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MEDICAL IMAGING AND DATA RESOURCE CENTER.

### Task-Based Distribution of Data for Evaluating COVID-19 AI

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## GOALS of MIDRC TDP3d



- 1) Develop a sequestering algorithm and oversee the sequestering of data as it comes in
- 2) Develop methods and software for task-based distribution that will be made available via the MIDRC website to MIDRC users and to others so that they can use such methods in their AI development, training, and testing
- 3) Combine task-based distribution with the sequestered dataset so that MIDRC can independently evaluate AI algorithms for a specific clinical task, claim, and population, which might be used in the regulatory process.



## **Characteristics of sequestered data**

- ~20% of data (images and meta data) will be sequestered
  - Balanced patient-based distributions across primary data elements
    - Site
    - Acquisition modality
    - COVID status
    - Gender
    - Age
    - Race & Ethnicity
    - Disease severity
- 80% released for public use (majority) and challenges (subset)
- Challenge data will eventually become public





Equal probabilities of these in public and sequestered data

Large data sets plus balancing across case attributes enables apples-to-apples comparisons

And the rare cases will be equally apportioned as well







#### Example data from ACR and RSNA

	ACR	RSNA	
Patients	4,662	4,578	Data will be shared or sequestered on a per patient basis
Imaging studies	4,662	15,240	



#### Hypothetical gender data from ACR and RSNA



Courtesy Karen Drukker





# Statistical distributions of datasets will evolve

- Current snapshot is just the beginning
- As more batches arrive, equitable batch splitting will shift distributions of public and sequestered data similarly
- MIDRC is actively seeking data contributors to build out data sets and ensure representation across sites, acquisition systems, and patients



#### Task-based distribution methods – process

- For a specific clinical task, (e.g., diagnosis of COVID-19 from presentation of pneumonia), a distribution of cases, matched to the clinical claim and intended patient population, will be randomly drawn from the sequestered dataset
- Validation done by MIDRC; summary performance metrics reported back to requestor
- Subsequent validation request will be performed using new random sample drawn from relevant distribution
- Growth of sequestered data set size over time reduces ability to "learn" test set
- Software will be made available to assist with study design and power calculations



## Task-based distribution methods – value

Large, standardized, diverse data vetted by MIDRC:

- Quality of data will be known
- Diversity of data will be high
- Integrity of AI algorithm testing process will be ensured
- Accelerate acceptance and clinical use
  - Confidence in generalizability to real world use



## FDA's interest in participation in MIDRC

- Public or sponsor's testing datasets can be used in device submissions
- However, use of such data can raise questions during device review:
  - Data may not meet standards for regulatory use limited in terms of devices used for acquisition, data quality, patient populations, reference standard, inclusion/exclusion criteria.
  - Up to sponsor to demonstrate integrity of testing process.
- MIDRC data vetting will increase data quality and diversity
- MIDRC testing process ensures integrity of test results
- FDA participation helps ensure data meet regulatory needs
  - Access to data facilitates device innovation, a core element of FDA's mission
  - Speeds device review through confidence in data and evaluation process



# Medical Device Development Tool (MDDT) program

- MDDT can be a data set or a statistical package for AI algorithm eval.
- Qualification of an MDDT by FDA means:
  - The results of an assessment using the MDDT can be relied upon for device development & evaluation, within a specified <u>context of use</u>
  - Device industry need not reconfirm the suitability of a qualified MDDT
  - More efficient regulatory decision-making
- <u>Context of use</u> ≈ boundaries within which evidence & justification supports tool use

https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-development-tools-mddt

#### **Additional FDA Resources**



#### Guidances

- CADe: <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-assisted-detection-devices-applied-radiology-images-and-radiology-device-data-premarket</u>
- <u>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-performance-assessment-</u> <u>considerations-computer-assisted-detection-devices-applied-radiology</u>
- Software as a Medical Device (SaMD) Clinical evaluation: <u>https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm524904.pdf</u>

Draft guidances and discussion papers

- Quantitative Imaging: <u>https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM636178.pdf</u>
- Modifications to AI/ML Software <a href="https://www.regulations.gov/document?D=FDA-2019-N-1185-0001">https://www.regulations.gov/document?D=FDA-2019-N-1185-0001</a>
- AI/ML Action Plan <u>https://www.fda.gov/news-events/press-announcements/fda-releases-artificial-intelligencemachine-learning-action-plan</u>

Regulations/reclassification orders

- CADx: <u>https://www.accessdata.fda.gov/cdrh\_docs/pdf17/den170022.pdf</u>
- CADx+CADe: <a href="https://www.accessdata.fda.gov/cdrh\_docs/pdf18/DEN180005.pdf">https://www.accessdata.fda.gov/cdrh\_docs/pdf18/DEN180005.pdf</a>
- Triage: <u>https://www.accessdata.fda.gov/cdrh\_docs/pdf17/DEN170073.pdf</u>
- Retinal diagnosis: <u>https://www.accessdata.fda.gov/cdrh\_docs/pdf18/DEN180001.pdf</u>
- Image Acquisition and/or Optimization guided by AI: <u>https://www.accessdata.fda.gov/cdrh\_docs/pdf19/DEN190040.pdf</u>

### <u>Summary</u>



MIDRC will facilitate AI device innovation and validation...

- Resources available to developers of COVID-19 AI algorithms around the world
- Large, diverse data sets for algorithm development
- Sequestered data for rigorous, independent AI algorithm evaluations
- Apples-to-apples task-based algorithm comparisons
- Confidence in evaluation process by regulatory bodies
- Confidence in performance by future users in clinical practice

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