

For Immediate Release

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Health Level Seven and TransCelerate BioPharma Working Together to Facilitate Use of eSource for Clinical Research with HL7® FHIR®

Ann Arbor, Michigan – December 4, 2017 – Health Level Seven® (HL7®) International, the global authority on interoperability of health information technology with members in 55 countries, and TransCelerate BioPharma Inc., a non-profit organization to improve the health of people around the world by simplifying and accelerating the research and development of innovative new therapies, are working together to advance the use of eSource in clinical trials and facilitate interoperability by enabling the use of electronic health records (EHRs) in clinical research, enabled by the use of the HL7® FHIR® platform standard.

Although regulators have encouraged use of eSource for several years, sponsor adoption for clinical trials has been slow, largely due to challenges in integrating systems and accessing standardized data from research sites. TransCelerate's <u>eSource initiative</u> has been working to overcome these real and perceived challenges to influence more efficient data gathering practices to benefit patients, sites and sponsors.

"The widespread adoption and advanced capabilities of HL7 FHIR for making a consistent view of clinical data available through APIs offers an unprecedented opportunity to bridge the historical chasm between healthcare and research, and the HL7 and FHIR communities are delighted to be working with TransCelerate toward our common goals of interoperability," said Wayne Kubick, HL7 Chief Technology Officer. "We are delighted to work with TransCelerate to capitalize on FHIR to help meet the ambitious goals of the 21st Century Cures Act, and the desire of FDA leadership to reinvent clinical trials and bring real world evidence to improve the way we do research."

At HL7's recent Plenary Working Group Meeting in San Diego, dozens of participants from TransCelerate member companies, academia, investigative sites, and technology providers participated in the 16th FHIR
Connectathon exploring three different use cases interactively with implementers from the healthcare

community, demonstrating real progress in making use of eSource practically achievable with current systems using FHIR.

"The Connectathon was a tremendous event that explored multi-stakeholder perspectives on what may be possible to advance the use of eSource in clinical research. Collaboration is a most critical component and we very much look forward to continued partnership with HL7 to successfully enable greater use of eSource in a compliant, effective, global way," said Brett Wilson, Data Monitoring and Management TA Lead, Global Biometrics & Data Management, Pfizer, and TransCelerate eSource Initiative Co-Lead.

HL7, TransCelerate and the FHIR community are planning several additional upcoming events to continue to advance progress in the use of eSource, including HL7's Partners in Interoperability in New Orleans in December, and FHIR Connectations throughout 2017 and 2018.

About Health Level Seven International (HL7)

Founded in 1987, Health Level Seven International is the global authority for healthcare information interoperability and standards with affiliates established in more than 30 countries. HL7 is a non-profit, ANSI accredited standards development organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's members represent approximately 500 corporate members, which include more than 90 percent of the information systems vendors serving healthcare. HL7 collaborates with other standards developers and provider, payer, philanthropic and government agencies at the highest levels to ensure the development of comprehensive and reliable standards and successful interoperability efforts.

For more information, please visit: www.HL7.org

About TransCelerate BioPharma, Inc.

TransCelerate BioPharma Inc. is a non-profit organization dedicated to improving the health of people around the world by simplifying and accelerating the research and development (R&D) of innovative new therapies. The organizations' mission is to collaborate across the global biopharmaceutical R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines. TransCelerate evolved from conversations at various forums for executive R&D leadership to discuss current issues facing the industry, and examine solutions for addressing common challenges. The founding member companies are AbbVie, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly and Company, GlaxoSmithKline, Johnson & Johnson, Pfizer, the Roche Group, and Sanofi. Additional members that have joined since the inception of TransCelerate include Allergan, Inc., Amgen, Astellas Pharma Inc., EMD Serono, Inc. (a subsidiary of Merck KGaA,

Darmstadt, Germany), Merck & Co., Inc., Novartis International AG, Novo Nordisk, Shionogi & Co., Ltd. and UCB.

Membership in TransCelerate is open to pharmaceutical and biotechnology companies with Research & Development operations. Executive offices are located in Philadelphia, PA. For more information, please visit http://www.transceleratebiopharmainc.com.