

## Statement of Understanding (SOU)

This Statement of Understanding (“*SOU*”) is between:

Health Level Seven International  
3300 Washtenaw Avenue, Suite 227  
Ann Arbor, Michigan 48104-4261

Hereinafter identified as “*HL7*”

AND

TransCelerate Biopharma, Inc., a Delaware non-profit corporation, with offices located at 100 Four Falls Corporate Center, Suite 655, 1001 Conshohocken State Road, West Conshohocken, Pennsylvania 19428

Hereinafter identified as “*TransCelerate*”

This SOU shall have an effective date of: Sep 25, 2017, 2017

### Statement of Purpose

HL7 has as its mission the goal of providing reliable standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of healthcare services. HL7 encourages the creation of flexible, cost-effective approaches, standards, guidelines, methodologies, and related services for the interoperability of healthcare information systems. HL7 provides a forum for the effective and efficient communication between the constituents of the healthcare community as represented by its membership: an international community of healthcare organizations, vendors and developers of healthcare information systems, consultants and systems integrators, and related public and private healthcare service agencies.

TransCelerate, a non-profit organization, was formed in September 2012 by ten leading pharmaceutical companies with the aim to develop new innovative systems to accelerate the development of new medicines, initially by identifying ways to make the clinical trial process more efficient. The number of TransCelerate member companies (“*TransCelerate Member Companies*”) has grown since TransCelerate’s formation, and a current list of TransCelerate Member Companies can be found at the following link: <http://www.transceleratebiopharmainc.com/about/meet-the-members/>. All TransCelerate Member Companies participate actively in the TransCelerate board of directors.

Recognizing that complementary efforts are underway to create and extend comprehensive standards in the healthcare and clinical research communities, HL7 and TransCelerate are entering into a relationship to help advance the use of eSource in clinical trials and facilitate interoperability by enabling the use of electronic health records (EHRs) in clinical research.

This SOU defines the objectives regarding the relationship and potential collaborations between HL7 and TransCelerate. Among the potential collaborations between HL7 and TransCelerate is participation in “HL7 FHIR Connectathons” (“*Connectathons*”) which are gatherings of implementers interested in testing use cases to determine whether they can implement and successfully interoperate applications using some portion of the

HL7 FHIR specification. HL7's objective of the Connectathon is to give implementers experience working with the FHIR specification outside a production environment and to provide feedback that improves FHIR. A Connectathon is focused on an open consensus-based Interoperability (Connection) specification (*i.e.*, Implementation Guides).

## **1.0 Collaborations**

1.1 Joint meetings between TransCelerate and HL7 may be scheduled where such meetings serve a common purpose and are convenient to TransCelerate and HL7 meeting agenda.

1.2 The parties to this SOU shall each appoint a liaison for interactions between the parties for the purpose of discussing potential collaborations, including, without limitation, collaborating with respect to Connectathons, stakeholder roundtable(s), discussions on the use of HL7 Data Platform Standards applicable to clinical trial use (*e.g.*, policy discussion participation) and otherwise with respect to the EHR) community.

1.3 Such projects as might be jointly undertaken by HL7 and TransCelerate will be clearly defined and delineated by a joint project charter which should include a succinct description of the proposed project, an estimate of time required and resources expected to be committed by each party ("***Joint Project Charter***"), substantially in the form included as Attachment A (Form Joint Project Charter). Each Joint Project Charter shall be agreed upon by both parties. Any potential collaboration that has been approved by the parties pursuant to a Joint Project Charter is deemed an "***Approved Collaboration***."

## **2.0 Attendance**

2.1 Representatives of TransCelerate and the TransCelerate Member Companies are encouraged to attend the Connectathons and any other events relating to the Approved Collaborations. One TransCelerate representative (who will be designated in advance and who may be a TransCelerate Member Company employee serving in their capacity as a TransCelerate workstream team member) will be provided with complimentary access to the Connectathons.

## **3.0 No Financial Commitment**

3.1 For the avoidance of doubt, there shall be no financial commitment by TransCelerate to HL7 in entering into this SOU.

## **4.0 Obligations**

4.1 HL7 and TransCelerate expressly agree that:

- a. Except as stated in Section 5.2, rights to the HL7 trademarks or standards or the TransCelerate trademarks or standards are neither licensed, extended nor transferred to TransCelerate or HL7, respectively; and
- b. There shall be no exchange of mailing lists or general membership information.

## **5.0 Connectathon Works; Trademark License**

5.1 HL7 shall ensure that any works of authorship developed by HL7 or any Connectathon implementer in connection with the Clinical Research Track of each Connectathon (“*Connectathon Works*”), including, without limitation, specifications, documentation, materials, writings, drawings, photographs, reports, plans, compilations, databases, or software (including, without limitation, source code and object code), are made available to TransCelerate and the TransCelerate Member Companies and licensed (under the FHIR Release 3 (STU) License, currently located at <http://www.hl7.org/fhir/license.html>), which among other things, would permit TransCelerate and the TransCelerate Member Companies to freely use, copy, modify, distribute and perform the Connectathon Works, even for commercial purposes, all without asking permission from HL7 or any third party.

5.2 During the Term (as defined below), each party hereby grants to the other party a limited, non-exclusive, royalty-free, personal, non-transferable, non-assignable, revocable right and license to use its name and the logos provided in writing by such party from time to time (“*Permitted Marks*”) solely for purposes of promoting Approved Collaborations in a manner consistent with this SOU and as agreed upon in the applicable Joint Project Charter. Each party acknowledges that the other party is the sole owner of the other party’s Permitted Marks and of their associated goodwill, that the other party’s Permitted Marks are and will remain at all times the sole and exclusive property of such party, and that HL7 and TransCelerate, by reason of this SOU or otherwise, has not acquired any right, title, interest, or claim of ownership to the Permitted Marks of TransCelerate or HL7, respectively. HL7’s and TransCelerate’s use of the Permitted Marks of TransCelerate or HL7, respectively, and any and all goodwill arising from that use, will inure solely to the benefit of TransCelerate or HL7, respectively. The parties agree that a party’s use of the other party’s Permitted Marks must be of a high and uniform quality to establish and maintain the reputation and distinctive quality of such party’s Permitted Marks and the goodwill associated with them, and each party agrees not to use the other party’s Permitted Marks in connection with any services or goods that are defamatory, obscene, or that otherwise tarnish the other party’s Permitted Marks. Without limiting the generality of the foregoing, each party must comply with all standards with respect to the other party’s Permitted Marks furnished by such party from time to time, and all uses of the other party’s Permitted Marks in proximity to the trade name, trademark, service name or service mark of any other person or entity must be consistent with the standards furnished by the other party from time to time. If a party in good faith reasonably determines that the other party’s use of its Permitted Marks does not satisfy such standards, then such other party will promptly take corrective actions.

## **6.0 No Warranties**

6.1 HL7 and TransCelerate make no express or implied warranties.

## **7.0 Termination**

7.1 Either HL7 or TransCelerate may terminate this SOU upon 30 days written notice to the other party.

7.2 In the event of such termination all registrations for HL7 sponsored events recorded prior to the termination date shall be honored.

## **8.0 Term**

8.1 This SOU shall have a two-year term commencing on the Effective Date of this SOU (the “*Term*”), renewable upon expiry by written agreement of the parties for subsequent two-year terms.

## **9.0 Miscellaneous**

9.1 No public release or announcement concerning the relationship contemplated herein shall be issued by either party without the prior consent of the other party.

9.2 This SOU constitutes the entire agreement and complete understanding of the relationship between HL7 and TransCelerate.

9.3 This SOU may be amended or modified only by a writing executed by the parties.

9.4 Neither party may assign, delegate or otherwise transfer any of its rights or obligations under this SOU without the written consent of the other party, and any attempted assignment, delegation or other transfer without such written consent shall be null and void.

9.5 Nothing contained in this SOU shall be construed to make either HL7 or TransCelerate partners, joint venturers, fiduciaries, principals, agents or employees of the other. It is further understood and agreed that each of the parties has no right or authority, nor shall it hold itself out as having the right or authority, to assume, create or undertake any obligations of any kind whatsoever, express or implied, or make any representation, promise or agreement on behalf of the other party, except for such obligations, representations, promises, or agreements as such other party shall specifically, in writing, authorize the party to make.

Authorized Signatures:

**For** **For**  
**HEALTH LEVEL 7 INTERNATIONAL TRANSCCELERATE BIOPHARMA, INC.**

Signed: 

Charles Jaffe, MD PhD  
Chief Executive Officer

Signed:   
[Dalvir Gill \(Sep 25, 2017\)](#)

Dalvir Gill, PhD  
Chief Executive Officer

Signed: 

Mark McDougall  
Executive Director

**Attachment A**  
**Joint Project Charter**  
**[Insert Name of Project]**

This Joint Project Charter is agreed upon on \_\_\_\_\_, 2017 by TransCelerate and HL7 pursuant to the Statement of Understanding entered into between the parties on \_\_\_\_\_, 2017 (the “*SOU*”) and is governed by the terms and conditions of the *SOU*.

Description of the Project (the “*Project*”):

[Insert description of the Project]

Responsibilities:

[Include specifics regarding timing and resource commitments of the parties and any other relevant details]

Promotions for the Approved Collaborations:

The parties will have the right to use the Approved Marks solely for purposes of promoting the Project pursuant to Section 5.1 of the *SOU* as follows:

[Add any relevant detail regarding the promotions of the events and the ability to use each other’s marks.]