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Vulcan FHIR® Accelerator Connects CDISC, HL7, and ICH M11 in a Project to Digitize Exchange of Clinical Research Protocols

HL7 Vulcan and CDISC are announcing a project that will deliver an electronic exchange standard for the ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

Ann Arbor, MI. and Austin, TX — June 6, 2023 — A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vison. Vulcan is an HL7® FHIR Accelerator dedicated to connecting clinical and translational research to clinical care through Fast Healthcare Interoperability Resources (FHIR®). CDISC is a non-profit standards development organization that develops standards that support acquisition, exchange, submission, and archive of biopharmaceutical data. CDISC is also a member of Vulcan. ICH M11 is the topic of the International Council for Harmonization to create a Clinical electronic Structured Harmonised Protocol (CeSHarP).

"The project marks an important milestone in the long journey towards a digital protocol." said Vulcan Co-Chair, Amy Cramer. "Over the years, various organizations have contributed key building blocks. Vulcan is pleased to serve as a convener where contributors across the global research community can collaborate towards this shared and important goal."

"We are looking forward to partnering with ICH M11 and HL7 on this important project that aims to enable the digital transformation of protocols in support of automation," said David Evans, President and CEO, CDISC. "This project represents another step in CDISC's strategic evolution to embrace governance of clinical research information standards, not just clinical data standards."

FHIR-based exchange standard for ICH's Clinical electronic Structured Harmonised Protocol (CeSHarP), aligned to CDISC standards, will enable value across the clinical trials ecosystem. ICH M11 is developing a clinical protocol template, guideline, and technical specification, which will serve as the project's foundation.

CDISC's Unified Study Definition Model (USDM), co-developed with TransCelerate BioPharma, will be leveraged to accelerate development of the content model in addition to other inputs such as CDISC Controlled Terminology and Vulcan FHIR® Implementation Guides,

The project will be executed within the HL7 Vulcan Project Framework and supplemented by a Joint Leadership Forum to foster alignment among CDISC, ICH M11, and HL7 Vulcan. It is now in the discovery and scoping phase with full kick off anticipated this summer.

ABOUT CDISC

CDISC creates clarity in clinical research by convening a global community to develop and advance data standards of the highest quality. Required by the United States Food and Drug Administration (FDA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA), recommended by the China National Medical Products Administration (NMPA) and adopted by the world's leading research organizations, CDISC standards enable the accessibility, interoperability, and reusability of data. With the help of CDISC standards, the entire research community can maximize the value of data for more efficient and meaningful research that has invaluable impact on global health. CDISC is a 501(c)(3) global nonprofit charitable organization and is headquartered in Austin, Texas, with hundreds of employees, volunteers, and member organizations around the world. www.cdisc.org.

ABOUT HL7

Health Level Seven® International (HL7) is an ANSI-accredited, not-for-profit standards developing organization with the mission of empowering global health interoperability. With affiliates in over 30 countries, HL7's global membership envisions a world in which everyone can securely access and use the right data when and where they need it. Widely implemented by vendor and healthcare systems, and required by governing bodies around the world, HL7 standards deliver solutions for health information technology, including HL7® Fast Healthcare Interoperability Resources (FHIR®), Version 2 (V2) and Clinical Document Architecture (CDA®). For more information, visit HL7.org. www.HL7.org

ABOUT VULCAN

A HL7® FHIR® Accelerator, Vulcan's mission is to accelerate interoperability of health data to seamlessly integrate clinical and translational research with clinical care in order to reduce burden, enable learning health systems, and improve patients' lives. Vulcan is a diverse research community that creates FHIR® implementation guides for the exchange of health and research data, creating alignment at the development of standards through to implementation. HL7 Vulcan Accelerator is currently accepting new members. To learn more about participating in Vulcan, please contact vulcan@hl7.org or visit https://hl7vulcan.org/.