiftly respond to your inquiries

• FDA consumer protection activities ongoing, aimed at fraudulent medical products
Communications

• status of White Oak campus facilities: open
• FDA staff using maximum telework option
• virtual meetings of review teams and meetings with Sponsors
• similar changes in large scale scientific meetings
• no announced date for resumption of duties at White Oak
• interested to hear stakeholders’ comments to quality of virtual meetings
General Operational Timelines

• working to continue to meet PDUFA timelines, e.g. two recent NME approvals F18 fluoroestradiol and F18 flortaucipir
• advisory committee meetings and FDA workshops have been postponed or cancelled
• conducting clinical site and manufacturing facility inspections challenging due to travel restrictions
• receipt of responses to FDA information requests delayed
• recruitment and training new FDA staff more complex
Additional Scope of FDA Emergency Preparedness Programs

• medical countermeasures are FDA-regulated products (drugs, biologics, devices) for use in the event of a public health emergency due to:
  – a naturally occurring emerging disease such as COVID-19
  – a mass casualty event with biological, chemical, or radiological/nuclear material
  – DIRM active in inter-agency work to enhance the development of products for radio-nuclear emergencies

Summary

• ongoing FDA responses to COVID-19 public health emergency
• FDA seeks input from SNMMI stakeholders
• discussion of lessons learned
• potential for best new practices as lasting changes
• for available online resources see:
Danae Christodoulou

Branch Chief with the Office of New Drug Products, Office of Pharmaceutical Quality, CDER/FDA currently supporting medical imaging drugs and radiopharmaceuticals. Danae has been with FDA since 1998 and served as a CMC reviewer, CMC Lead and Branch Chief. She has a Ph.D. in Inorganic Chemistry from the University of Michigan and worked previously as a senior chemist in R&D at Johnson Matthey Inc. and the NCI.
Recent Approvals – Quality Assessments during COVID-19

Danae Christodoulou, Ph.D.
Branch Chief, Office of New Drug Products
FDA/CDER/OPQ
Outline

• Recent NDA Approvals during 2020 Pandemic

• Highlights of Critical Quality Considerations in Recent NDA approvals

• IND assessments during COVID-19

• Letters of Authorization for successful quality assessments
Recent NDA Approvals during 2020 Pandemic

- Pulmotech MAA (kit for preparation of technetium Tc 99m aggregated albumin injection) in March 2020. The former NDA was converted to BLA on March 23, 2020. Tc 99m aggregated albumin injection is a diagnostic radiopharmaceutical for lung scintigraphy and scintigraphy of peritoneovenous shunt.

- Cerianna, fluoroestradiol F 18 injection in May 2020, an in-vivo PET diagnostic targeting estrogen receptors

- Tauvid, flortaucipir F 18 injection in May 2020, a novel PET diagnostic for Alzheimer’s Disease AD
Integrated Quality Assessment (IQA)

A team of experts in the Office of Pharmaceutical Quality (OPQ):

• Precursor
• Radiopharmaceutical drug substance and product
• Microbiology
• Manufacturing and Inspectional
• Biopharmaceutics
Critical Quality Considerations during Recent Approvals

• Due to continued COVID-19 restrictions, in lieu of inspections scheduled between March through May 2020 manufacturing facilities were assessed by a desk review process under FDASIA 706/704(a)4 provisions.

• Risk mitigation approach and adequate responses by the manufacturers allowed for successful assessment completion by OPMA-OPQ team.
Comparability Protocol Assessments during Recent Approvals

• Approval of comparability protocols for additional manufacturing site(s) for radiopharmaceutical drug products during NDA first review cycle

• Alternate manufacturing sites with acceptable inspectional history and GMP requirements using the same validated manufacturing process to ensure the same drug product composition and purity profile may be submitted in a “Changes Being Effected” (CBE-30) supplement
Comparability Protocol Assessments during Recent Approvals

Major changes 21 CFR 314.70:

• Change(s) in the precursor (different leaving group, different protecting group)
• Change of synthesizer
• Change(s) of critical process parameters of the radiosynthesis and deprotection reaction
• Change of the purification method relating to the radiosynthesizer
• Major change(s) in the analytical method analyzing impurities in the drug product (e.g., column, mobile phase, elution method (gradient-isocratic), run time)
IND 30-day Quality Assessments

• Due to physical restrictions and inability to access buildings during the 2020 pandemic, responses to quality information requests by IND sponsors have been delayed during the 30-day assessment period

• Quality assessment team(s) have requested IND sponsors to provide written agreement/commitment to submit missing CMC information to the IND prior to initiation of clinical studies for diagnostic radiopharmaceuticals

• Insufficient quality information to assess risk to subjects may lead to a recommendation for clinical hold per 21 CFR 312.42(b)(1)(iv)
Letter of Authorization (LoA)

Referencing IND

- Provide an LoA
- State the referenced sections, e.g., CMC
- Referenced IND is active, no deficiencies

SUCCESSFUL REVIEW

Referencing DMF

- Provide an LoA
- DMF is active
- New DMF has been submitted
Conclusions

• During the 2020 COVID-19 pandemic, FDA remains committed to timely assessments of safe, effective and high quality medical isotopes and radiopharmaceuticals

• FDA encourages innovation and engages with stakeholders and other government agencies working towards availability of new technologies to patients

• Challenges to accessing necessary data and traveling restrictions for FDA inspectors had minimal impact on recent approvals of diagnostic radiopharmaceuticals.
Thank You
FDA
10903 New Hampshire Ave
Silver Spring, Maryland 20993
Questions

1. For PAIs, can it be confirmed that FDA will do virtual/paper-based inspection with an on-site follow-up inspection to be scheduled at a later date?

2. What is the timeline for virtual inspections through to EIR through site approval in an application?

3. Does FDA think GDUFA goal dates are still on target? If not, will the FDA project manager follow-up with the applicant with an update?
4. Does FDA have any recommendations to streamline the process from submission to approval for sites that are virtually identical with the same footprint, equipment, and procedures being the same so that a new site doesn't sit idle for up to 10 months while awaiting

5. How are inspectors being trained specifically for 212 vs 211?

6. Is there a way to streamline ANDA approval time? The field is expecting that some important PET drugs will receive approval at academic institutions. We need to make the agents available at more locations in the county.
7. As the FDA considers launching live facility inspections in the wake of the coronavirus shutdown, it is important to consider that academic and commercial firms have policies to limit the number of employees in facilities and to restrict outside visitors from entering facilities. This varies state by state and firm by firm. Some firms may have more restrictive policies than those adopted by local and state governments, especially now that phased re-openings have begun even as the number of COVID-19 cases continues to increase in some localities. Further, some commercial firms have terminated air travel by employees, which prevents necessary inspectional support from corporate RA/QA functions. How does the FDA plan to account for these factors as the agency begins live inspections?