June 23, 2025

Dr. Marty Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Exploration of Health Level Seven Fast Healthcare Interoperability Resources for Use in Study Data Created from Real-World Data Sources for Submission to the Food and Drug Administration; Establishment of a Public Docket; Request for Comments

Dear Commissioner Makary:

Civitas Networks for Health ("Civitas") appreciates the opportunity to respond to the FDA's "Exploration of HL7 FHIR for Use in Study Data Created from Real-World Data Sources" Request for Comments (Docket No, FDA-2025-N-0287), published in the *Federal Register* on April 23, 2025. Civitas is a national nonprofit collaborative comprised of more than 175 member organizations—health information exchanges (HIEs), regional health improvement collaboratives (RHICs), quality improvement organizations (QIOs), All-Payer Claims Databases (APCDs), and providers of services to meet their needs—working to use information infrastructure, and multi-stakeholder, cross-sector approaches to better health for individuals and communities. We educate, promote, and guide the private sector and policymakers on matters of interoperability, quality, coordination, and cost-effectiveness within the health system.

Our member organizations primarily operate on the state and regional levels, encompassing a wide range of capabilities and varying levels of connectivity to national networks and TEFCA. Civitas HIEs and APCDs directly manage data infrastructure, and in recent years have almost universally adopted HL7 FHIR with accompanying USCDI version 3 data elements as their baseline functionality ahead of ASTP/ONC's CERHT program and the wider federal regulatory framework. As such, they have become leaders in FHIR implementation and technical assistance within their service areas by leveraging the extensive participation of hospitals, outpatient clinics, long-term care facilities, public and private payers, diagnostic labs, pharmacies, public health authorities, community-based organizations, and other stakeholders across their networks. Many of these participating organizations and attached EHR platforms rely on HIEs and APCDs to convert older data formats to and from FHIR for transmission between different systems (including statewide disease registries), making the HIEs the *de facto* "endpoints" for use case-specific APIs like prior authorization.

HIEs' position at the center of the health data transmission matrix and the emerging FHIR-enabled health technology ecosystem thus makes them a key source of what FDA refers to in this Request as "real-time data"—one that remains largely underutilized by federal agencies. This is particularly true of the federal research enterprise, which has generally not collected HIE data for clinical studies in any regular or systematic way. Civitas HIEs have supplied de-identified clinical information for research to academic medical centers, state PHAs, and other non-federal entities supported in part by federal research dollars, while APCDs collect statewide claims data from

payers via HIEs for study by state authorities and CMS (studies which have led to policy innovation on balanced billing and value-based care on both the state and federal level). CDC's collection of surveillance data from hospitals, labs, and state registries for research and analytics adjacent to its public health reporting mission is also facilitated and in some cases directly enabled by HIEs. Yet research submissions to FDA from non-federal networks that the agency is now exploring have yet to materialize.

The obstacles to doing so are not insurmountable. Notably, six Civitas member HIEs in OK, RI, CA, NY, TX, and MI were partners in prototyping a new phase of the FDA Sentinel Initiative, involving real-time clinical data transfer at scale from state and regional networks to the agency's system for active nationwide surveillance of drug and medical device reactions. The prototype was successful, but the data involved was entirely synthetic—because the scattershot and fragmentary quality of real deidentified data typically handled by HIEs would have made much of it useless for Sentinel's purposes, and the Sentinel system does not run on FHIR. The same problems persists to an even greater degree for research applications, which require much more detailed clinical datasets and correspondingly more stringent individualized release protocols than exist for public health reporting.

Firmly establishing FHIR as the FDA's foundational exchange standard and incentivizing FHIR-based APIs for clinical research (using existing implementation guides like US Core, Vulcan Accelerator, and the Gravity Project) are essential first steps to remedy the problem, but they are not the only steps the agency can take. Given the absence of a research-based CEHRT criterion, FDA should work with ASTP/ONC to create one within the existing program or consider establishing its own testing and validation framework for the necessary components of clinical research activity under its jurisdiction A centerpiece of such a program would be additional data elements beyond those available through USCDI version 3, such that more granular medication administration data and pharmacovigilance metrics could be routinely captured in a standard format for the kind of post-market evaluations FDA conducts. The same data elements would be required if TEFCA's (currently limited) FHIR functionality was scaled up under the auspices of a separate "research" exchange purpose as floated in this Request, though working "down" from a still-emerging TEFCA, rather than "up" from CEHRT and HIEs risks cutting off large swathes of the ecosystem.

A TEFCA research XP, CEHRT research criterion, or a CEHRT-like FDA equivalent would likewise need to establish more explicit and robust de-identification requirements, patient consent protocols, and safeguards for transparency and privacy commensurate with the greater depth and complexity of information being shared. Lack of trust is as significant an obstacle to data collection as data quality and completeness—and potentially harder to fix. Civitas members' success in expanding network participation across their service areas and establishing deep stakeholder partnerships is as much a function of gaining and retaining the confidence of patients, providers, and policymakers through open dialogue, education, and consensus-building through open governance as any technical capability. The proliferation of state laws in recent years governing data disclosure on top of federal HIPAA obligations reflects the sensitivity of the subject, and necessitates that the FDA work in a deliberate way to align its RWD collection with consent-to-share processes both at the point of care and at in network-to-network exchange. The alternative route of attempting to circumvent privacy safeguards or dilute them through federal rulemaking or

legal battles, especially if done without working from national consensus positions on the purposes and parameters of data collection for research use, will only foster greater distrust and reluctance to participate in a system that requires maximal buy-in to function.

On behalf of Civitas and our members, thank you again for the chance to comment on this RFI and for considering our recommendations. The Civitas community is deeply engaged in multiple corners of the health data policy and regulation space, and we stand ready to collaborate to achieve our shared goal of creating a higher-value health system.

Please do not hesitate to reach out if you have any questions or comments for us.

Sincerely,

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