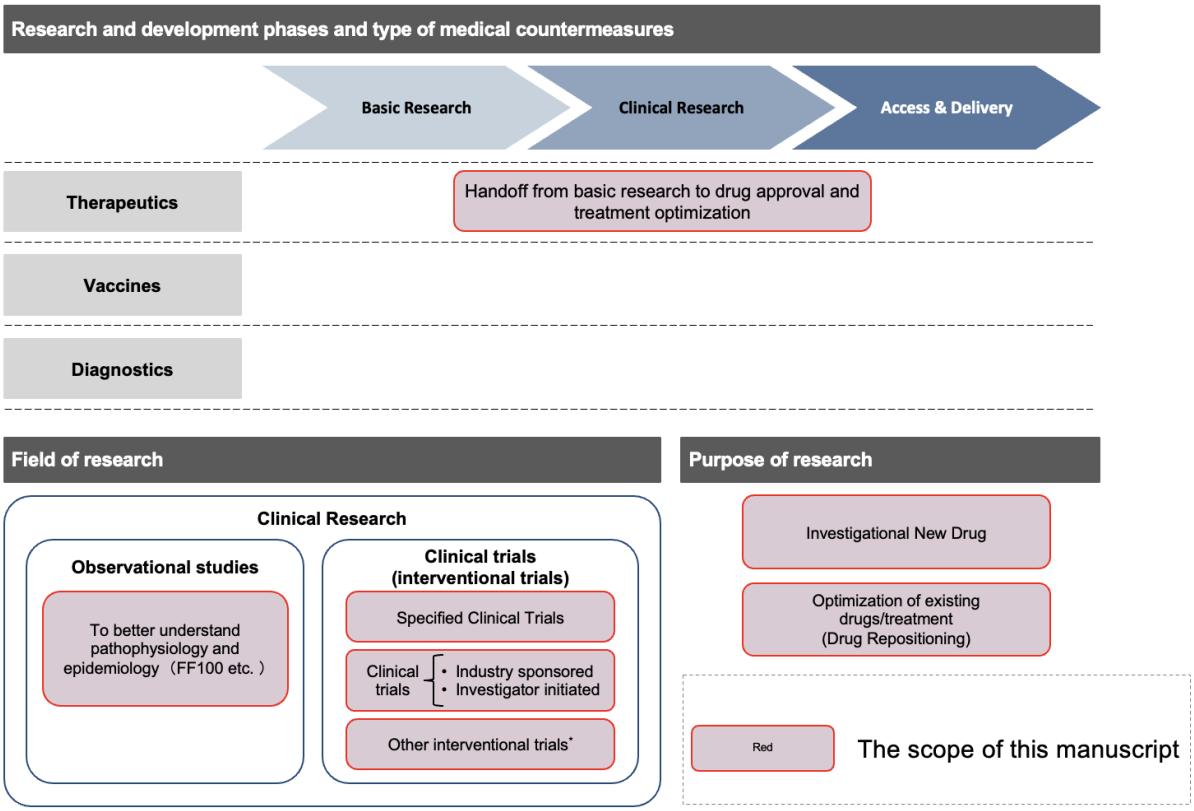
Appendix

Supplemental Table S1. Characteristics of the RECOVERY trial

1. Clinical trial design	• Platform trial, focusing on disease condition rather than particular interventions • Pragmatic design with minimum and simple eligibility criteria • Set objective endpoints (mortality, etc.), mitigating impact of open-label design • Minimize additional trial-specific data collection, limiting to a necessary minimum • Prepare and inspect standard protocols in advance
2. Clinical trial enabling environment	• NIHR built the CRN system, reducing burden of participating medical institutions • Senior leadership in the government advocated embedding clinical trials into everyday practice • PPIE activities even in the inter-pandemic period, leading to deep understanding of participation in research activities among patients • Standardization of electronic medical records, enabling seamless use of clinical data in clinical trials • Clear processes in obtaining consent and ethics review • Design healthcare system that facilitates participation of academia and medical institutes in clinical research/clinical trials

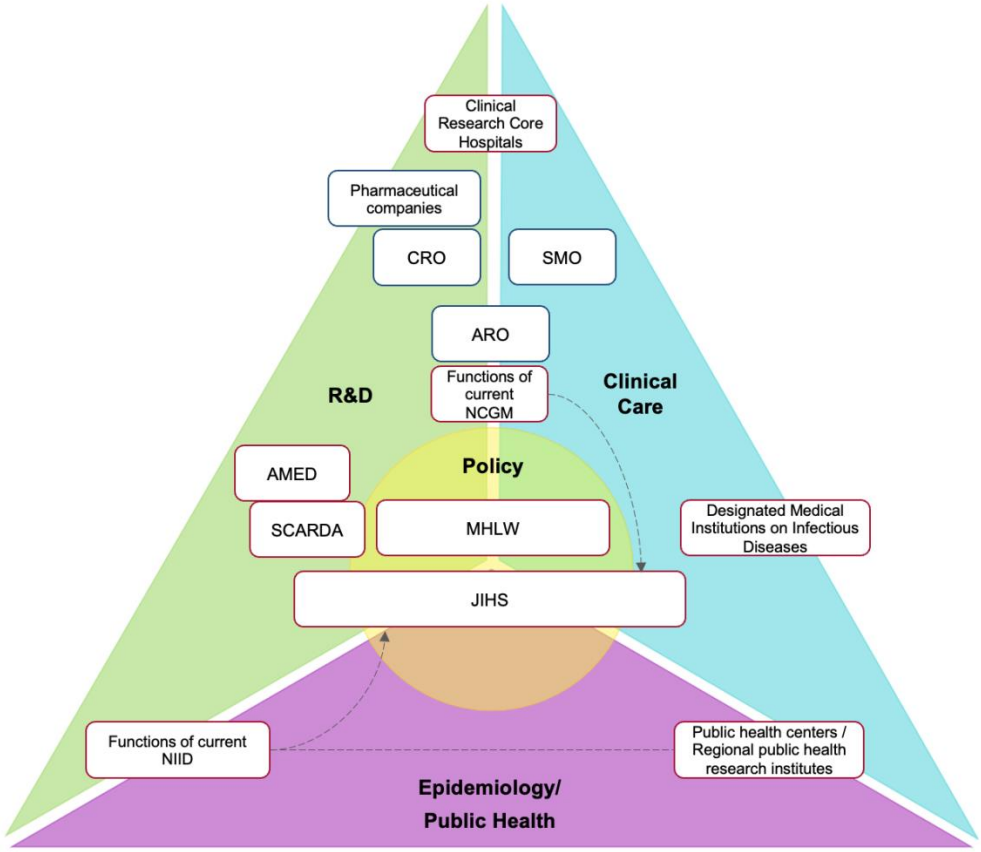
CRN: Clinical Research Network; NIHR: National Institute for Health and Care Research; PPIE: Patient and Public Involvement and Engagement.



Supplemental Figure S1. Types of research and the scope of the recommendations.

* Includes comparative effectiveness studies to optimize clinical practice.

FF100: First Few Hundred project



Supplemental Figure S2. Stakeholder map of infectious diseases clinical trials in Japan.

AMED: Agency for Medical Research and Development; ARO: Academic Research Organization; CRO: Contract Research Organization; JIHS: Japan Institute for Health Security; MHLW: Ministry of Health, Labour and Welfare; NCGM: National Center for Global Health and Medicine; NIID: National Institute of Infectious Diseases; SCARDA: Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response; SMO: Site Management Organization.

Appendix (Acknowledgement of the meeting participants)

We would like to express our sincere gratitude to the following experts and organizations who participated in the culminating meeting and the interview sessions (listed in random order and honorifics titles omitted). Of note, only experts who agreed to be included in the acknowledgement section are listed here. We also thank Yu Yajima Nanamatsu at Indiana University School of Medicine, Sana Uchikoba at National Institute of Infectious Diseases, Hiromi Hibino at National Center for Global Health and Medicine, and British Embassy Tokyo for their support in coordinating with international experts.

The culminating meeting on February 15, 2023

Organization	Name
Global Health Innovative Technology Fund	Osamu Kunii
Clinical Investigation and Research Unit, Gunma University Hospital	Tetsuya Nakamura
Department of Infectious Diseases, Keio University School of Medicine	Ho Namkoong
Disease Control and Prevention Center, National Center for Global Health and Medicine	Norio Ohmagari
Research Center for Drug and Vaccine Development, National Institute of Infectious Diseases	Yoshimasa Takahashi
Drug Development and Regulatory Science Division, SHIONOGI & CO., LTD.	Takeki Uehara
Division of General Internal Medicine and Infectious Diseases, Rinku General Medical Center	Masaya Yamato
Japan Agency for Medical Research and Development	

Individual or group interview sessions

Japan

Date of interview	Organization	Name
June 9, 2022; and June 28, 2022	National Institute of Infectious Diseases	Itsuro Yoshimi
November 24, 2022	National Institute of Infectious Diseases	Motoi Suzuki
December 9, 2022	National Institute of Infectious Diseases	Yoshimasa Takahashi
December 14, 2022	National Institute of Infectious Diseases	Tadaki Suzuki
September 21, 2022	The University of Tokyo	Shunsuke Ono
January 13, 2023	National Cancer Center Hospital	Kenichi Nakamura
October 28, 2022	Japan Pharmaceutical Manufacturers Association	Group interview
January 6, 2023	SHIONOGI & CO., LTD	Group interview
October 5, 2022; October 11, 2022; and November 28, 2022	Ministry of Health, Laboure and Welfare	Group interview
October 3, 2022	Pharmaceuticals and Medical Devices Agency	Group interview
October 21, 2022; November 4, 2022; and November 15, 2022	Japan Agency for Medical Research and Development	Group interview

United States

Date of interview	Organization	Name
November 8, 2022	National Institute of Allergy and Infectious Diseases	L. Jean Patterson
November 15, 2022	National Institute of Allergy and Infectious Diseases	Elizabeth Higgs

November 16, 2022	Bellevue Hospital	Vikramjit Mukherjee
December 1,2022	US Food and Drug Administration	Peter Marks
February 21, 2023	Centers for Disease Control and Prevention	Timothy Uyeki
December 1, 2022	Gilead Sciences, Inc.	Rob Hyland
October 21, 2022	Biomedical Advanced Research and Development Authority	Group interview

United Kingdom

Date of interview	**Organization**	**Name**
August 2, 2022	London School of Hygiene and Tropical Medicine	Ian Roberts
January 27, 2023	Welcome Trust	Tim Jinks; Bethan Hamilton; Leon Lau; and Divya K. Shah
July 26, 2022; and January 18, 2023	The Department of Health and Social Care	Group interview