

## BACKGROUND / OBJECTIVES

Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA). Its mission is to create capabilities to monitor the safety of marketed medical products using routinely collected electronic health data. These resources include a distributed dataset containing electronic healthcare data from 18 health plans. The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership established by the FDA and Duke University. Its mission is to identify and promote practices that will increase the quality and efficiency of clinical trials. CTTI is now comprised of more than 60 organizations from across the clinical trial enterprise.

**Mini-Sentinel, CTTI, and FDA are assessing the feasibility of using the health plans' electronic health data to facilitate recruitment and follow-up of participants in randomized trials, including both individual and cluster randomized trials.**

## APPROACH

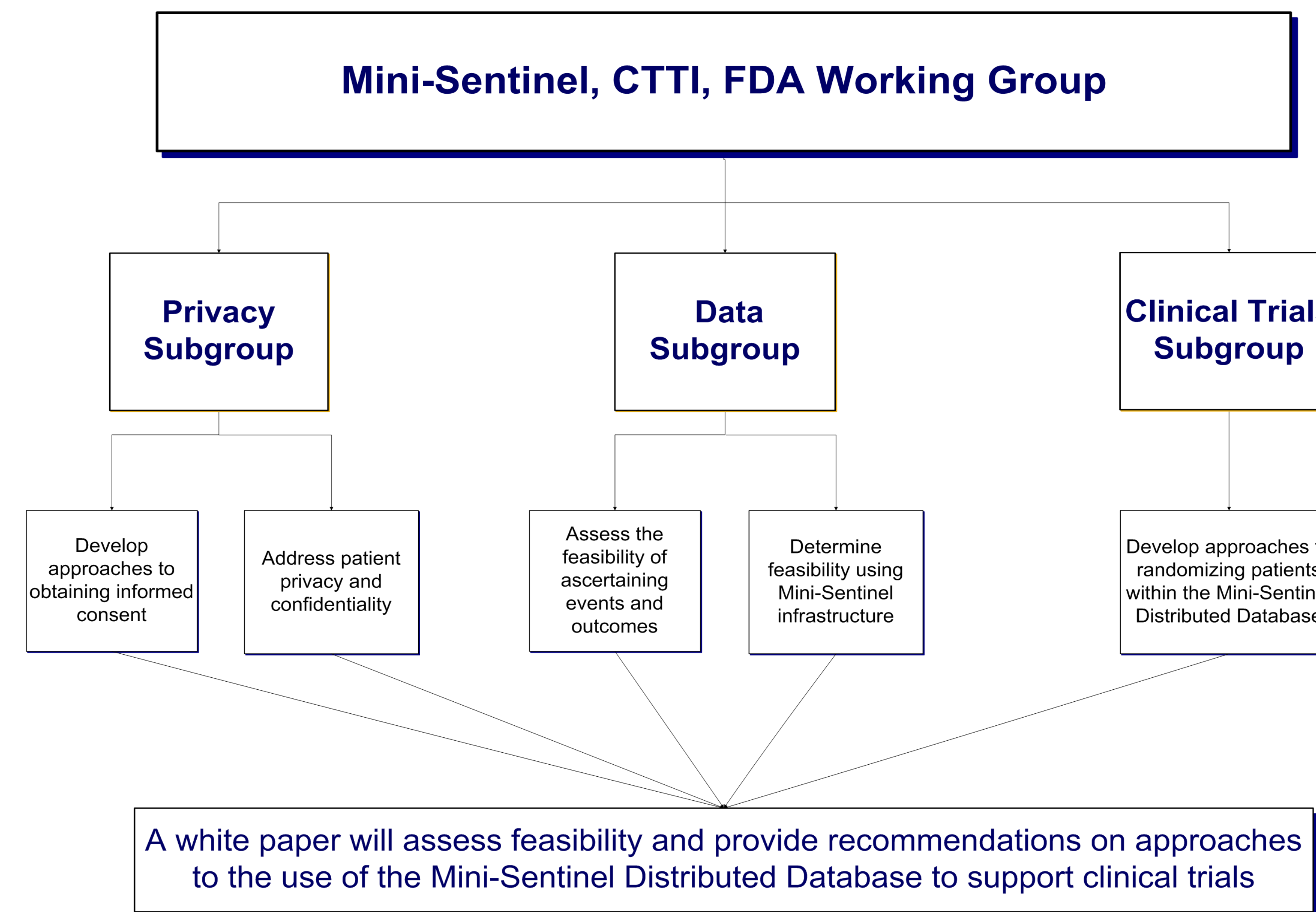
The Mini-Sentinel's distributed dataset may be able to identify potential trial participants by finding individuals who meet a trial's major enrollment criteria. The dataset might also capture some clinical trial outcomes by monitoring both treatments and diagnoses.

Recruitment for randomized clinical trials will need methods for a) identifying potential subjects for a prospective study, and b) working with corresponding clinicians to contact potential subjects.

Follow-up will focus on capturing using existing automated data and also Mini-Sentinel's procedures for obtaining and reviewing full text medical records.

Implementing such a system will require development of policies and procedures in three domains: **privacy, data, and clinical trial design.**

## WORKING GROUP STRUCTURE



## PRIVACY CONSIDERATIONS

Legal and ethical issues related to the use of Protected Health Information (PHI) for these purposes include:

- Patient privacy and confidentiality
- Engagement of Institutional Review Boards (IRBs)
- Procedures and approaches to obtaining informed consent
- Applicability of laws and regulations governing research involving human subjects, including the Health Insurance Portability and Accountability Act (HIPAA)

## DATA CAPABILITIES

Technical issues concerning the use of the Mini-Sentinel Distributed Dataset to facilitate patient recruitment and follow-up include:

- Ascertainment of exposures and outcomes
- Addressing Data Partners' willingness to participate in clinical trials
- Understanding organizational and infrastructure needs for participation
- Engaging clinicians and healthcare facilities
- Processes for identifying and contacting potential research subjects

## CLINICAL TRIALS DESIGN

Individual and cluster randomized trials design considerations include:

- Characterizing protocols that are appropriate for this organizational setting
- Describing clinical trial infrastructure and coordination needs
- Outlining an implementation protocol
- Estimating the cost and resources needed for implementing such a trial
- Providing worked examples of potential studies

## OVERALL ASSESSMENT

A white paper will recommend approaches to using the Mini-Sentinel Distributed Dataset for clinical trials, including:

- Approaches to obtaining informed consent and related privacy considerations
- Implications of use of Mini-Sentinel data to conduct research (as opposed to public health surveillance)
- Implementation and oversight of such research