Digital Therapeutic Accreditation

For The

HEALTHCARE INDUSTRY

Version 1.0
Released: DRAFT

Governed by the Electronic Healthcare Network Accreditation Commission (EHNAC)

For additional information see the DirectTrust website:
www.DirectTrust.org

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

Prefatory Notes

If a criterion is marked with [MANDATORY] it must be both responded to and fully met. Any MANDATORY criteria that are not fully responded to and met will cause the candidate to FAIL accreditation.

Applicants for accreditation are expected to provide responses for each and every criterion, whether "MANDATORY" or not. If a particular criterion is not applicable based on unique services provided by the candidate, the response must state "Not Applicable" along with a clear explanation of why that particular criterion doesn't apply. The EHNAC Commission will make final determination as to whether or not such criterion can be excluded.

Please make sure that no Protected Health Information (PHI) is included in any of the responses or evidence submitted.

At the end of each criterion a unique number is shown inside braces (e.g., {123}). This number can be used to cross-reference criteria across multiple DirectTrust programs and versions. This index is sometimes followed by legal references citing regulations related to the criterion.

Please refer to DirectTrust's Glossary of Terms for definitions of any unfamiliar terms referenced throughout this document. The Glossary of Terms is located at http://ehnac.org/glossary.

Location Review Note: DirectTrust realizes that some of the supporting documentation might not be able to be included in the Self-assessment for many reasons. If you deem this to be the case, clearly indicate what your supporting documentation is, why you are not including it in your self-assessment and how you will demonstrate it during the location review with the assessor. Please note that your organization may need to compensate DirectTrust for an additional location review, if the time required to review the documents exceeds one day.

Certain Criteria may apply or not apply to some applicants. Each Criterion has been given a designation to indicate the type of entity to which it applies. These designations are as follows:

- G – To be addressed by all candidates (General).

Note that if your organization supports more than one type of processing, you will need to complete the appropriate Criteria module for each type.

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

Table of Contents

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION I: GENERAL

I.A. Industry Standards

I.A.1 [MANDATORY] (G) Candidate SHALL demonstrate that it understands and conforms with ANSI/CTA-2098.
{10334}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION II: EVIDENCE

II.A. Clinical Evidence

II.A.1 [MANDATORY] (G) Candidate SHALL demonstrate that one or more studies must show clinically meaningful impact on a reliable and valid endpoint using a controlled study design with a comparison group.

Example comparison groups may include a waitlist, treatment as usual (TAU)/non-inferiority design, synthetic control arm, sham, active or attentional control, or psychoeducational control.
{10335}

II.A.2 (G) Candidate SHOULD demonstrate durability of treatment effect in line with standards of care.
{10343}

II.A.3 [MANDATORY] (G) Candidate SHALL demonstrate that statistical analyses are appropriate and follow standard practice for given research design (e.g. analysis should not include only those who use the product as instructed).

Completers/per-protocol analysis is only acceptable if offered alongside "all comers" analysis.
{10344}

II.A.4 (G) Candidate SHOULD demonstrate that sample size is adequately powered to detect clinically meaningful effects on predetermined endpoints.
{10345}

II.A.5 (G) Candidate SHOULD demonstrate that study enrollment is comparable to/representative of the intended treatment population.
{10385}

II.A.6 (G) Candidate SHOULD demonstrate that pre-specified study design and endpoints are listed within clinical trial registry as appropriate for jurisdiction.
{10347}

II.A.7 (G) Candidate SHOULD demonstrate publication in peer-reviewed journal.
{10348}

II.B. Real-World Evidence (postmarket)

II.B.1 [MANDATORY] (G) Candidate SHALL demonstrate via a data monitoring process that it has a plan for collecting, analyzing, and taking action to respond to problems in real-world product safety data.
{10336}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

II.B.2 (G) Candidate SHOULD demonstrate via a data monitoring process that it has a plan for collecting, analyzing, and deriving actionable insights from in real-world product performance data (e.g. patient satisfaction; impact on clinical outcomes).
{10337}

II.C. Marketing Claims

II.C.1 [MANDATORY] (G) Candidate SHALL demonstrate that marketing claims are appropriate to results of research, in accordance with local regulations.
{10386}

II.C.2 (G) Candidate SHOULD demonstrate that claims are reinforced by real-world data where possible.
{10387}

II.C.3 (G) Candidate SHOULD demonstrate that, if claims are not consistent between clinical trials and RWE, they are adjusted appropriately.
{10340}

II.D. Regulatory status

II.D.1 [MANDATORY] (G) Candidate SHALL demonstrate that product is reviewed by regulatory bodies as required to support product claims of risk, efficacy, and intended use, when required by local jurisdiction.
{10341}

II.D.2 [MANDATORY] (G) Candidate SHALL demonstrate that claims related to the product are appropriate to regulatory status.
{10342}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION III: SAFETY

III.A. Clinical Intervention

III.A.1 (G) Candidate SHOULD, during postmarket surveillance, demonstrate internal documentation that lists any anticipated risks due to product use.
{10349}

III.A.2 (G) Candidate SHOULD, during postmarket surveillance, demonstrate patient-facing documentation outlining anticipated risks of product use.
{10352}

III.A.3 (G) Candidate SHOULD, during postmarket surveillance, demonstrate provider-facing documentation outlining anticipated risks of product use.
{10353}

III.A.4 (G) Candidate SHOULD demonstrate that all studies include safety endpoints to assess product safety.
{10388}

III.A.5 [MANDATORY] (G) Candidate SHALL demonstrate that adverse events related to product use are documented in clinical studies
{10355}

III.A.6 [MANDATORY] (G) Candidate SHALL demonstrate a system for documenting adverse and other notable events related to product use in postmarket surveillance. Must include a mechanism for consumers to report adverse events.
{10356}

III.A.7 (G) Candidate SHOULD demonstrate mitigations for algorithmic bias in products using AI/ML.
{10357}

III.B. Product

III.B.1 (G) Candidate SHOULD demonstrate that risk of product failure is assessed (e.g. what is the risk to the patient in the event of product failure) and addressed via safety measures.
{10350}

III.B.2 (G) Candidate SHOULD articulate risks of product failure in patient-facing documentation.
{10351}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION IV: FUNCTIONALITY

IV.A. Clinical Mechanism

IV.A.1 [MANDATORY] (G) Candidate SHALL demonstrate that clinical impact, including intervention modality and relationship to other therapies, is defined and supported by evidence.
{10389}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION V: USABILITY

V.A. User Testing

V.A.1 [MANDATORY] (G) Candidate SHALL demonstrate that it follows processes in line with existing standards for usability testing (e.g. IEC 62366-1) to identify and mitigate risks associated with both suboptimal use and abnormal use of product, and that testing is conducted in target user population.
{10359}

V.A.2 [MANDATORY] (G) Candidate SHALL demonstrate that factors that would render DTx system unusable at system or product levels are specified and anticipated.
{10367}

V.A.3 (G) Candidate SHOULD demonstrate that human factors testing (or similar) is in place to demonstrate usability of product consistent with intended use; and that any potential restrictions to audiences that may use product. Precautions should be identified and articulated.
{10368}

V.A.4 [MANDATORY] (G) Candidate SHALL demonstrate that it offer a process for users to get assistance with product use as needed.
{10369}

V.B. Compatability

V.B.1 (G) Candidate SHOULD demonstrate that hardware and software system components required are articulated, for consumers and providers (if applicable), including iOS/Android compatibility, or other hardware/software components needed to deliver intervention such as memory, screen size requirements.
{10360}

V.B.2 (G) Candidate SHOULD demonstrate and provide justification that, based on anticipated clinical workflow and target population, compatability is suitable for desired use cases.
{10361}

V.C. Accessibility

V.C.1 [MANDATORY] (G) Candidate SHALL demonstrate that product usability considerations such as language, culture, disability, and age are documented for target user population and considered in product development roadmap
{10362}

V.C.2 (G) Candidate SHOULD address usability considerations such as language, culture, disability, and age in product development as appropriate for target user population.
{10363}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

V.C.3 (G) Candidate SHOULD demonstrate that it has assessed and documented the extent to which users in target user population are able to comprehend product content, including user agreement, with any shortcomings mitigated.
{10364}

V.C.4 (G) Candidate SHOULD demonstrate that accessibility best practices (e.g. readability at an 8th grade reading level for adult users) are implemented as appropriate for target user population.
{10365}

V.C.5 (G) Candidate SHOULD document and communicate infrastructure requirements (e.g. WiFi, 5G, or bluetooth connection) and any feature set limitations depending on available infrastructure
{10366}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION VI: MANUFACTURING

VI.A. Quality

VI.A.1 [MANDATORY] (G) Candidate SHALL document its software development lifecycle methodology and demonstrate adherence to methodology.
{10370}

VI.A.2 (G) Candidate SHOULD demonstrate that it implements a Quality Management System.
{10371}

VI.A.3 (G) Candidate SHOULD demonstrate that it implements configuration management systems, including version control, if applicable.
{10372}

VI.A.4 (G) Candidate SHOULD establish quality metrics and monitor postmarket data to ensure ongoing product integrity.
{10373}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION VII: INTEGRATION

VII.A. Product integration

VII.A.1 [MANDATORY] (G) Candidate SHALL articulate how DTx may be embedded in larger health ecosystem and how it may impact the larger health ecosystems including clinician workflow and technology systems, including risks.
{10374}

VII.A.2 [MANDATORY] (G) Candidate SHALL provide documentation, if applicable, describing any software components that operate in conjunction with the digital therapeutic (e.g. a clinician dashboard) and articulating its role in the digital therapeutic's functioning.
{10378}

VII.B. External components

VII.B.1 [MANDATORY] (G) Candidate SHALL, if applicable, articulate any hardware systems, such as sensors, meant to be used in conjunction with DTx software, including description of how hardware systems operate in conjunction with the digital therapeutic.
{10375}

VII.B.2 [MANDATORY] (G) Candidate SHALL demonstrate that it applies product deployment, management, and maintenance best practices for external components.
{10376}

VII.C. Interoperability

VII.C.1 [MANDATORY] (G) Candidate SHALL articulate how, if applicable, DTx may be interoperable with relevant systems, including electronic health records, electronic prescribing, and data privacy risks.
{10377}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION VIII: SECURITY

VIII.A. Security

VIII.A.1 [MANDATORY] (G) Candidate SHALL specify the process for maintaining product authenticity through supply chain.
{10390}

VIII.A.2 [MANDATORY] (G) Candidate SHALL specify patient privacy and data governance requirements (e.g. end user privacy notice).
{10391}

VIII.A.3 [MANDATORY] (G) Candidate SHALL demonstrate that cybersecurity certifications appropriate to region and device risk level are possessed.
{10381}

VIII.A.4 [MANDATORY] (G) Candidate SHALL demonstrate that data breach management processes and vulnerability testing are outlined.
{10382}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.

SECTION IX: PRIVACY

IX.A. Privacy

IX.A.1 [MANDATORY] (G) Candidate SHALL demonstrate that it adheres with data privacy laws of relevant country (e.g. GDPR, US-based state laws).
{10392}

IX.A.2 [MANDATORY] (G) Candidate SHALL specify data processing, access, and ownership, including use of any data received back from DTx product.
{10384}

© Copyright DirectTrust. All rights reserved.

This document is the property of DirectTrust and may not be used, disclosed or reproduced, in whole or part, without express written consent. The unauthorized copying, dissemination or use of this document or any information contained therein may constitute a violation of U.S. law and be grounds for civil or criminal penalties. This document contains information owned by DirectTrust and may be used only subject to the terms and conditions of a program accreditation.