

MEMORANDUM OF UNDERSTANDING

AMONG

International Federation of Clinical Chemistry and Laboratory Medicine [IFCC] and the International Union of Pure and Applied Chemistry [IUPAC],

International Health Terminology Standards Development Organisation FMBA [IHTSDO] established under the laws of Denmark (CVR [30363434](#)),

The Regenstrief Institute, Inc. [RI]

REGARDING

**AN OPERATIONAL TRIAL OF A DIVISION OF LABOR
IN LABORATORY TEST TERMINOLOGY DEVELOPMENT**

INVOLVING

LOINC, NPU & SNOMED CT

Introduction

The IHTSDO includes some Member countries committed to using SNOMED CT in combination with LOINC, which is owned by RI and the LOINC Committee and maintained by RI; some Member countries committed to using SNOMED CT in combination with NPU terminology (NPU), which is owned by IFCC-IUPAC; and some Member countries who expect SNOMED CT to include the level of laboratory test terminology required to meet their needs.

The IHTSDO would like SNOMED CT to work effectively in combination with either LOINC or NPU in computer systems that support electronic patient records in a way that minimises patient risk and optimises effective communication, decision support, and secondary uses. Likewise the IFCC-IUPAC and RI would like their respective terminologies to work effectively in combination with SNOMED CT.

With these ends in mind, the IHTSDO, in cooperation with LOINC and NPU experts, developed an Observables Model, based upon the models of LOINC and NPU, to represent explicit relationships between SNOMED CT and both LOINC and NPU.

IHTSDO, IFCC-IUPAC, and the LOINC Committee would like to decrease duplication of effort in the development of laboratory test terminology. As an initial data gathering step, the three parties have agreed to conduct an operational trial (“Trial”) of prospective divisions of labor in the generation of laboratory test terminology content.

Purposes of the Trial

The principal purpose of this joint Trial is to test a division of labor in which:

- original laboratory test terminology content is created by either RI or IFCC-IUPAC, but not by the IHTSDO;
- SNOMED CT modelling of such content is done as a by-product of creating new content for LOINC or NPU; and
- SNOMED CT codes are used to represent appropriate parts of LOINC and NPU entities.

Secondary purposes are:

- to assess the robustness of the SNOMED CT Observables Model as a structure for representing LOINC and NPU laboratory test terminology content;

- to gain a clearer picture of the differences between LOINC and NPU as background for future discussions about the feasibility of a more unified effort between them that will further reduce duplication of effort; and
- to identify whether any of the laboratory test terminology requested is country-specific and therefore not suitable for inclusion in the international release of SNOMED CT.

Trial Period

From April 1, 2009 to the earlier of: October 1, 2009 - OR - until RI has processed 400 laboratory test content requests and IFCC-IUPAC has processed 200 laboratory test content requests.

Resources for the Trial

Each party will furnish the resources needed for their participation in the Trial.

Trial Description

1. To initiate this Trial, the IHTSDO, IFCC-IUPAC, and RI will use mutually agreed text to announce the Trial on their websites and via other appropriate means as a component of the cooperation discussions between the IHTSDO and IFCC-IUPAC and the IHTSDO and RI. The IHTSDO will encourage its Members to submit any backlogged requests for laboratory test terminology during the Trial period.
2. During the Trial period, requests for laboratory test terms will be submitted to RI, IFCC-IUPAC, or to the IHTSDO, at the requester's discretion, and using the normal channels and procedures of each organisation. Requests for laboratory test terminology received by the IHTSDO during the Trial period will be referred for processing on a 2:1 random basis, to RI or IFCC-IUPAC, respectively. The IHTSDO will inform the requester that the Trial is underway, indicate to whom the request has been referred for action, and say that RI or IFCC-IUPAC may contact the requester for additional information needed to understand the meaning of the request.

Those submitting requests for laboratory test terminology via the IHTSDO will be strongly encouraged to submit the items marked with an asterisk (*) below. They will be informed that RI and IFCC-IUPAC may request these and other items if needed to understand and accurately process the requests:

- (a) * the name of the country and contact information of the Member's representative including telephone, fax, and email address (if applicable).
- (b) * Contact information from the original submitter including telephone, fax, and email address.
- (c) * The purpose of the requested code, e.g. to diagnose Tay-Sachs disease, to determine a substance concentration in blood (plasma) glucose.

- (d) * The requestor's internal code for the result (if applicable).
 - (e) * The name of this examination/test/report as it would appear on the requester's report.
 - (f) * For measurements, the reporting units of results and reference range.
 - (g) * For observations with categorical answers, sample reports.
 - (h) If needed to understand the meaning and characteristics of the test, de-identified sample reports, spectrum of possible values, package inserts for test kits, etc.
 - (i) Order ID and order name (if available).
3. RI and IFCC-IUPAC will accept requests and information required to process them as email content and spreadsheets. RI and IFCC-IUPAC will accept and process requests for laboratory test terms that they receive from the IHTSDO, in addition to processing their normal flow of requests, in accordance with their regular procedures. If the meaning of a request is not clear, they will ask the original requester for clarification and/or additional information (possibly including de-identified test report samples, package inserts and/or literature references). In the case of requests referred from the IHTSDO, they will use jointly developed standard introductory language and will copy the IHTSDO and, if relevant, the IHTSDO Member on all messages going to the original requester.
- If, after dialogue with the original requester, RI or IFCC-IUPAC determines that it is inappropriate to create a code, the IHTSDO will be notified of this decision and the rationale for it.
4. In all cases, whether there is an existing code that meets the requester's need or a new one is created, RI and IFCC-IUPAC will translate the requested term into an instance of the SNOMED CT Observables Model, according to a draft style guide provided by the IHTSDO, and deliver this instance to the IHTSDO in a machine-readable table or other mutually agreed format. RI and IFCC-IUPAC will build the initial model using LOINC or NPU parts (as is currently done), and translate/map these parts into the corresponding SNOMED CT codes when they exist. When RI or IFCC-IUPAC does not find an existing SNOMED CT code for the part in question, their own part will be included in the model sent to the IHTSDO - as a placeholder. The IHTSDO will initiate the process to add this concept to SNOMED CT and, once created, send the new SNOMED CT code to the party that sent the placeholder. If RI or IFCC-IUPAC processes a laboratory test request that presents unusual modelling challenges, a best effort model will be sent with an accompanying comment about the issues involved.
5. The IHTSDO will perform quality review of the submissions from RI and IFCC-IUPAC. If the IHTSDO agrees with the modelling done by RI and IFCC-IUPAC, it will signal its agreement, assign SNOMED CT codes, and add the content to SNOMED CT.

6. If the IHTSDO reviewer disagrees with the modelling done, s/he will send recommended changes back to RI or IFCC-IUPAC, as the case may be. RI or IFCC-IUPAC will make the changes or iterate with the IHTSDO as necessary to reach agreement on how to handle the specific case. If no agreement is reached, the case will be referred for resolution by a three-party panel of designated RI, IFCC-IUPAC, and IHTSDO laboratory test terminology experts. The panel's decision will be final and will be reflected in a revision to the style guide.
7. If an existing LOINC or NPU code is responsive to a request submitted directly to RI or IFCC-IUPAC, the code will be returned to the requester immediately according to current procedures, but with a message including jointly developed standard language explaining that the content is also being modelled for SNOMED CT as part of the Trial. If an existing LOINC or NPU code is responsive to a request received via the IHTSDO, the existing content will not be sent to the requester until after the content has been modelled in SNOMED CT and a SNOMED CT code assigned. RI or IFCC-IUPAC will then send both their native terms and codes and the SNOMED CT code back to the requester, using jointly developed standard language.

Early termination of participation in the Trial

Either RI or IFCC-IUPAC may withdraw from the Trial at any time for any reason, upon written notice to the other parties. If either RI or IFCC-IUPAC withdraws from the Trial, for any reason, the Trial will continue between the remaining parties.

The IHTSDO may stop the Trial with a party (RI or IFCC-IUPAC) upon thirty (30) days written notice to that party.

Report and assessment of the Trial results

1. Each party will keep track of any resources, including estimated staff time, employed for the Trial that are above and beyond the resources required for their regular operations.
2. The IHTSDO will keep statistics on number of modelled concepts received from RI and from IFCC-IUPAC, the number accepted without change, the number changed by RI and IFCC-IUPAC in response to comments from IHTSDO, the number referred for decision to RI and IFCC-IUPAC -IHTSDO expert panel, and the number (if any) that are deemed inappropriate for inclusion in the international release of SNOMED CT.
3. Each party will identify what worked well in the Trial and what can be improved to make a more effective and efficient process.

Rights to content generated during the Trial

“LOINC Content” means any terminological content of LOINC, consisting of the more than 53,000 observations terms and codes and the Parts used to construct them.

“NPU Content” means any terminological content of NPU, consisting of a set of about 15,000 coded elements. Each of these elements is made of a series of information, ordered according to a definite syntax: System--Component; kind-of-property = ? unit. Each element also includes a definition with a reference source, spaces for specifications, indication of scale and speciality classification and management data.

“SNOMED CT Content” means terminological content of SNOMED CT, consisting of concepts, descriptions and Relationships (as defined in the IHTSDO Articles of Association), each of which is identified using a SNOMED CT Identifier (as defined in the IHTSDO Articles of Association).

“Trial LOINC Content” means any LOINC Content created, and any modifications to any existing LOINC Content made, under this Trial to process the specified laboratory term requests, including any such LOINC Content that incorporates, or is a derivative work of, any SNOMED CT Content.

“Trial NPU Content” means any NPU Content created, and any modifications to any existing NPU Content made, under this Trial, including any such NPU Content that incorporates, or is a derivative work of, any SNOMED CT Content.

“Trial SNOMED CT Content” means any SNOMED CT Content created, and any modifications to any existing SNOMED CT Content made, under this Trial, including any such SNOMED CT Content that incorporates, or is a derivative work of, any NPU or LOINC Content. This includes the SNOMED CT Observables Model and Style Guide.

Ownership

1.1.1. RI owns the Intellectual Property Rights in, and maintains, LOINC. RI will continue to retain ownership of all Trial LOINC Content.

1.1.2 IFCC-IUPAC jointly own the Intellectual Property Rights in, and jointly maintain, NPU. IFCC-IUPAC will continue to retain ownership of all Trial NPU Content.

1.1.3 IHTSDO owns the Intellectual Property Rights in, and maintains, SNOMED CT. IHTSDO will continue to retain ownership of all Trial SNOMED CT Content.

1.1.4. To the extent that any party acquires any right, title or interest in any Intellectual Property Rights in the course of this Trial that is inconsistent with paragraphs 1.1.1 to 1.1.3 above, that party assigns all such right, title and interest to the party in who, in accordance with paragraphs 1.1.1 to 1.1.3, that right, title and interest should vest.

Licenses

1.1.5 To the extent that using, loading, executing, storing, transmitting, displaying copying, modifying, amending, decompiling, creating derivative works of, distributing, or publishing Trial LOINC Content or Trial SNOMED CT Content would otherwise infringe any right, title, or interest of the IHTSDO or RI, respectively, in any intellectual property rights, that

party grants the other a perpetual, irrevocable, transferable, sub-licensable, worldwide, royalty-free license to perform those acts.

1.1.6. To the extent that using, loading, executing, storing, transmitting, displaying copying, modifying, amending, decompiling, creating derivative works of, distributing, or publishing Trial NPU Content or Trial SNOMED CT Content would otherwise infringe any right, title, or interest of the IFCC-IUPAC or the IHTSDO, respectively, in any intellectual property rights, that party grants the other a perpetual, irrevocable, transferable, sub-licensable, worldwide, royalty-free license to perform those acts.

This Agreement may be signed in counterparts.

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Signatures:

For: **International Health Terminology Standards Development Organisation**

/s/

Martin Severs Date
Chair, Management Board

/s/

Jennifer Zelmer Date
Chief, Executive Officer

For: **International Federation of Clinical Chemistry and Laboratory Medicine**

/s/

Graham Beastall IFCC President Date

For: **International Union of Pure and Applied Chemistry**

/s/

Françoise Pontet C-SC-NPU Chair Date

For: **Regenstrief Institute**

/s/

Mary Gray Date
Director of Administration

/s/

Daniel Vreeman Date
Associate Director of Terminology Services