

SNOMED CT® SUB-LIZENZBEDINGUNGEN

Wichtiger Hinweis – Bitte die nachfolgenden Lizenzbedingungen sorgfältig lesen

Im nachfolgenden sind die Sub-Lizenzvereinbarungen (1) des TMF- Technologie- und Methodenplattform für die vernetzte medizinische Forschung e. V., Charlottenstr. 42, 10117 Berlin, in seiner Funktion als „National Release Center“ für SNOMED CT in Deutschland (siehe unten), (im Folgenden der „Sub-Lizenzgeber“) - und (2) der Organisation, die das Internationale Release von SNOMED CT zugeteilt oder auf andere Weise, im Rahmen einer Mitgliedschaft oder Kooperationspartnerschaft innerhalb der Medizinischen Informatik Initiative Deutschland, zugänglich gemacht wird (im Folgenden der „Sub-Lizenznehmer“) dargestellt.

Der Sub-Lizenzgeber wurde vom Bundesministerium für Bildung und Forschung (im Folgenden: BMBF) mit der Einrichtung und dem Betrieb des Koordinierungsbüros der Initiative für Medizinische Informatik (im Folgenden: MII) beauftragt. Die MII ist eine vom BMBF finanzierte gemeinsame Initiative, bei der alle universitären Einrichtungen in Deutschland an über 30 Standorten mit Forschungseinrichtungen, Unternehmen, Krankenkassen und Patientenvertretern zusammenarbeiten, um den Austausch und die Nutzung von Daten aus der klinischen Patientenversorgung und biomedizinische Forschung über die Grenzen von Institutionen und Standorten hinweg zu ermöglichen. Im Rahmen des Projekts entwickelt die MII zusammen mit den teilnehmenden Organisationen und Partnern institutionenübergreifende Definitionen von Datensatzstrukturen und deren syntaktische Implementierung.

Die Bundesrepublik Deutschland, vertreten durch das BMBF, hat für die erste Pilotphase im Rahmen der MII eine Lizenzvereinbarung mit der International Health Terminology Standards Development Organisation, firmierend als SNOMED International (im Folgenden: Lizenzgeber) für die internationale Version von SNOMED CT geschlossen. Im Auftrag des BMBF wird der TMF e.V. als Sub-Lizenzgeber das „National Release Center for SNOMED CT“ betreiben und ist daher berechtigt, den Teilnehmern oder Partnern des MII Sub-Lizenzen für die internationale Version von SNOMED CT zu erteilen und die Erprobung von SNOMED CT in enger Zusammenarbeit mit der MII zu koordinieren.

Die Nutzung einer entsprechenden Sub-Lizenz erfolgt daher unter der Bedingung, dass Umfang und Vorgehen der Implementierung von SNOMED CT in den beteiligten Einrichtungen in geeigneter Weise dokumentiert werden. Diese Dokumentation sowie ggf. weitere Auskünfte müssen dem BMBF oder den damit beauftragten Institutionen sowie dem National Release Center zeitnah für eine Begleitforschung zur Verfügung gestellt werden. Weitere Einzelheiten zu den zu erfolgenden Dokumentationen stellt der Sub-Lizenzgeber zur Verfügung.

Durch das Herunterladen, Zugreifen auf oder Verwenden eines Teils der internationalen Version von SNOMED CT oder das Ausüben von Rechten, die im Rahmen dieser Sub-Lizenzvereinbarung gewährt werden, erklärt sich der Sub-Lizenznehmer zudem mit den weiteren nachfolgenden Bestimmungen dieser Sub-Lizenzvereinbarung einverstanden.

SNOMED CT® SUB-LICENSE AGREEMENT

IMPORTANT NOTICE – PLEASE READ THE FOLLOWING CAREFULLY

This is a Sub-license Agreement between (1) TMF- Technologie- und Methodenplattform für die vernetzte medizinische Forschung e. V., Charlottenstr. 42, 10117 Berlin, acting as National Release Center for SNOMED CT in Germany (see below), (hereinafter called the “Sub-Licensors”) and (2) the organization to which the International Release of SNOMED CT is distributed or otherwise made available as a participant or a cooperation partner of the Medical Informatics Initiative Germany (hereinafter called the “Sub-Licensee”).

The Sub- Licensors was commissioned by the Federal Ministry of Education and Research (hereinafter called: BMBF) to set up and operate the Coordination Office of the Medical Informatics Initiative (hereinafter called: MII). The MII is a joint initiative funded by the BMBF, in which all university medical institutions in Germany at over 30 locations work together with research institutions, companies, health insurance companies and patient representatives to enable the exchange and use of data from patient care, clinical and biomedical research across the borders of institutions and locations. Within the framework of the project, the MII is developing, together with the participating organisations and partners, cross-institutional definitions of data set structures and their syntactic implementation.

The Federal Republic of Germany, represented by the BMBF, has been granted a license of the International Release of SNOMED CT under a License Agreement with the International Health Terminology Standards Development Organisation, trading as SNOMED International (hereinafter called: Licensors), for an initial pilot-phase in the course of the MII.

On the behalf of the BMBF the TMF e.V. will operate the “National Release Center for SNOMED CT” as the Sub-Licensors and as such is entitled to grant sub- licenses for the International Release of SNOMED CT to the participants or partners of the MII as SNOMED CT shall be tested in close cooperation with the MII.

The use of a corresponding sub-license therefore requires that the scope and procedure for implementing SNOMED-CT are documented in a suitable manner in the participating institutions. This documentation as well as any further information must be made available to the BMBF or the institutions responsible for it and to the National Release Center promptly for accompanying research. The Sub-Licensors provides further details on the documentation to be carried out.

By downloading, accessing or using any part of the International Release of SNOMED CT, or exercising any rights granted under this Sub-License Agreement, the Sub-Licensee also agrees to be bound by the following terms of this Sub-License Agreement.

SUB-LICENSE AGREEMENT

1. Defined Terms

In this License Agreement, terms defined in **Appendix A (Defined Terms)** have the meanings set out in that Appendix.

2. Grant of Sub-License

The Sub-Licensors grants the Sub-Licensee, subject to the terms of this License Agreement, a territorially limited, non-exclusive, non-transferable license for the term of this License Agreement to:

- 2.1. use, and permit the Sub-Licensee's officers, employees, agents and contractors to use, the International Release;
- 2.2. create, use and modify Extensions and Derivatives from the International Release;
- 2.3. modify the manner of formatting of the copy of the SNOMED CT Core distributed to the Licensee as part of the International Release or as part of the Sub-Licensee's National Release, and
- 2.4. incorporate the Sub-Licensee's National Release (including the International Release) into Licensee Products, and distribute Licensee Products;

within the License Territory.

3. Rights and obligations

Unless otherwise specified the following general rights and obligations shall apply between the parties:

- 3.1. The Sub-Licensee may only use the International Release and must ensure that their respective officers, employees, agents and contractors only use the International Release:
 - for their respective internal business purposes (including the creation by the Licensee of Extensions, Derivatives and other Licensee Products along with the licensing and distribution by the Licensee of the Licensee Products);
 - in the development and operation of their respective information systems;
 - for their respective research purposes; and/or
 - in their respective systems (including browsers and data analysis systems) made available to the general public for accessing and/or retrieving any part of the International Release and/or data encoded using the foregoing, provided that
 - users of those systems are not able to extract any substantial portion of SNOMED CT; and
 - no fee is charged for access to those systems except where access is incidental to the provision of training or consulting

services.

- 3.2. The Sub-Licensee is only permitted under this License Agreement to create Extensions from the International Release and to create Derivatives from the International Release and from those Extensions
- 3.3. The Sub-Licensee is not permitted to translate any part of the International Release into any other human language without the prior written consent of the Sub-Licensors and the Licensor.
- 3.4. The Sub-Licensee is not allowed to grant sub- licences or transfer any of its rights.
- 3.5. The sub-license terminates automatically upon expiry or termination of the License Agreement between Germany and the Licensor.
- 3.6. The Sub-Licensee may apply directly to the Licensor upon receiving notice that the sub-license will terminate in accordance with **clause 3.5.**, and that the Licensor may in such circumstances (but shall not be obliged to):
 - grant the Sub-Licensee a license in respect of the International Release for a limited period in order to enable the End User to continue to use the Licensee Products that are subject to the sub-license during that period; or
 - give the Sub-Licensee an assurance or undertaking that for a limited period the Licensor will not seek to prevent the Sub-Licensee from using the Licensee Products.
- 3.7. The right of the Sub-Licensee to use SNOMED CT shall be limited in a reasonable manner to the specific purposes of the specific project to be carried out by the Sub-Licensee.
- 3.8. The Sub-Licensee shall provide the Sub-Licensors with the names, titles, contact details (including email addresses and telephone numbers) of those representatives and officers of the respective Sub-Licensee, who are in charge of the conclusion of this agreement.
- 3.9. The Sub-Licensee shall, at least once in each contractual year, submit a report to the Sub-Licensors in such manner and form as the Sub-Licensors may prescribe from time to time, setting out the Sub-Licensee's activities since the end of the period covered by the previous report submitted under this **clause 3.9.** (or, in the case of the first statement of account under this **clause 3.9.**, since the date on which this License Agreement became effective).
- 3.10. If the Sub-Licensee becomes aware of any material error or change or correction needed in the International Release, the Sub-Licensee agrees to advise the Sub-Licensors promptly of such error, change or correction by following the Licensor's procedures for change notification that the Licensor prescribes by Regulations and notifies to the Sub-Licensors and Sub-Licensee from time to time.
- 3.11. The Sub-Licensee shall comply with the Internet security measures that the

Licensors prescribe by Regulations and notify the Sub-Licensors and Sub-Licensees from time to time.

4. Extensions and Derivatives

- 4.1. The Sub-Licensee may not create any Standards-Based Extension or any Standards-Based Derivative unless it has first been issued with a Namespace Identifier by or on behalf of the Licensor.
- 4.2. The Sub-Licensee may request that the Licensor issue it with a Namespace Identifier, and the Licensor shall not unreasonably refuse to do so taking into account amongst other things quality assurance, governance processes, Standards and Regulations.
- 4.3. The Sub-Licensee shall ensure that all Standards-Based Extensions and Standards-Based Derivatives that the Licensee creates under this License Agreement are created in accordance with, and comply with, all applicable Standards (including, without limitation, as to the use of Namespace Identifiers). A list of Applicable Standards as of Effective Date is included as **Appendix B** of the license agreement.
- 4.4. Subject to **clauses 4.5 and 4.6**, the Sub-Licensee shall own all Intellectual Property Rights in all Extensions and Derivatives that the Sub-Licensee creates under this License Agreement. The Sub-Licensee may not assign or otherwise transfer those Intellectual Property Rights to any other person or legal entity.
- 4.5. The Sub-Licensee shall, if requested by the Sub-Licensors, transfer to the person or legal entity nominated by the Sub-Licensors (including the Licensor) all of its Intellectual Property Rights in such Standards-Based Extensions (or parts thereof) as the Sub-Licensors may specify.
- 4.6. The Sub-Licensee shall, if requested by the Sub-Licensors and agreed by the Sub-Licensee in the Sub-Licensee's sole discretion, transfer to the Sub-Licensors or to the person or legal entity nominated by the Licensor (including the Licensor) all of its Intellectual Property Rights in such Standards-Based Derivatives (or parts thereof) as the Sub-Licensors may specify.
- 4.7. Upon the transfer to the Sub-Licensors of the Intellectual Property Rights in any Standards-Based Extension (or part thereof) or Standards-Based Derivative in accordance with **clauses 4.5 or 4.6**:
 - responsibility for the maintenance and distribution of that Extension (or part thereof) or Derivative shall transfer from the Sub-Licensee to the Sub-Licensors; and
 - accordingly, in the case of a Third Party Extension, that SNOMED CT Content shall cease to be a Third Party Extension and shall become part of the Sub-Licensors' National Extensions (if transferred to the Sub-Licensors) or the SNOMED CT Core (if transferred to the Licensor).

5. Modifications of the International Release

- 5.1. Subject to **clause 2.3.**, the Sub-Licensee may not modify any part of the SNOMED CT Core distributed as part of the International Release or as part of the Sub-Licensee's National Release.
- 5.2. Subject to any express and specific statement to the contrary in the documentation distributed as part of the International Release, the Sub-Licensee may not modify any of the documentation (including Specifications) or software (unless provided in source code form) distributed as part of or in connection with the International Release (including the Member Licensing and Distribution Service Software).
- 5.3. The Sub-Licensee may, by written notice, request the Sub-Licensors to modify the SNOMED CT Core. Upon receipt of such written notice, the Sub-Licensors and the Licensor shall consult with the Sub-Licensee and shall give due consideration as to whether the proposed modification should be made based on the Licensor's editorial guidelines and policies. Following due consideration of the matter, including consideration of any information presented by the Sub-Licensee, the Sub-Licensors shall inform the Sub-Licensee whether the proposed modification shall be made and if the Sub-Licensors and the Licensor agree that the proposed modification should be made, the Sub-Licensors shall give a non-binding indication of when, reasonably and in good faith, it anticipates that the proposed modification will be made. If the Sub-Licensee would like the content of the proposed modification to be developed more quickly than the Sub-Licensors and Licensor have indicated, the Sub-Licensee may itself undertake or procure the undertaking of the development of the content of the proposed modification (outside of any existing Licensor's support services contract). On receipt of the developed content of the proposed modification, the Licensor together with the Sub-Licensors will then give due consideration as to whether the developed content meets the Licensor's quality assurance, other governance processes, Standards and Regulations. If the developed content meets the Licensor's quality assurance, other governance processes, Standards and Regulations then the Licensor shall incorporate the modification into the SNOMED CT Core according to its schedule which will give due consideration as to when the proposed modification shall be incorporated into the SNOMED CT Core, taking into account other proposals for the modification of the SNOMED CT Core and the work required to include the proposed modification in the SNOMED CT Core.

6. Term and Termination

- 6.1. This License Agreement shall commence on the Effective Date and shall have a term of three years. It will terminate automatically upon expiry or termination of the License Agreement between Germany and SNOMED International or if the Sub-Licensors are no longer operating the "National Release Center for SNOMED CT".
- 6.2. Either Party may terminate this License Agreement with immediate effect for a reason lying outside the sphere of responsibilities of the Party desirous to terminate and making it appear unreasonable to expect such Party to

continue the contractual relationship (German: *fristlose Kündigung aus wichtigem Grund*). This is, in particular, the case if

- the other Party commits a material breach of any of its obligations under this License Agreement and does not cure this breach within four weeks after receipt of a second reminder that was sent no earlier than one week after the sending of the first reminder,
- a third party
 - files a complaint against the Sub-Licensor or the Sub-Licensee based on an allegation and reasonable substantiation of an infringement of intellectual property rights, which infringement allegedly follows from a use of SNOMED CT in the License Territory; or
 - threatens to file a complaint against the Sub-Licensor or the Sub-Licensee based on an allegation and reasonable substantiation of an infringement of intellectual property rights, which infringement allegedly follows from a use of SNOMED CT in the License Territory.

6.3. **Clauses 7 and clauses 11 to 15** inclusive shall survive expiry or termination of this License Agreement.

7. Consequences of Termination

- 7.1. Upon expiry or termination of this License Agreement, all sub-licenses granted under this License Agreement shall automatically and immediately be terminated.
- 7.2. In case of termination of this License Agreement under clause 6.1 the Sub-Licensor shall:
- following either Party giving a Termination Notice for any reason, or
 - by no later than ninety (90) days in advance of the expiry or termination of this License Agreement, whatever comes earlier, give written notice of such expiry or termination to the Sub-Licensee.
- 7.3. The Sub-Licensor and the Licensor shall be entitled to publicize the expiry or termination of this License Agreement to such persons and legal entities (including Members, other Affiliates of the Licensor and End Users) and in such manner as it sees fit.
- 7.4. The Sub-Licensee shall, by no later than thirty (30) days after expiry or termination of this License Agreement for any reason, submit a report in accordance with **clause 3.11**. in respect of all periods that have not previously been covered by a report under that clause.
- 7.5. The Sub-Licensee shall, by no later than forty-five (45) days after expiry or termination of this License Agreement for any reason,
- remove all copies of the International Release and the Sub-Licensee's National Release from its computer systems and destroy all copies of

electronic, paper copy and other media containing or representing any part of the International Release or the Licensee's National Release;

- ensure that all the Sub-Licensee's officers, employees, agents and contractors remove all copies of the International Release and of the Sub-Licensee's National Release from their respective computer systems and destroy all copies of electronic, paper copy and other media containing or representing any part of the International Release or the Sub-Licensee's National Release; and
- if requested by the Sub-Licensors, certify in writing to the Sub-Licensors that the Licensee has complied with its obligations under this **clause 7.5**.

7.6. Notwithstanding the provisions in **clause 7.5**, the Sub-Licensee, its officers, employees, agents and contractors shall continue to have the right to maintain, use, edit and modify, after expiry or termination of this License Agreement, any diagnostic and therapy documentation and data obtained and stored in compliance with this License Agreement, before expiry or termination of this License Agreement, in a manner and to the extent that the maintenance, use, editing or modification of such diagnostic and therapy documentation and data does not require any use of SNOMED CT, after expiry or termination of this License Agreement.

7.7. Any expiry or termination of this License Agreement, for any reason, is without prejudice to the accrued liabilities of each Party as at the date of expiry or termination.

8. New Versions

8.1. The Sub-Licensors shall notify the Sub-Licensee when a new version of the International Release is made available and there shall be a mechanism for the Sub-Licensee to access or obtain copies of the new version of the International Release. The Sub-Licensee shall be liable for any reasonable distribution charge, if applicable, established by the Sub-Licensors for each copy of the new version of the International Release.

8.2. Within one-hundred and eighty (180) days after the Sub-Licensors has notified the Sub-Licensee of the release of a new version of the International Release, the Sub-Licensee must upgrade the version of the International Release in its own systems and in the Licensee Products to that new version (or alternatively, if a subsequent version of the International Release is or has been released during the 180-day period, to that subsequent version at the Sub-Licensee's option).

9. License Fees

The grant of this Sub- License is free of charge.

10. Protection of Licensors' Intellectual Property

10.1. Nothing in this License Agreement transfers to the Licensee any right, title or interest in or to the Intellectual Property Rights in the International Release or any part of it, or grants the Sub-Licensee any (sub-) license in respect of

the International Release or any part of it except as expressly set out in **clause 3**.

10.2. The Sub-Licensee shall not:

- use any trademark or service mark (or any registrations thereof) other than the Licensor's trademarks, in any name that includes the word "SNOMED" or that is confusingly similar to "SNOMED CT" or any other similar trademark;
- apply for any trade mark or service mark (or any registrations thereof) in any name that includes the word "SNOMED", or that is confusingly similar to "SNOMED", "SNOMED CT" or any other similar trade mark;
- abbreviate the marks "SNOMED" or "SNOMED CT"; or
- do anything with respect to the foregoing trademarks that damages or could reasonably be deemed to reflect adversely on the Licensor or such trademarks.

10.3. The Sub-Licensee shall:

- include the following notice on all media on which the Sub-Licensee Products are distributed:

"This material includes SNOMED Clinical Terms® (SNOMED CT®) which is used by permission of SNOMED International. All rights reserved. SNOMED CT®, was originally created by The College of American Pathologists. "SNOMED" and "SNOMED CT" are registered trademarks of SNOMED International"; and

- specify in all media on which any Sub-Licensee Product is distributed the version and date of the International Release contained in the Sub-Licensee Product.

10.4. The Sub-Licensee shall be entitled to use the "SNOMED" and "SNOMED CT" trademarks only on the Sub-Licensee Products distributed and modified in accordance with this License Agreement and any services relating thereto but not otherwise and subject to the trade mark utilization Regulation developed by the Licensor and published by the Licensor from time to time. A current version of the trademark utilization Regulation current as of the Effective Date will be included in **Appendix C**. All use by the Sub-Licensee of the "SNOMED" and "SNOMED CT" trademarks, and all goodwill resulting from that use, shall inure to the Licensor's benefit.

10.5. The Sub-Licensee shall maintain quality standards with respect to modifying, supplementing, marketing and distributing the Sub-Licensee Products, and any services relating thereto, that are in accordance with applicable law and are at least as stringent as the Regulations developed by the Licensor and published by the Licensor from time to time. A description of these quality standards will be provided as **Appendix D**.

10.6. Upon reasonable written notice from the Sub-Licensor , the Sub-Licensee shall provide the Sub-Licensor with representative samples of materials,

software products, advertising, agreements for use of the Licensee Products (other than the terms of those agreements that are unrelated to the Licensor's rights and obligations under this License Agreement) and/or other written materials relating to the Sub-Licensee's use of the International Release and the Licensor's trademarks to enable the Sub-Licensor reasonably to ascertain the Sub-Licensee's compliance with its obligations under this License Agreement. In the absence of circumstances giving the Sub-Licensor reasonable grounds to suspect a breach of this License Agreement, the Sub-Licensor may not give notice under this **clause 10.6** more frequently than once per year.

- 10.7. If any use of the International Release (including without limitation use through a Sub-Licensee Product) is reasonably determined by the Sub-Licensor to be below the standards of quality required under this License Agreement, the Sub-Licensor shall notify the Sub-Licensee of such deficiency in writing. Upon receipt of such notice, the Sub-Licensee shall take all necessary steps to correct such deficiency (including such steps as the Sub-Licensor may reasonably specify).

11. Representations and warranties

- 11.1. To the extent permitted by law, the Sub-Licensor excludes all representations, warranties and conditions that would otherwise be implied by law in this License Agreement (including, without limitation, all implied warranties of quality or fitness for a particular purpose).
- 11.2. Without limiting **clause 11.1**, the Sub-Licensor does not represent or warrant that the International Release or any part of it will satisfy any of the Sub-Licensee's requirements, operate in combinations selected by the Sub-Licensee or be free from defects or errors.

12. Limitation of Liability

- 12.1. The Sub-Licensor shall not be liable to the Sub-Licensee or to any other person or legal entity, whether in contract, tort (including negligence), misrepresentation, breach of statutory duty or otherwise, for any of the following arising under or in connection with this License Agreement (including, without limitation, in respect of the Sub-Licensee's use of or inability to use the International Release or any part of it):
- indirect or consequential loss;
 - special or punitive damages;
 - loss of profits, loss of savings and loss of revenue;
 - loss of business, loss of reputation and loss of goodwill; and
 - loss of data.
- 12.2. Neither the Sub-Licensor nor the Licensor or any Member shall be liable to the Sub-Licensee or any other person or legal entity for any failure by the Sub-Licensor, Licensor or the Member (as the case may be) to maintain or distribute any Extension (or part thereof) or Derivative transferred to the

Sub-Licensors, the Licensor or the Member (as the case may be) in accordance with **clauses 4.5 or 4.6**.

- 12.3. Nothing in this License Agreement excludes or limits the liability of either Party for:
- intent;
 - fraud (including fraudulent misrepresentation);
 - death or personal injury caused by the negligence of that Party;
 - any other liability that by law cannot validly be excluded or limited (but only to the extent that the liability cannot validly be excluded or limited).

13. Confidentiality

- 13.1. Each Party shall keep strictly confidential and shall not publish or otherwise divulge or use for any purpose other than as contemplated by this License Agreement,
- any confidential information received from the other Party to this License Agreement, and
 - any of its own confidential information that is disclosed to the other Party pursuant to this License Agreement, all of which information shall be regarded as confidential, except such which:
 - can be shown to have been known to the receiving Party prior to disclosure by the providing Party, or
 - is now, or comes into, the public domain by publication or otherwise without the fault of the Party seeking exemption from this **clause 13.1**, or
 - is made known to the receiving Party from another source under no obligation to the providing Party, or
 - is required by law, regulation or judicial order to be disclosed.
- 13.2. Notwithstanding the foregoing, either Party may disclose confidential information to governmental agencies to the extent that this is required by law, or to outside consultants provided the relevant persons are subject to a secrecy agreement which mirrors the secrecy agreement of this **clause 13**.
- 13.3. Each of the Parties to this License Agreement shall be responsible for the imposition of the confidentiality provisions provided for in this **clause 13** upon its own officers, employees, agents, contractors and consultants, Sub-Licensees and others prior to disclosing any confidential information.
- 13.4. All information on the License Fees is confidential for both Parties.
- 13.5. Notwithstanding the foregoing the Sub-Licensors is expressly permitted to:
- disclose the terms of this License Agreement to the Licensor; and

- provide the names, titles and all relevant contact details of the representatives and officers of the Sub-Licensee (including email addresses and telephone numbers) to the Licensor.

14. Media relations

- 14.1. Once the Parties have executed this License Agreement, both will simultaneously publish a statement to the media, in mutual agreement.
- 14.2. The regulations on media relations agreed in clause 14 are limited to the subject of this contract and thus to the use of the SNOMED CT license.
- 14.3. For media relations concerning one Party individually, such Party is responsible solely. Sub-Licensee will refer any media enquiries regarding Sub-Licensor individually to Sub-Licensor and vice versa.

15. Communications

Communications to the Sub-Licensor shall be made to TMF e. V. Charlottenstr. 42, 10117 Berlin, Email: snomed-ct@tmf-ev.de

16. Assignment

- 16.1. Neither Party may assign, novate or otherwise transfer any of its rights or obligations under this License Agreement to any person or legal entity without the prior written consent of the other Party, such consent not to be unreasonably withheld.
- 16.2. The Sub-Licensor may transfer all of its rights and obligations under this License Agreement to any person or legal entity to whom the Sub-Licensor transfers the Intellectual Property Rights in respect of which the licenses under this License Agreement are granted.

17. General Provisions

- 17.1. This License Agreement contains the entire agreement between the Parties relating to the subject matter of this License Agreement, supersedes all previous agreements between the Parties relating to that subject matter and sets out the entirety of the Sub-Licensee's rights in respect of the International Release.
- 17.2. No oral ancillary agreements to this License Agreement have been made. All and any amendments and supplements to this License Agreement and all other declarations of either Party relating to the contractual relationship shall be made in writing and sent to the address last communicated to such Party. The above written form requirement shall extend to apply to an agreement abrogating such written form requirement.
- 17.3. The invalidity or impracticability of any provisions of this License Agreement shall not affect the validity either of the remaining provisions or of the Agreement as a whole. Such invalid or impracticable provision shall be deemed to have been replaced with retroactive effect by another, legally valid and practicable provision that as closely as possible attains the commercial goal pursued with such invalid or impracticable provision. The above shall apply mutatis mutandis in the event of an inadvertent omission in

this License Agreement concerning an issue that requires to be provided for.

- 17.4. Each Party acknowledges that, in entering into this License Agreement, it has not relied on any representation, warranty, collateral contract or other assurance made by or on behalf of the other Party before the date of this License Agreement.
- 17.5. Nothing in this License Agreement shall give either Party the ability to act or incur obligations or liability on behalf of the other Party or constitutes a joint venture, agency, partnership or employment relationship between the Parties.
- 17.6. This License Agreement shall be governed by, and construed in accordance with, the substantive laws of Germany.
- 17.7. The Regional Court of Berlin (German: *Landgericht Berlin*) shall have exclusive jurisdiction for any dispute arising out of or in connection with this License Agreement (including a dispute regarding its existence, validity or termination).

Appendix A

Defined Terms

In this License Agreement, the following defined terms have the following meanings:

Affiliate	an affiliate of the Licensor in accordance with the Licensor's Articles of Association;
Contractual Year	each period of 12 months commencing on the Effective Date of this License Agreement or an anniversary of that date;
Core (or SNOMED CT Core)	SNOMED CT Content that is controlled, maintained and distributed by the Licensor from time to time;
Cross-Map	a work consisting of (i) SNOMED CT Content and (ii) content of another nomenclature, classification or knowledge structure, together with a set of relationships between (i) and (ii) ;
Derivative	a work consisting of (a) SNOMED CT Content, from the Core or an Extension together with (b) either (i) additional properties and/or information about such SNOMED CT content and/or (ii) any set of relationships between that SNOMED CT Content and content of other nomenclature, classification or knowledge structure, and includes a Cross-Map and a Sub-Set;
Effective Date	23.03.2020
Extension	a work consisting of SNOMED CT Content

alone that is supplementary to other SNOMED CT Content and that depends on that other SNOMED CT Content, and includes a translation of any SNOMED CT Content into any language other than the original language of its development;

Intellectual Property Rights

patents, trademarks, service marks, copyright (including rights in computer software), moral rights, database rights, rights in designs, trade secrets, know-how and other intellectual property rights, in each case whether registered or unregistered and including applications for registration, and all rights or forms of protection having equivalent or similar effect in any jurisdiction;

International Release

the release produced and distributed by or on behalf of the Licensor, consisting of the SNOMED CT Core, the Specifications and the Licensor's Derivatives and other documents and software;

License Territory

The territory of the Federal Republic of Germany;

Licensee's National Extension

an Extension that is controlled and maintained by the Licensee under this License Agreement and is SNOMED CT Content supplementary to the Core;

Licensee's National Release

the release produced and distributed by the Licensee, consisting of the International Release, the Licensee's National Extensions, the Licensee's Derivatives and other documents and software;

Licensee Products

products distributed or licensed by the Licensee that (i) include or interoperate with the International Release (or any part

of it) and/or any Extensions or Derivatives created by the Licensee under this License Agreement, or (ii) read or write records or other data that is encoded using SNOMED CT;

Member

a member of the Licensor;

Member Licensing and Distribution Service Software

software solution for the use and licensing of SNOMED CT by Members;

Member Territory

a territory that is represented by a Member (as published by the Licensor from time to time);

MI-I

German network Medizininformatik-Initiative, c/o Geschäftsstelle TMF e.V., Charlottenstraße 42, 10117 Berlin, Germany;

MI-I Legal Entity

a legal entity participating in the German network MI-I

Namespace Identifier

a code or that part of a code that identifies the organization responsible for creating and maintaining a Standards-Based Extension or a Standards-Based Derivative and is used as an element of SNOMED CT Identifiers;

National Extension

an Extension that is controlled and maintained by a Member and is SNOMED CT Content supplementary to the Core;

National Release

in respect of each Member, the release produced and distributed by the Member, consisting of the International Release, the Member's Extensions, the Member's Derivatives and other documents and software;

National Release Center	a governmental body or separate legal entity established and operated by the Licensor for the purposes of implementing this License Agreement and, in particular, granting sub-licenses under this License Agreement;
Non-Member Territory	a territory that is not a Member Territory;
Regulations	regulations made by the Licensor;
Relationship	a relationship, of a kind defined by the Licensor in Specifications, between concepts {which may be, without limitation, a hierarchical or an associative relationship) or between a concept and a description;
SNOMED CT	the concept-based work of clinical nomenclature and classification with multiple hierarchies and semantic definitions known as SNOMED Clinical Terms (SNOMED CT);
SNOMED CT Content	terminological content, consisting of concepts, descriptions and Relationships, each of which is identified using a SNOMED CT Identifier;
SNOMED CT Identifier	a code, of a kind defined by the Licensor in Specifications, for identifying concepts, descriptions and Relationships;
Specification	specifications promulgated by the Licensor for products and processing relating to SNOMED CT, including specifications of the internal logic of SNOMED CT, editorial policies, guidelines and characteristics;

Standard	a Specification that is formally adopted by the Licensor;
Standards-Based	in respect of an Extension or a Derivative, an Extension or Derivative the creation of which is the subject of one or more Standards; and
Sub-Set	a sub-set of SNOMED CT Content that is grouped together for one or more purposes;
Termination Notice	a written notice sent by one Party to the other Party, giving the other Party notice of the termination of this License Agreement;
Third Party Extension	an Extension that is controlled and maintained by an Affiliate and is SNOMED CT Content supplementary to the Core or a National Extension (or both).

Appendix B: Standards as of Effective Date

Each release of SNOMED CT is released with an EffectiveTime, which is specified in its own field in each of the SNOMED release files. This is done to ensure that each release used by systems can interoperate by using the same version of SNOMED CT. The EffectiveTime specifies the first date a release can be used by. The EffectiveTime, along with Active status supports the creation and maintenance of SNOMED history. Details of every concept ever released in SNOMED CT are included in the current release, with some marked for current usage and other that are identified as legacy. Details of the history of a concept are specified in the Relationships file, along with EffectiveTime and Status which are found in all release files.

Further details on the EffectiveTime can be found here -

<https://confluence.ihtsdotools.org/display/DOCRELFMT/3.1.3+Fields+Present+in+All+Release+Files>

Further details on Active status can be found here -

<https://confluence.ihtsdotools.org/display/DOCRELFMT/3.1.4+Meaning+of+the+Active+Field>

Appendix C: Trademark utilization Regulation as of Effective Date

As of January 1, 2017 the international Standards Development has adopted the trading name of SNOMED International. This change aligns our organizational title with the leading product, SNOMED CT and reflects the move towards a product and service oriented organization. This document provides guidance on how to use the brand marks. The link provided gives guidance on the use of SNOMED trademark (brand).

<https://confluence.ihtsdotools.org/display/COM/Branding>

Appendix D: Description of quality standards as of Effective Date

The IHTSO (SNOMED International) is committed to providing a quality assured product, and to underpin this aim the organization has developed an overall framework to provide a structured approach to quality assurance. The IHTSDO Quality Assurance Framework provides a description of the Quality Assurance Framework for use in helping to identify, and subsequently monitor, appropriate and meaningful quality components for the activities and products of the International Health Terminology Standards Development Organization (IHTSDO). The document should be read in conjunction with a separate toolkit document which gives further examples and templates to be used. Structurally, the Quality Assurance Framework is a merger of models from the world of software quality engineering, from healthcare quality assurance and existing terminology quality assurance processes, recognizing both the wider international harmonization responsibilities of the IHTSDO, as well as the role of its terminology products in healthcare delivery.

The principles which underpin the original development of the IHTSDO Quality Assurance Framework are: In order to satisfy its stated purposes the IHTSDO will undertake many activities. By identifying these activities, it is then possible to specify the components (themselves identifiable in terms of 'structure', 'process' and 'outcome' components) that are needed to enable these activities. By identifying suitable characteristics by which to assess these components, it will then be possible to measure, demonstrate and improve the quality of each activity the IHTSDO undertakes, by generating quality metrics and setting quality targets against which the characteristics of the components can be assessed. The ability to measure the degree of adherence to (or achievement of) such targets will then allow the IHTSDO to satisfy itself, its stakeholders and its potential stakeholders of the quality of the activities it performs.

The Quality Assurance Framework and the Quality Assurance Toolkit are available at the following link:

<https://confluence.ihtsdotools.org/display/PL/Quality+Assurance>