



CASE WESTERN RESERVE
UNIVERSITY
Clinical and Translational
Science Collaborative



2024 Annual Pilot Technical Webinar

September 24, 2024



Presenters



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Clinical and Translational
Science Collaborative



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Collaborative



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CTSC of Northern Ohio



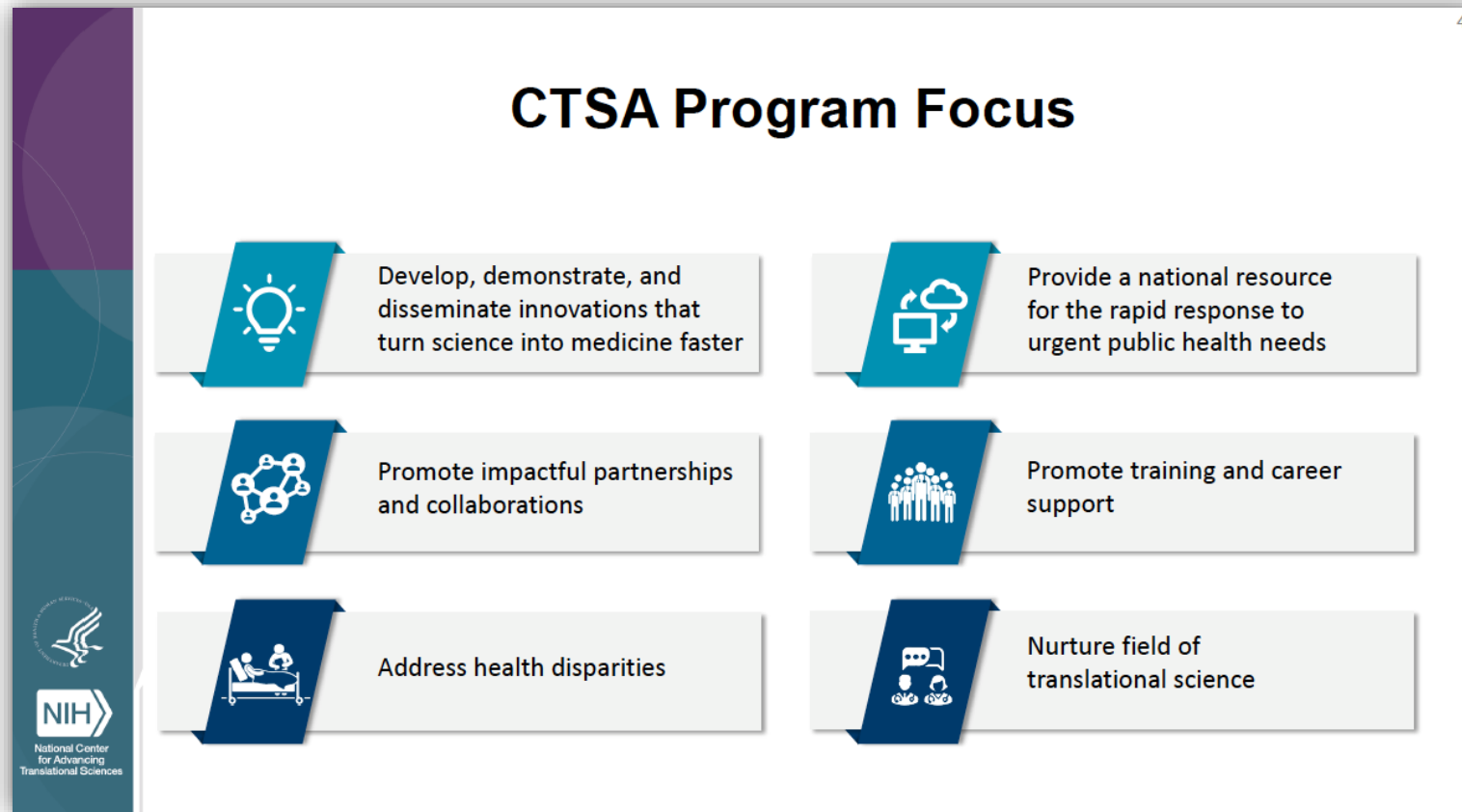
CASE WESTERN RESERVE
UNIVERSITY
Clinical and Translational
Science Collaborative

Clinical and Translational Science Awards



National Center
for Advancing
Translational Sciences

A network of over 60 medical research institutions working together to improve the process of translational research.



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CTSC Mission and Aims

Our mission is to be a catalyst for high quality clinical and translational science and transformative research to positively impact the health of those in Northern Ohio and beyond



COMMUNITY ENGAGEMENT & COLLABORATION



DISSEMINATE & IMPLEMENT FINDINGS FROM NOVEL AND RESPONSIVE RESEARCH PROGRAMS



OPTIMAL RECRUITMENT OF UNDERREPRESENTED GROUPS IN CLINICAL TRIALS



DEVELOP & TRAIN THE NEXT GENERATION OF RESEARCHERS AT ALL LEVELS



About the CTSC of Northern Ohio

Partners

- CWRU (Lead), Cleveland Clinic, University Hospitals, MetroHealth, Cleveland VA Medical Center, University of Toledo, and NEOMED

First CTSA Award Sept. 2007

- 2023 Cycle - \$56.3M, 7 years
- Current theme: Catalyzing Linkages to Equity in Health (CLE Health)

Companion Programs

- K12 (career development)
- T32 (predoc & postdoc)
- R25 (undergrad research)
- RC2 (innovation program; roadblocks in C/T Science) *RFA open now— contact Sue Marasco at sam164@case.edu*



Translational Science & Translational Research



Stages of Translation

- **Translation** - the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public - from diagnostics and therapeutics to medical procedures and behavioral changes.
- **Translational Research** - The endeavor to traverse a particular step of the translational process for a particular target or disease.
- **Translational Science** - The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.
 - **Disease agnostic**

TRANSLATIONAL SCIENCE IS IMPROVING THE PROCESS:

NIH National Center for Advancing Translational Sciences

Learn more at: ncats.nih.gov

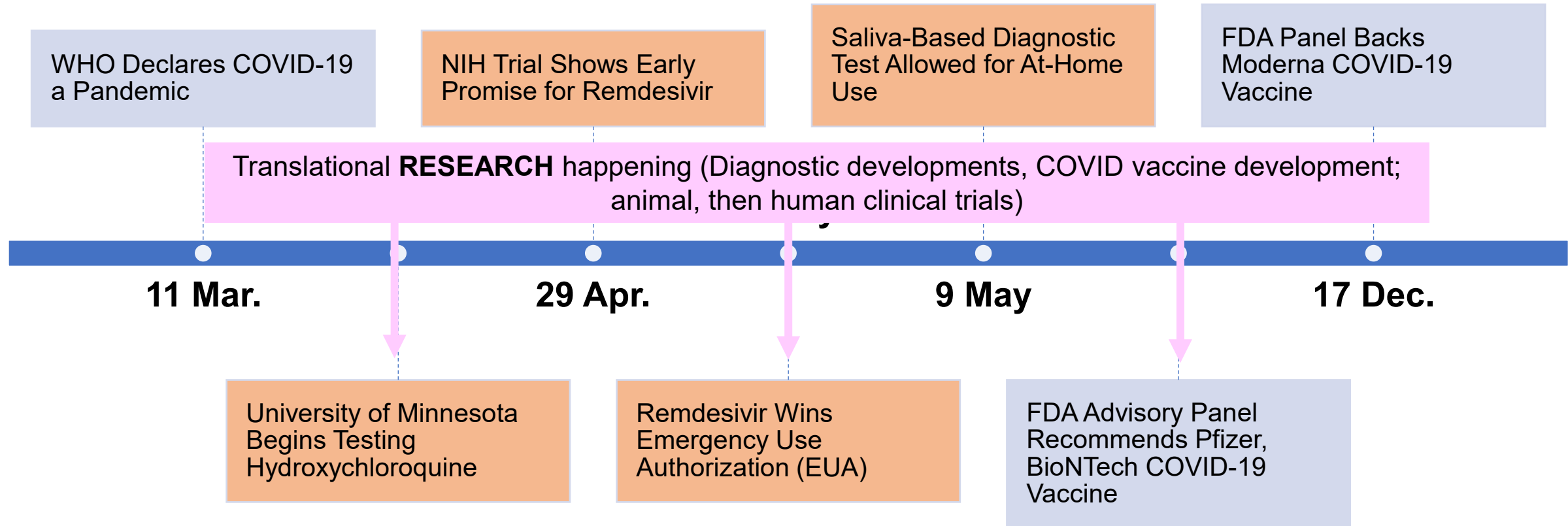
- Understanding what's similar across diseases to help develop multiple treatments at a time
- Developing models that better predict a person's reaction to a treatment
- Enhancing the design and conduct of clinical trials so the results more accurately reflect the patient population



Translational Science & Research In Action



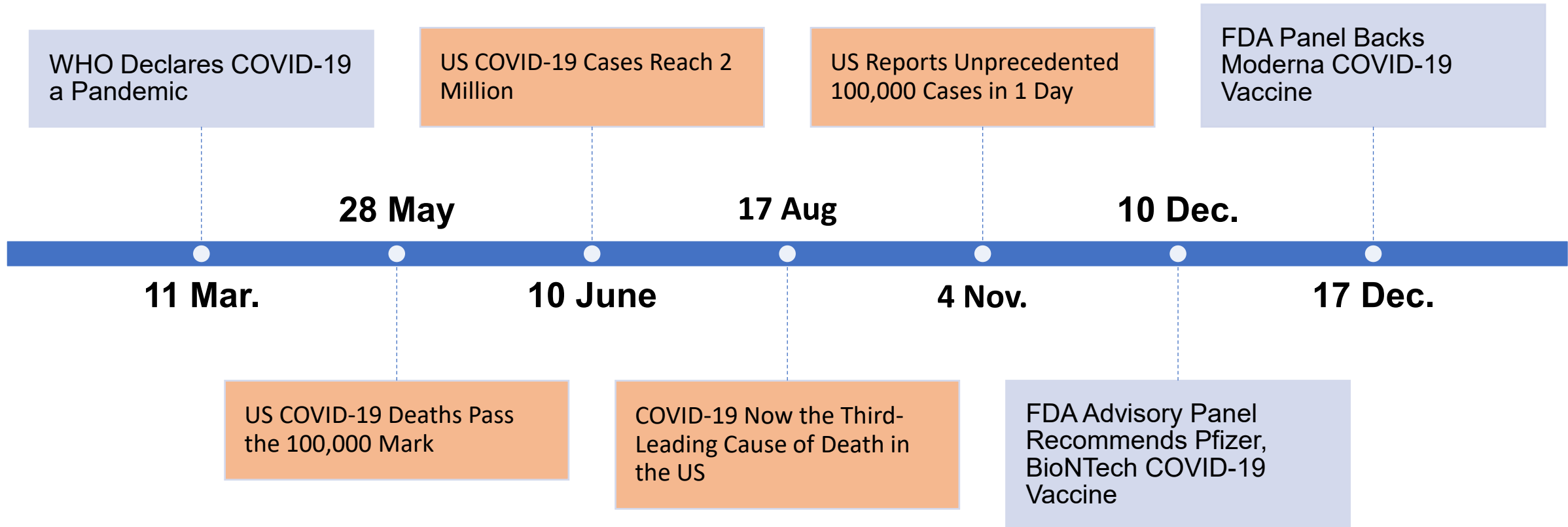
COVID-19 Timeline 2020



Translational Science In Action



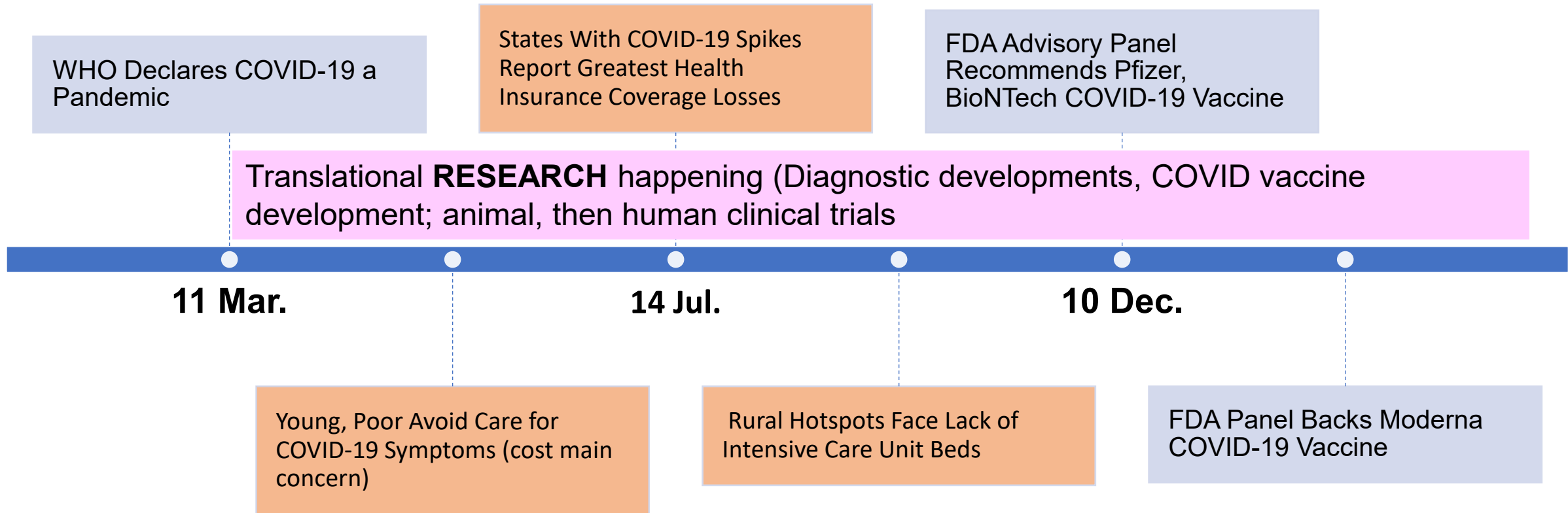
COVID-19 Timeline 2020



Translational Science & Research In Action



COVID-19 Timeline 2020



Imagine Another Way

How could translational research have done more to...

- Understand the pathogenesis of coronavirus infection more quickly
- Develop more pathogen detection methods for SARS-CoV-2 RNA
- Screen for community asymptomatic and serological testing SARS-CoV-2 RNA for staff, students, and the wider population for public health benefit
- Support increased recruitment of patients into COVID-19 clinical trials of novel therapeutics and vaccines.

How could translational science have made these processes better...

- 100% adoption of the COVID-19 vaccine
- Access to treatment for those in need
- Trust in healthcare
- Understanding of how policy helped reduce social drivers of risk
- Guidance for implementation of better approaches in healthcare, government, community settings, universities, drug companies, etc. as we plan for the next crisis

Edgeworth JD, Batra R, Nebbia G, Bisnauthsing K, MacMahon E, Sudhanva M, et al. (2020) Translational Research in the Time of COVID-19—Dissolving Boundaries. PLoS Pathog 16(9): e1008898. <https://doi.org/10.1371/journal.ppat.1008898>



Translational
Spectrum
&
RFA Scope



Translational Spectrum examples for Annual Pilot applications

Examples of T2 research include:

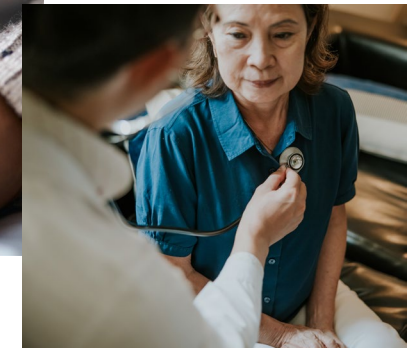
- Phase 2 and 3 clinical trials
- Development of clinical guidelines
- Comparative effectiveness trials

Examples of T3 research include:

- Community-based participatory research (CBPR)
- Phase 4 clinical trials
- Dissemination and implementation research


Examples of T4 research include:

- Population-level outcomes research
- Monitoring of morbidity, mortality, benefits, and risks
- Cost-benefit analysis
- Policy analysis
- Surveillance studies
- Program evaluation



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What is Dissemination & Implementation research

D&I sciences consider the role of people and systems in the adoption, dissemination, and sustainability of innovations in real-world settings.

- Studies that identify, develop, and/or test strategies for overcoming barriers to the adoption, adaptation, integration, scale-up, and sustainability of evidence-based interventions, practices, programs, tools, treatments, guidelines, and policies
- Studies that promote equitable dissemination and implementation of evidence-based interventions among underrepresented communities are encouraged.

Annual Pilot Specifics



Annual Pilot goals



Foster innovative clinical and translational research development addressing urgent questions or developing preliminary data establishing proof of concept used to launch new NIH or other externally-funded research proposals



Encourage interdisciplinary teams of investigators in clinical and translational science (spanning CTSC partners) to develop collaborations or new research avenues



Support research collaborations with community partners and organizations

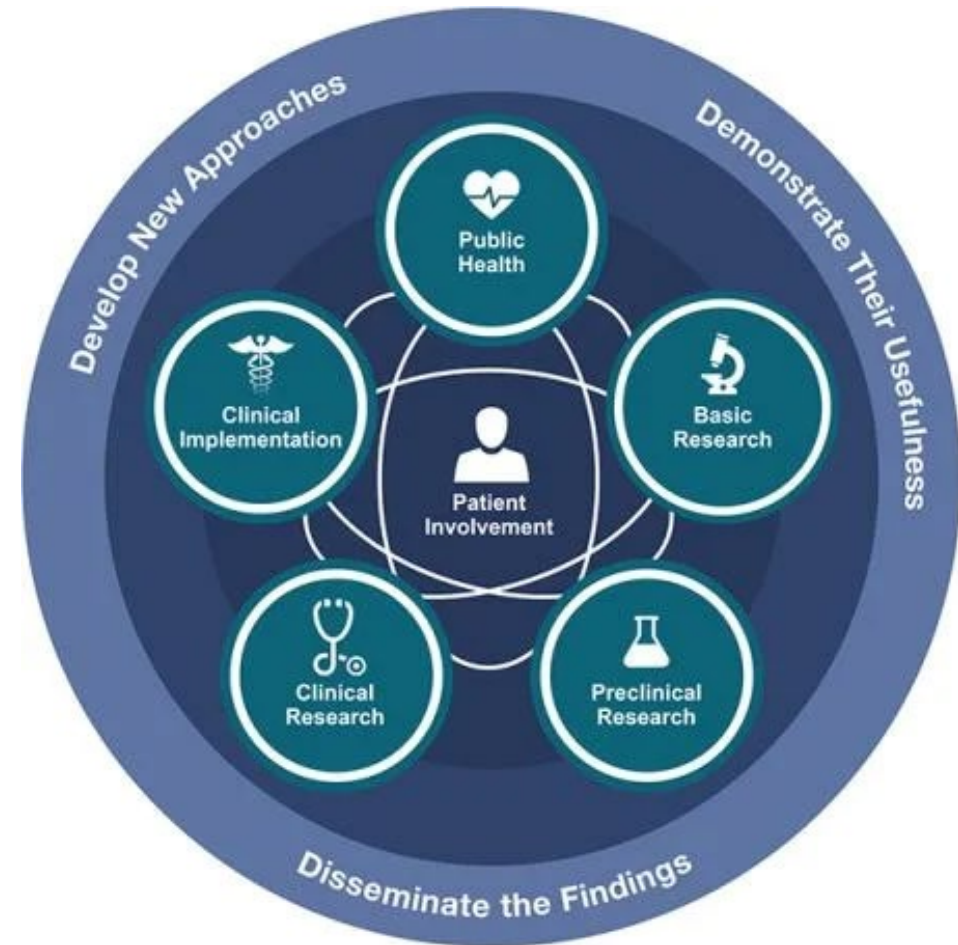


Ultimately advance health equity in Northern Ohio through research



Application considerations

- Projects must be feasible within the proposed 12-month timeframe
- High methodological and scientific quality and answer important scientific questions
- Up to 8 grants will be awarded with budgets of up to **\$50,000** each in direct costs.
- **All research activities must be completed by June 30, 2026.**



Credit: National Center for Advancing Translational Sciences



Additional considerations

- Both Translational Research and Translational Science projects are eligible (see RFA Appendices).
- Any CWRU school may apply
- For this RFA, applications MUST include 2 or more CTSC partner institutions or they will not be considered for funding
- NEOMED and University of Toledo faculty can be Co-Investigators (not PIs).
- Community organizations and additional institutions can be Co-Investigators and involved in projects as a 3rd partner.



Eligibility to apply

- ✓ PIs must have a faculty appointment at Case
- ✓ PIs from multiple partners
- ✓ Be affiliated with a CTSC partner: CWRU, CC, MetroHealth, UH, VA
- ✓ Eligible for a NIH grant
- ✓ *Applications from new investigators and/or under-represented minorities are highly encouraged.*

- ✓ Co-I may include University of Toledo faculty, NEOMED faculty, community health leaders, trainees, coordinators

https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.5.4_determining_eligibility_of_individuals.htm



Annual Pilot Priority Areas

Disease-agnostic projects that focus on the process of turning research results into real-world applications

Innovative, multi-center clinical studies that integrate community and clinical partners

Dissemination & Implementation of research evidence & innovation to clinical practice

Projects that leverage Cosmos or TriNetX informatics tools

Priority areas continued

Health issues related to the environment

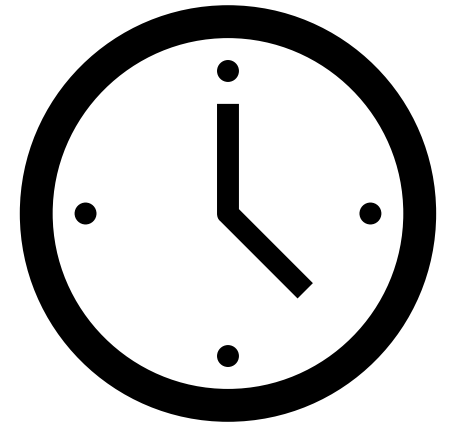
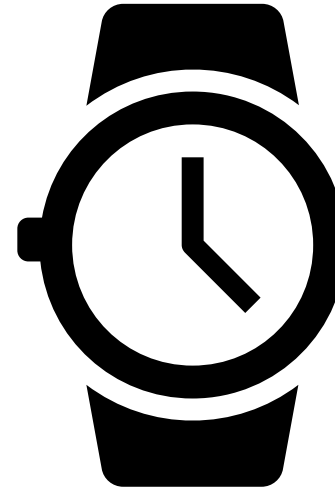
Innovative implementation methods promoting uptake of findings into routine healthcare in clinical or policy contexts

Interventions at community and/or clinical practices to promote health equity

Studies focusing on methods to improve research processes.

Letter of Intent

- The **required *one-page*** letter of intent (LOI) is due Nov. 15, 2024, 11:59 PM.
- Applicants selected to submit a full proposal will be notified on Dec. 15, 2024.



Letter of Intent components



Project Title, Names and Affiliations of PI, Co-PIs, Co-Investigators and Collaborators and project sites

- Brief, focused project summary
- Question/Hypothesis
- Innovation/Translation section
- Feasibility section
- Project Milestones
- Statement of Translation
- Budget Summary
- Human Subjects/IRB
- Intellectual Property questions
- Special Considerations

(see RFA for more detailed information)



Step 1 for applying: SPARC

- Head to sparc.case.edu
- Sign up for an account if you don't already have one
- **Option 1** – Under Funding Opportunities, find Annual Pilot and enter your project, get your Project ID #
- **Option 2** – Go to Research Navigation Services and choose a consultation before applying
- Problems with SPARC? Email sparc-help@case.edu

The screenshot shows the SPARC Request website interface. At the top, the URL sparc.case.edu is circled in red. Below the navigation bar, a horizontal flowchart displays five steps: STEP 1: Add/Update Services (blue), STEP 2: Services & Project Information (teal), STEP 3: Milestones & Calendar Structure (green), STEP 4: Documents, Notes & Forms (orange), and STEP 5: Review Your Request (red). The current view is 'STEP 1: Add/Update Services'. On the left is a 'CTSC Service Catalog' with a list of services including Bionutrition, Biostatistics, Clinical Research, Clinical Trial Resources, Community Engagement, Dissemination & Implementation, Funding Opportunities, Grant Development, Informatics, REDCap, Regulatory & Compliance, Research Education & Training, Research Equity Accessibility Diversity & Inclusion (READI), and Research Navigation Services. A green arrow points from the text 'Under Funding Opportunities' in the list to the 'Funding Opportunities' menu item, and an orange arrow points from 'choose a consultation' to the 'Research Navigation Services' menu item. The main content area features a search bar and a list of services. A 'My Services' sidebar on the right shows 'Open' and 'Completed' tabs, with a message: 'You do not have any active requested Services'. At the bottom, there are buttons for 'Continue', 'FAQs', and 'Feedback'.

Notes on applying for CTSC funding

- **A TWO-STEP process: SPARC + InfoReady**
(CTSC's request system + CWRU's centralized online grant proposal management system)
- To apply for a CTSC Funding Opportunity, you will first need a Project ID number from [SPARC](#). This Project ID allows access to the RFAs and applications in InfoReady.
- Consult services for CTSC resources are available for investigators at CWRU and all CTSC partners.

Step 2: InfoReady

- Go to [CWRU InfoReady](#) website
- Sign up for an account if you don't already have one (CWRU users can use SSO, outside users need to register for an account.)
- Use the search bar or scroll down to find **2024-2025 CTSC Annual Pilot Grant Application**
- Enter detailed RFA information here *(this is where you'll need your SPARC project #)*
- Problems with InfoReady? Email Wesley Chen, Pilot Funding Coord., at wxc520@case.edu

cwru.infoready4.com/CompetitionSpace/#homePage


CASE WESTERN RESERVE UNIVERSITY EST. 1826

Grants & Opportunities Management System

Log In | Help

CASE WESTERN RESERVE UNIVERSITY CALENDAR

InfoReady Grants & Opportunities Management System



InfoReady is a centralized, online grant proposal management system which facilitates the submission and review of competitive research initiatives within the university. It is designed to provide easy access to users allowing applicants to search and apply for opportunities, submit progress reports online, process reports or historical information, and receive timely notifications and reminders. From here you can access pilot proposals, bridge funding, external limited submissions and other funding opportunities through the , , and the .

InfoReady is the replacement program for the WebGrants portal, so bookmark this page.

First-time user? No problem! InfoReady uses CWRU Single Sign-On, so your CaseID and password provide immediate access! External users and those without a CaseID, will need to register. The process is simple, and we are happy to help if you have questions.

Search:

Title	Due Date	Organizer	Category	Cycle
		All	All	All
The Blood, Heart, Lung, and Immunology Research Center Membership Application	12/31/2029	Office of Research Administration and Strategic Initiatives		
Case Comprehensive Cancer Center:		Case Comprehensive Cancer Center	Case CCC Membership	

Customizing InfoReady Review

InfoReady uses CWRU Single Sign-On, so your CaseID and password provide immediate access! now! External users and those without a CaseID will need to go through this simple process with results in 24hrs or less!

This site will host pilot funding opportunities for the , , and the as well as the Bridge Funding Program and Limited Submission opportunities.

Click on a funding link (listed to the left) to go directly to the application, or visit one of the host pages: . . .

If you'd like more information, please visit our , or reach out to one of the admins for support at infoready_admin@case.edu



- ✓ Submit a Letter of Intent (LOI) by November 15, 11:59 PM
- ✓ If you'd like a consultation before submitting a LOI, request a Research Navigation Consultation in SPARC.
- ✓ Be aware of critical Annual Pilot dates:

November 15:	LOI submission due via InfoReady
December 15:	LOI results announced
Feb. 14, 2025:	Full proposals due
April 21:	Annual Pilot awards announced
April 30:	Any applications with IRBs must have IRB approval <i>IN PLACE</i> by this date
July 1:	Annual Pilot project start date
June 30, 2026:	Annual Pilot project end date



FAQs

Q. Does a community partner count as a 2nd partner?

A. No, for this RFA, applications must have 2 or more *CTSC partner institutions*. A community organization can be a co-investigator and would count as a 3rd partner

Q. How long should my LOI be?

A. Your letter of intent should be **one page maximum**. All LOI instructions are located on Page 4 of the Annual Pilot RFA.

Q. What if my project needs IRB approval?

A. Include a statement outlining plans to obtain IRB approval by April 30, 2025, dates of submission, and/or approval (*projects with already approved or nearly approved IRB will be more favorably reviewed*).

Q. Is a consultation required?

Add IP, collaborators, etc.



Q & A



More CTSC Opportunities



ATLAS: Advanced Translational Leadership Program in Academic Science (Early-Stage Investigators)

Applications open NOW!

Contact **McKenzie Ritter** at mxr864@case.edu for a nomination form and more information (self-nominations accepted)

High Impact Specialized Innovation Program (RC2)

1 RC2 grant awarded at \$500,000 per year in direct costs/
Requested project period up to 5 years

LOI due Sept. 30

Contact **Sue Marasco** at sam264@case.edu for a copy of the RFA and more information



Coming in 2025...

CTSC Discovery Day

March 21, 2025

Volunteer to be a mentor!

*(help 3 to 4 Cleveland area high school
STEM students judge scientific posters)*

**Submit a poster about your
CTSC-related research!**

More information to come in our newsletter...



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Collaborate with the CTSC in multiple ways

Become a CTSC member and access CTSC resources, funding opportunities, and events by scanning the QR code below:



ctsc-research-concierge@case.edu
216-368-5252

