Transforming Clinical Research: COVID-19 and Clinical Data Registries

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Chair, ACR's COVID-19 Imaging Research Registry (CIRR)

Session Objectives

- Brief history of ACR efforts in registries for research and quality and safety

- Understand value of research registries and why ACR is uniquely positioned in this space

- Review COVID-19 as a use case

- Panel discussion sharing considerations when working with research registries

NIH Definitions

Clinical Trial

- *"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."*

Registry

- *"…a collection of information about individuals, usually focused around a specific diagnosis or condition."*

Medical Registries

- Data taken from patient encounters that allow study of clinical questions.

- Familiar registries used for research:
    - Medicare and Medicaid claims databases (used by ACR Harvey Niemen Health Policy Institute).
    - SEER (for cancer outcomes)
    - National Breast Cancer Surveillance Consortium registry.

- ACR has multiple Quality Improvement Registries under the National Radiology Data Registry (NRDR) program
    - E.g. National Mammography Database (NMD), Dose Index Registry (DIR), Lung Cancer Screening Registry (LCSR)

Why are registries valuable?

- "Real world data" – longitudinal information on conditions – individual and aggregate
- Representative of diverse population
- Allows for:
    - Education
    - Research and development
    - Novel and more effective therapies and disease management
- Break down institutional silos

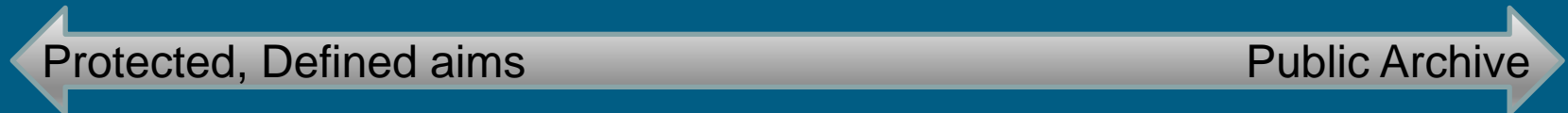# Research Registries: Key Considerations

- **Regulatory**

  ← IRB Common Rule   Exemption →

- **Patient Identifiers**

  ← Limited Identified Dataset   Fully De-identified →

- **Legal/Contracting**

  Various Agreement Types: Contract, MSA, BAA, PA, DTA, DUA

- **Data Protection and Use**

  ← Protected, Defined aims   Public Archive →

- **Data Standards**

  ← Structured, Rigorous   Variable, Passive →

Benefits to research/clinical community

- Reimbursement
  - Provide evidence for payment justification
- Research
  - Provide data for hypothesis generation
  - Supplement clinical trials and other kinds of data
  - Aggregated data -especially helpful for:
    - learning more about rare diseases
    - discover unusual outcomes and complications in large populations
    - AI/machine learning/radiomics
    - virtual clinical trials
- Education
- Public health surveillance

Benefits to research/clinical community

- Cross-disciplinary collaborations

- Multi-modality imaging and diagnostic data

- For ACR Registries- research benefits participating sites:
  - access to own curated data
  - research more accessible and robust to sites
  - site access to ACR research and informatics tools

COVID-19 as a Use Case

COVID-19

- Novel coronavirus is an emerging, rapidly evolving public health crisis

- Aggregating case data across the US is needed:
  - inform patient care
  - develop treatments
  - predict vulnerable groups

- Aggregate diagnostic imaging and clinical data
  - real-time integrated data stream that can serve as a public health surveillance and research tool

ACR COVID-19 Imaging Research Registry (CIRR)

CIRR established Spring 2020

Joint efforts:
- ACR Center for Research and Innovation™ (CRI),
- ACR Data Science Institute® (DSI)
- Society of Thoracic Radiology

Goal:
- translate new, evidence-based research into clinical practice

Population:
- adult and pediatric U.S. patients
- tested for COVID-19
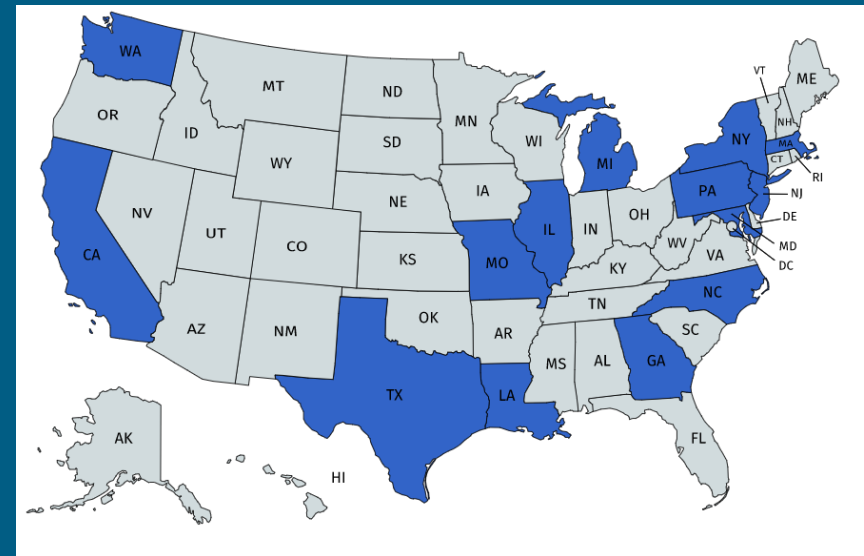- at least 1 imaging exam since Jan 1st 2020

CIRR Physician Steering Committee

Volunteer effort lending clinical expertise to inform and design registry build

Representation by:

- 30 Physicians
- 20 Institutions
- 14 States
- 8 Societies/Groups

- **Welcoming additional participating sites!**

https://www.acr.org/Research/Clinical-Research/COVID-19-Registry

CIRR@acr.org

CIRR Objectives

- Provide fertile opportunity for discovery
  - clinical presentation
  - course of the virus
- Provide aggregate multi-site, multi-state data across the U.S.
  - diverse populations and practice settings
  - critical in prevention, and treatment of this novel pandemic viral disease
- Provide robust clinical and imaging data:
  - clinical characteristics, demographics, diagnostic tests, and outcomes of patients tested for COVID-19

For sites that join CIRR and contribute data…

- Access to their own data and to the multi-site combined deidentified dataset
- Leverage the ACR informatics network for
  - future ACR research projects
  - institutional research initiatives
  - AI algorithm development, testing and implementation
- Access to ACR CONNECT
  - Communication services platform, APIs for seamless data exchange with vendor products, Single Sign On to ACR applications through ACR ID.

Why the ACR?

- TRIAD, first generation CONNECT, software installed at over 38,000 sites

- "Honest broker" neutral to vendor systems to aggregate the data

- Power and efficiency of leveraging ACR Programs – DSI, CRI, Quality and Safety

- Making research more accessible and robust to member sites
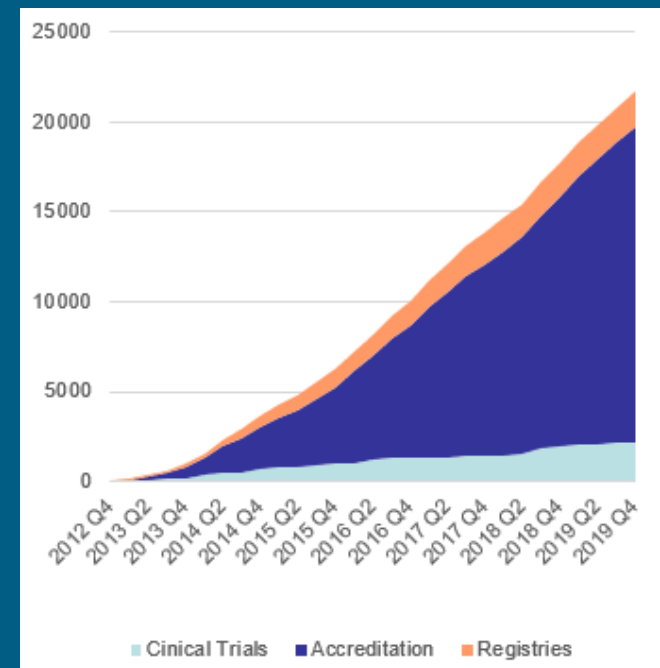
TRIAD installations over time

COVID-19 Registry Design

Imaging Data

- Multi-modality: CT, MRI, X-Ray, US
- Chest, Cardiac, Neuro imaging

Clinical Data

- Demographics
- Medical history
- Co-morbidities
- Symptoms, Vitals
- Laboratory tests
- Treatments, interventions, diagnoses
- Recovery, long-term effects

Thank you to our Pilot Sites and PIs!

- University of Pennsylvania – Dr Sharyn Katz
- MD Anderson Cancer Center – Dr Carol Wu
- University of Washington – Dr Martin Gunn
- UCLA – Dr Nancy Pham
- Wake-Forest Medical Center – Dr Caroline Chiles
- Louisiana State University – Dr David Smith

Progressive Partnerships in COVID-19

NIBIB Medical Imaging and Data Resource Center (MIDRC): Rapid Response to COVID-19 Pandemic
(Technology Resource Center – Data Commons)

Participating Organizations:

University of Chicago PI: Maryellen Giger

**American College of Radiology** (ACR): M-PIs Etta Pisano (ACR, Harvard University) and Michael Tilkin (ACR)

American Association of Physicists in Medicine (AAPM): M-PIs Maryellen Giger (University of Chicago) and Paul Kinahan (University of Washington)

Radiological Society of North America (RSNA): M-PIs Curtis Langlotz (Stanford University) and Adam Flanders (Thomas Jefferson University)

- Multi-group, $20M, 2-year NIBIB-funded project (potentially 5 years) that includes:
  - AAPM, ACR, and RSNA, as well as 23 other institutions
  - Imaging and data commons through technology development projects
    - intake portal(s)
    - virtual imaging and data repositories/registries
  - a public access portal on the UChicago Gen3 data ecosystem
- Data commons enabling researchers to address topics
- Initial research projects to expedite translation from scientific findings → public dissemination and clinical benefit
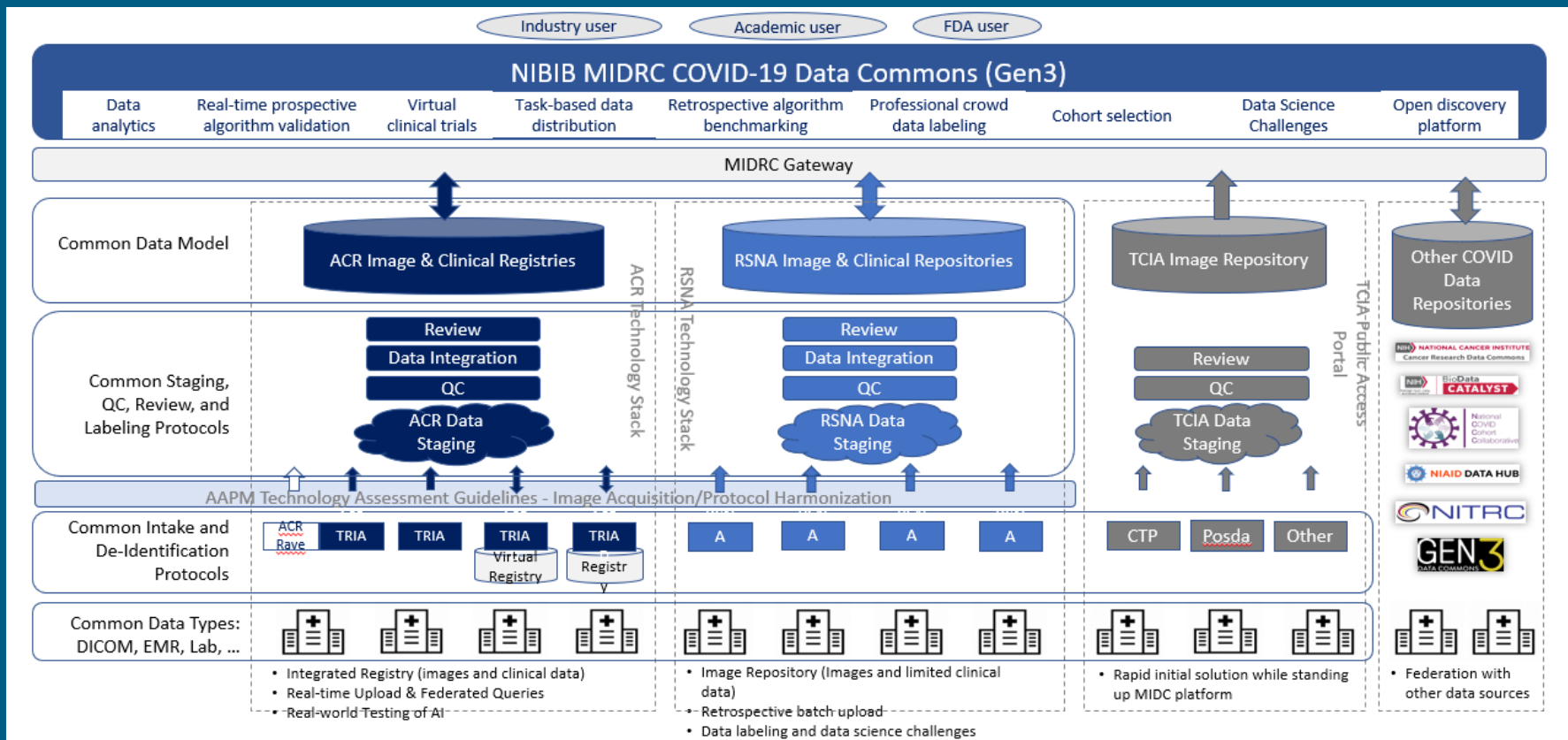
Subset of ACR's COVID-19 Registry data contributed to MIDRC

Research Projects on MIDRC

5 Technology Development Projects:
- Build infrastructure, collect images and data, conduct labeling
- Establish relationships with other organizations/data commons
- Development (engineering) work: (standards, harmonization, integrative dashboard, phantoms, labeling, metrology/distribution methods)

12 Collaborative Research Projects:
- Distributed through each organization's data science committees
- Projects in natural language processing, machine learning, image curation, radiomic feature analysis, virtual clinical trial

American College of Radiology

ACR Partnered with Other Organizations

- Society of Critical Care Medicine
- National Heart, Lung and Blood Institute, Prevention & Early Treatment of Acute Lung Injury Network
- National Center for Advancing Translational Sciences

Want to know more?

Contact us:

- https://www.acr.org/Research/Clinical-Research/COVID-19-Registry

- CIRR@acr.org

- Chat the RSNA 2020 ACR Exhibit Booth

Panel Discussion

Tessa Cook, MD, PhD
University of Pennsylvania
Diagnostic Radiology

Imaging informatics, Workflow Optimization, Artificial intelligence

Christopher Treml, MS
American College of Radiology

Director, ACR Data Science Institute

Keith E. Muller, PhD
University of Florida

Biostatistics, Health outcomes research, Statistical methods