NCI's Virtual Clinical Trials Office Pilot Program

James H. Doroshow, M.D.
Director
Division of Cancer Treatment and Diagnosis

NIH NATIONAL CANCER INSTITUTE

National Cancer Advisory Board and the Board of Scientific Counselors

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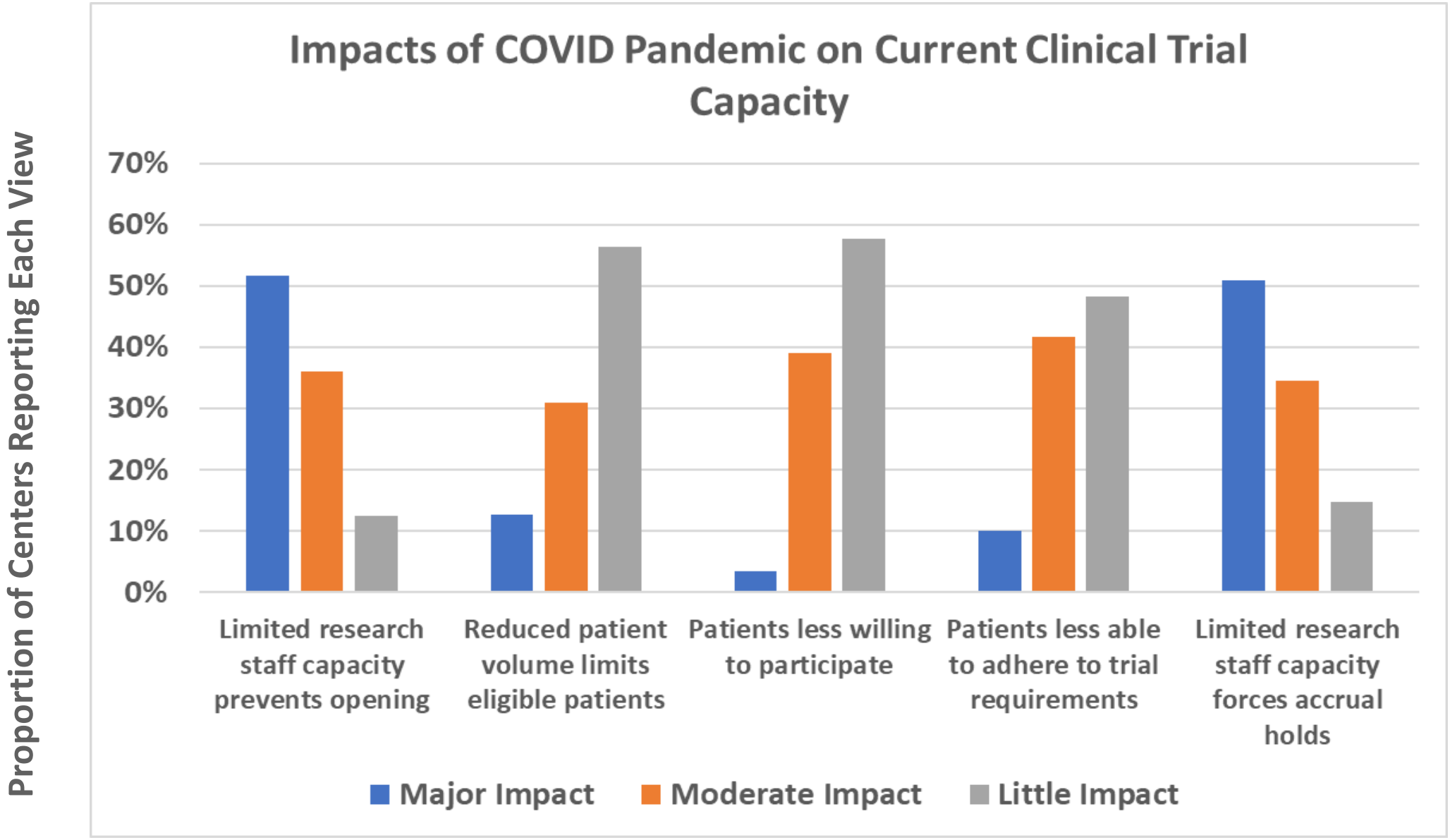
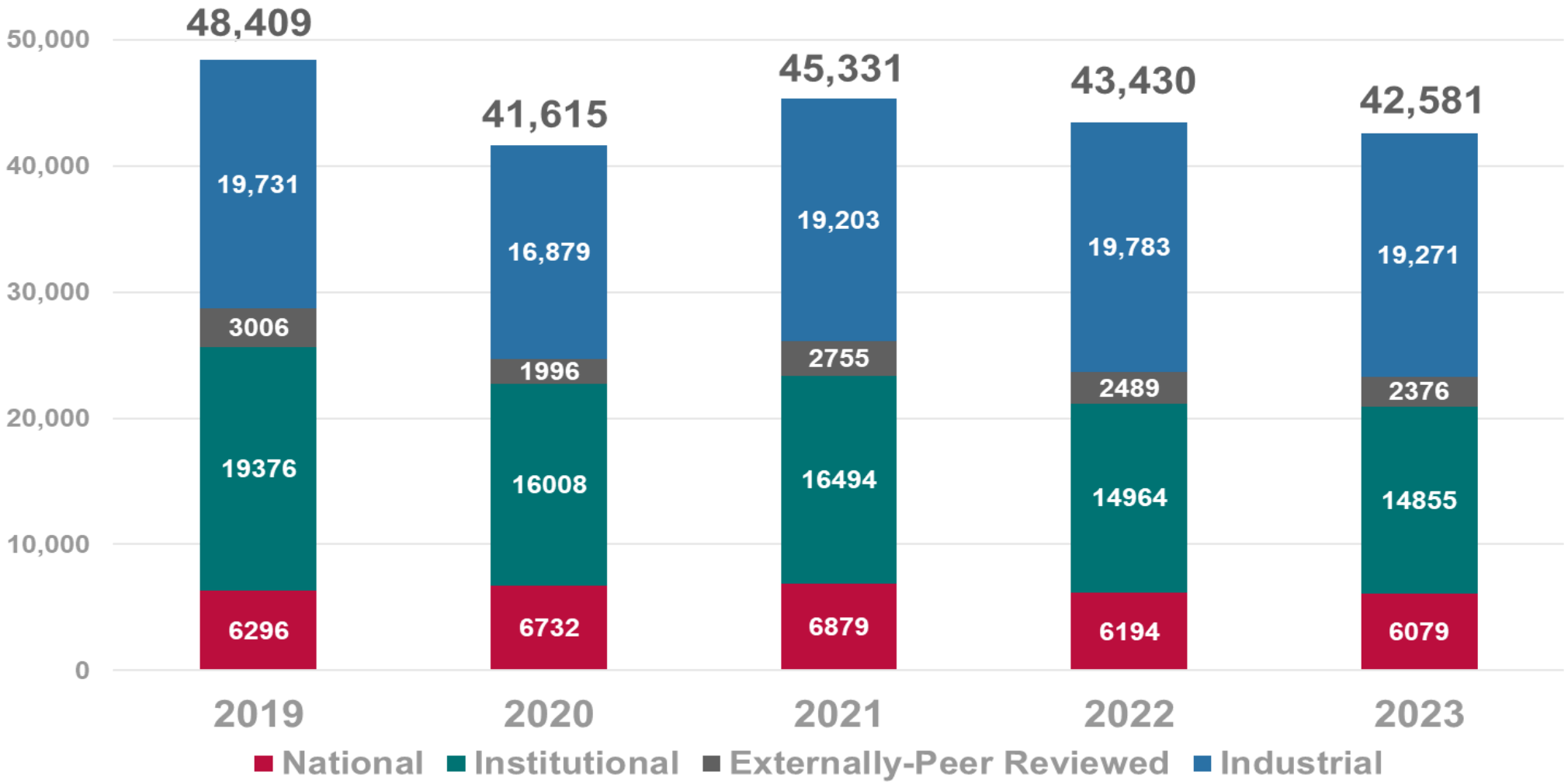
Overview

- Rationale for launching the Virtual Clinical Trials Office Pilot Program
- Initial program description, metrics, and lessons learned
- Future plans
- Dr. Augusto Ochoa: Pilot VCTO at Gulf South NCORP



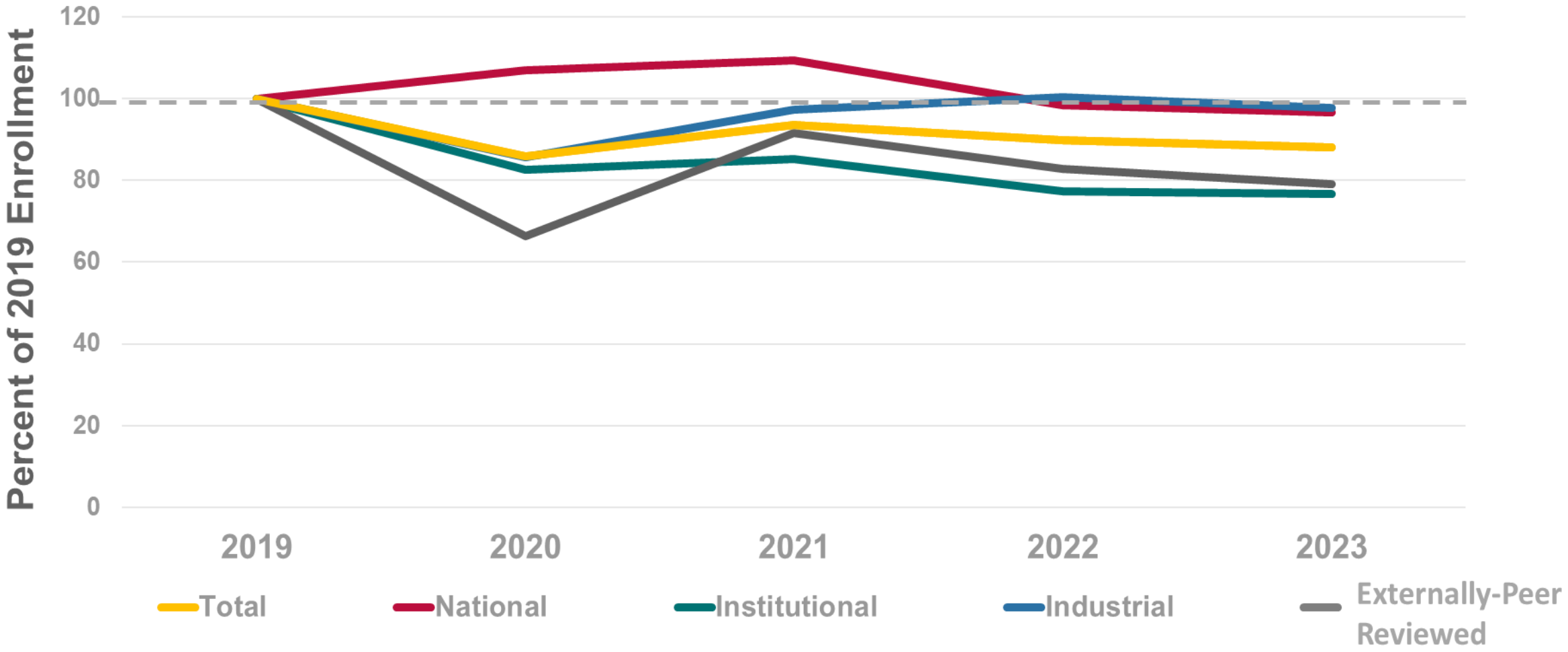
Respondent group for this question: all 64 clinical Cancer Centers

Treatment Trial Enrollment, 2019 – 2023*
NCI-Designated Cancer Centers



*Interventional Treatment Trial Data from NCI's Clinical Trials Reporting Program (CTRP) as of 4/23/24

2020 – 2023 Treatment Trial Enrollment* as a Percentage of 2019 Enrollment by NCI-Designated Cancer Center Study Source



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Virtual Clinical Trials Office Components

- Research nurses, CRAs, & regulatory affairs personnel organized through NCI-Frederick National Lab Clinical Research Directorate used in past primarily by NIAID
  - ✓ Long history of providing clinical trial professionals for NIAID antiviral studies both nationally and internationally; on site and virtually, including trial auditing from EHRs located at academic health systems and private practices
- Initial services by VCTO personnel (working remotely) to support local research site health professional staff:
  - ✓ Eligibility screening and study coordination; promoting trial entry of underserved/rural patients
  - ✓ Assistance with informed consent, enrollment, protocol queries, 'help desk' functions
  - ✓ Data entry/abstraction from EHR to Medidata-RAVE for NCTN, ETCTN, NCORP trials (requiring approval by health provider to access protocol patient data in EHR by remote login)
  - ✓ Coordinating study visits, procedures, and participant reminders; all to improve retention
  - ✓ Regulatory support
  - ✓ Adverse event reporting

Activation and Metrics

- Six sites selected to initiate program in Fall 2023 based on need for services and potential to accrue underserved and rural populations
  - ✓ Montefiore Medical Center, Einstein Campus (CCSG/NCORP)
  - ✓ University of Texas Mays Cancer Center (CCSG)
  - ✓ University of Kansas Cancer Center (CCSG/NCORP)

  On boarded and receiving full range of services: screening, consenting, data entry: 12/23 to 4/24

  - ✓ Kootenai Clinic Cancer Services, Post Falls, ID (NCORP)
  - ✓ St. Vincent Hospital Cancer Center, Green Bay, WI (NCORP)
  - ✓ Geisinger Cancer Institute, PA (NCORP)

  Expected to begin providing services end of May/early June 2024
- Initial focus on 13 NCTN/NCORP protocols; 12/23 through 4/24:
  - ✓ 4,221 patients screened
  - ✓ 88 eligible patients identified
  - ✓ 24 accruals facilitated

Onboarding Lessons Learned (1)

- Sequential and Concurrent Processes
  - ✓ Execution of MOU: Supplemental agreements: CDA & IT security agreements
  - ✓ Creation of site accounts for pilot staff : Addition to site CTSU roster and site delegation logs
- Epic Access
  - ✓ Prolonged process of submission to gain access to EHR, review, legal review, revision, and multi-party sign off
  - ✓ Third-Party Epic Administrators
- No Two Clinical Trial Sites the Same

Onboarding Lessons Learned (2)

Future Plans

- Expand services to original 6 sites
  - ✓ Add qualified affiliate sites
  - ✓ Expand range of protocols supported (from 12 to 20 including additional NCORP trials
- Add at least 3 more lead sites including sites using Cerner EHR
- Anticipate 25-35 total lead and affiliate sites participating in pilot; focus on streamlining on-boarding process
- Consider adding long-term follow-up services to pilot menu