

DIGITAL HEALTH VENDOR ASSESSMENT FOR CLINICAL TRIALS



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An open-source industry guidance to facilitate vendor qualification for clinical trials.

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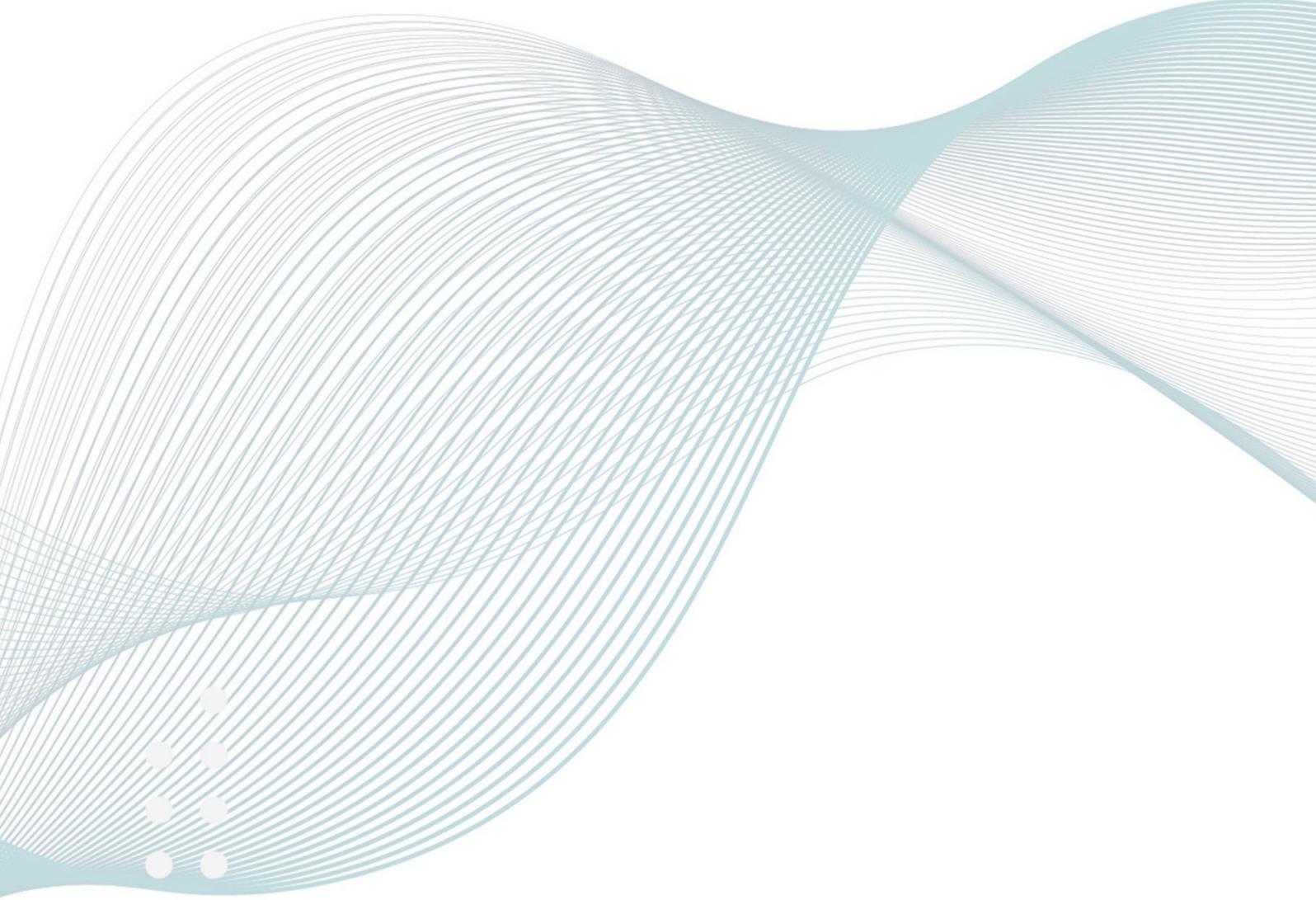
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INTRODUCTION



INTRODUCTION

HealthXL and a consortium of representative stakeholders from across the digital health ecosystem have been working to advance the understanding and adoption of digital health products used in clinical trials. To reduce variable implementations of similar quality standards, the interdisciplinary group began in Q4 2020 to work towards an open-source industry guidance to facilitate vendor qualification for clinical trials. With a standardized template, vendors will have a response package prepared with most of the expected documentation in a format that sponsors are ready to accept and review. This framework is meant to serve as a guidance for industry but can easily be adapted to suit individual needs and specifications.

The guidance in the form of a questionnaire covers topics like supply of digitally enabled technologies and associated data as well as the services that relate to their implementation. Having created an overview of relevant categories to be included in the questionnaire, the open-source guidance aims to help in the process of vendor assessment standardization for digital tools and products in clinical research programs. Selected questions around a vendor's operational suitability and qualifications guide sponsors and vendors alike in the evaluation process.

The objective is to align vendors' internal capabilities, structures, systems and procedures to what is commonly expected and accepted by sponsors. In anticipation of due diligence, this will allow vendors to build an information and documentation package describing their quality systems, data handling, logistics, and structure prior to contracting with a sponsor.

By standardizing the process, sponsors and vendors can save time and assure the quality and operational needs of a service are met and documented.

WHY THIS ASSESSMENT IS IMPORTANT AND ESSENTIAL

The goal of this open-source document is to guide both sponsors and vendors during the vendor selection process in the field of digitally enabled technologies that support clinical research programs. In addition, the aim is to ensure reliable quality for sponsors and their users offering vendors a way to prepare a documentation package to support the sponsor evaluation process.

At this stage, most vendor onboarding processes are aligned in principles but not in format. Consequently, this complex approach creates a burden on vendors not resulting in added quality or value. Therefore, the motivation for creating this questionnaire is to drive adoption of digital services and technologies that lead to improvements in the conduct of clinical research by providing patient centric solutions.

By deploying a more standardized approach, operational efficiency can be increased. Additionally, the need to create a common understanding was identified as essential to help vendors meet sponsor expectations during vendor onboarding by improving the identifications of risk and mitigation processes.

Therefore, the guidance document offers a first collection of relevant questions and a suggestion of common language related to digital technologies and adjacent services between sponsors and suppliers to accelerate their onboarding. Subsequently, this also provides better visibility & transparency for vendors into the vetting process. Aiming for an increased visibility and understanding for sponsors and vendors of respective capabilities and opportunities, the questionnaire targets to build a good foundation for a clearly defined and successful work together.

CATEGORIES

13 Vendor Assessment Categories



OUTLINE OF SELECTED VENDOR ASSESSMENT CATEGORIES

To cover the most relevant topics in this open-source guidance document, the group has established and worked out 13 categories that constitute the questionnaire.

Deriving from the 13 selected categories, the group has developed a set of questions as guidance for the evaluation process. These questions are meant to support the onboarding process. As this guidance is open source, the intention is to make this questionnaire grow with time through collective intelligence and collaboration. By clicking on one category (1-13) in the overview below, you can directly access the full array of questions aligned to each of the 13 categories.

HOW TO USE THIS GUIDE

1. Download the document.
2. This document is only meant to serve as a recommendation or guide and is non-binding. So, feel free to:
 1. Remove the categories and questions that are not relevant to your organizational use case*
 2. Add additional questions that you need to address*
3. Share this document with your prospective digital vendor(s) as a means to evaluate them to participate in your trial.
4. If you have any comments/suggestions on how to improve this guide, please reach out to judit.faus@healthxl.com

*** Useful information for sponsors and vendors to easily navigate the different categories:** by clicking on one category (1-13) in the overview below, you can directly access the full array of questions aligned to each of the 13 categories. In order to facilitate the navigation through the different categories, at the end of each category you will find a link back to the category overview page.

General consideration for sponsors and vendors: This guide includes questions on standard certification since it aims to standardize what might be asked for repeatedly even for vendors who hold these certificates.

OVERVIEW OF 13 VENDOR ASSESSMENT CATEGORIES

Category 1

General organizational operation and products 

This category covers topics around vendor size & location, geographic expertise and financial health. Additionally, it addresses questions related to the company's governance, capabilities, expertise and experiences, as well as commercial models.

Category 2

Quality Management principles 

This category contains topics around QMS structures, accreditation and certification in place and how the vendor manages audit requirements. This section is also about quality assurance, communication processes and training compliance.

Category 3

Practices of product or service 

This category handles the topics about good practices including the documentation and compliance of such. The majority of questions direct towards the user experience covering user centricity and engagement.

Category 4

Device supply and positioning import & export 

In this section topics around supply chain and manufacturing planning cycles are covered including the qualification process for 3rd party vendors. The emphasis lies on product approvals, regulations as well as processes in place to ensure monitoring, tracking and recovery of devices in use.

Category 5

Account provisioning 

This category provides questions related to the user account management, security mechanisms and related timelines at study closeout.

Category 6

Study specific materials (investigators)/ design/ usability 

This category contains selected questions about ICFs, manuals for study coordinators in place and instructions for use. Moreover, this part covers the topics of usability reports, lessons learnt and feedback data from previous activities.

Category 7

Live trial support for stakeholders 

In this section questions around the helpdesk, support levels and training of staff are covered. Questions tend to outline SLAs in place and the handling of feedback/complaints.

Category 8

Trial closeout activities 

This part covers in detail the topics of data collection and transfer as well as processes on query resolutions and the management of devices at trial closeout.

Category 9

(GxP) Data handling/ processing and data flow 

This section compiles questions around data management, technologies and tools involved in data flows as well as review processes.

Category 10

Device and data
(sensors+raw data)
algorithm accessibility for
review



In this section, topics like integration into third-party platforms, handling of data streams/personally identifiable information, specifics from algorithms as medical devices to version control are covered.

Category 11

Interoperability/
Integration



This category deals with the specifics around data interoperability standards and regulations, data formats used and accessible and information about data transfer specifications. If you are using third-party devices or data, there is a collection of additional questions included.

Category 12

Validation/ Clinical
Relevance/ standard of
documentation to
showcase



In this section, questions cover the topics around your evidence profile, relevant studies and reports and publications.

Category 13

Cybersecurity



In this part, topics regarding cybersecurity processes are covered including intrusion detection, access management and security patching as well as IT training management and compliance.



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Category 1

General organizational operation and products

This category covers topics around vendor size & location, geographic expertise and financial health. Additionally, it addresses questions related to the company's governance, capabilities, expertise and experiences, as well as commercial models.



1.1: Company size & location, financial health

Q: Summarize your organization's history, size, structure, and financial health:

Answer: Company name, type of legal entity, geographic locations & affiliates

Comments:

Q: Your organisation's history (incl. size & structure)

A:

C:

Q: Your funding runway and / or profitability, revenue

A:

C:

1.2: Governance (Data Trust, Advisory Board)

Q: Describe your organization's governance:

A:

C:

Q: How are interactions with affiliate organizations managed?

A:

C:

1.3: Capabilities, Products & Services, Commercial Experience

Q: Describe your organization's products and services (may be scoped appropriately for specific projects):

A:

C:

Q: Describe your organization's experience working with biopharma, CROs, academic research centers, and healthcare systems including the scale and duration of work:

A:

C:

Q: In which regions and countries and demographics have you deployed your solutions?

A:

C:

Q: Share details on patient groups and clinics you have supported:

A:

C:

1.4: Organisational structure and business model

Q: Provide an organizational chart and CVs of key leaders to demonstrate appropriately skilled staffing including relevant external consultants/contractors. Please note, CVs might not be retained after review for privacy reasons:

A:

C:

Q: Describe your business model:

A:

C:

Q: If you use human biological samples, please provide your company's HBS policy, HBS training, sample management system documentation:

A:

C:

1.5: Pre-existing partnership for pharma clients (use cases)

Q: Disclose any conflicts of interest or existing commitments that would limit business engagements with sponsor:

A:

C:

Q: Are there any current or expected challenges to your patent validity or enforceability, or a potential limitation for using your product in externally sponsored clinical trials?

A:

C:

[1.6 Intellectual property and trade secrets](#)

Q: Summarize your company's IP:

A:

C:

Q: Are there any current or expected challenges to your patent validity or enforceability, or a potential limitation for using your product in externally sponsored clinical trials?

A:

C:

Category 2

Quality Management Principles

This category contains topics around QMS structures, accreditation and certification in place and how the vendor manages audit requirements. This section is also about quality assurance, communication processes and training compliance.



2.1: Internal QMS structure / processes / guidelines

Q: Describe your quality management system. What are the organizational structures and processes that you have in place to manage and oversee the quality of the services and/or goods that you are offering? (max. 300 words)

A:

C:

Q: How do you manage quality issues (incidence, deviations, CAPA processes)? What controls do you have in place to manage incidents and deviations?

A:

C:

Q: What's your change control mechanism for data handling?

A:

C:

2.2: (Inter)National Accreditation / Certification proof

Q: List and confirm any (inter)national accreditations or certifications that are relevant for the services and/or goods that you are offering (e.g., 21 CFR Part 11, HIPAA, GDPR):

A:

C:

Q: Outline your accreditation credentials of all applicable external standards (e.g., ISO27001, SOC 2, ISO 13485 (QMS), FDA Quality System Regulation)?

A:

C:

2.3: Quality Assurance (Maintenance & documentation)

Q: Describe your practices about the update of procedures and guidelines. Describe how these are communicated in case of an impact towards customers:

A:

C:

2.4: (Third party) inspections / audits

Q: Describe how your internal quality assurance is organized:

A:

C:

Q: Provide inspection dates and outcomes from the past three (3) years. List any major observations and describe how these were resolved:

A:

C:

Q: Will you allow inspections in conjunction with your (sponsor) projects?

A:

C:

Q: How are training records made available for inspection?

A:

C:

Q: What is your process for notifying a sponsor of scheduled regulatory assessments?

A:

C:

2.4.1: Post-market surveillance

Q: Describe the organizational structures and processes that you have in place to ensure post-market approval surveillance:

A:

C:

Q: Does a trial sponsor have any responsibility in the Post-Market Approval Surveillance Plan / Program?

A:

C:

2.5: Breach Communication Plan

Q: Describe how any significant breaches (e.g., security, disasters) are communicated and how you are organized to respond to these:

A:

C:

Q: Describe your business continuity and disaster recovery plan. Include your disaster recovery facilities, system backup processes, and restore tests:

A:

C:

2.6: Role specific training

Q: Describe your training program for site staff, patients, study team, sponsors, and inspectors:

A:

C:

Q: Describe how your employees and contractors receive training on their role and the processes they need to follow:

A:

C:

2.6.2: IT security training and management

Q: Describe how you are maintaining training records for your employees and contractors and how these can be retrieved in case of an audit:

A:

C:

Q: Describe your training and annual refreshers:

A:

C:

Q: How do you incorporate regular updates for latest threats?

A:

C:

Q: Describe your data and hardware destruction policy enforcements:

A:

C:

2.6.3: Training compliance & training record

Q: Describe how you are following up on on-time training compliance.

A:

C:

Category 3

Practices of product or service design

This category contains topics around good practices including its documentation and compliance. Most questions direct towards the user experience focusing on user centricity and engagement.



3.1: GxP

Q: Describe your existing GxP guidelines (if applicable) you follow when customizing your product/services for a specific clinical trial:

A:

C:

Q: Describe your product/services including their purpose, key features, and all requirements (OS, connectivity, etc) for successful function:

A:

C:

Q: What are your customization features of your product/service?

A:

C:

3.2: Documentation and Compliance

Q: How do you manage and document system requirements, versions, builds, tests, and releases? Reference professional standards where possible:

A:

C:

Q: How are any changes communicated to the sponsor?

A:

C:

Q: Reference your process for documenting requirements, versions, builds, tests, and releases:

A:

C:

Q: Reference your process for documenting requirements, versions, builds, tests, and releases:

A:

C:

Q: How are upcoming changes communicated with a trial sponsor?

A:

C:

Q: How is downtime managed for cloud-based products in use on clinical trials? Provide data on your downtime over the past twelve (12) months:

A:

C:

Q: How are software and firmware updates distributed, and can they be declined by sponsors?

A:

C:

Q: How do you decommission systems and retain records at the end of a study or contract?

A:

C:

3.3: Customer / User Experience

Q: How do you track metrics for quality and use of your product?

A:

C:

Q: How do you manage emerging user issues?

A:

C:

3.3.1: Involvement of multi-stakeholder group End User / Patients of using/testing DBM

Q: Do you involve the end users in the product/service design?

A:

C:

Q: Describe how end users/patients are involved in the design of the solution:

A:

C:

3.3.2: Patient centricity and patient engagement

Q: Describe how your product is designed to optimise UI/UX

A:

C:

Q: Describe the characteristics of the patient populations where this product has been tested / feedback received from.

A:

C:

Q: How does the vendor account for gaps in any validation work?

A:

C:

Q: What language(s) is your product available in?

A:

C:

Q: Outline any other technology required for an end user to use your product:

A:

C:

Q: Describe the level of tech literacy required of the end user (e.g., medical staff, patients, admin) to properly use your product.

A:

C:

Q: Describe the broadband requirements end-users must have to properly use your product.

A:

C:

3.3.3 KPIs for Adoption / customization possible / new version

Q: What are your KPIs for patient engagement? How do you measure / benchmark these KPIs?

A:

C:

3.4: Mapping of Trial vs Product Requirements

Q: Describe your development, testing, release, and amending/updating processes according to quality standards and best practices. Include timelines where possible:

A:

C:

3.5: Format of the product / service

3.5.1: Deliverable to be defined / track progress / set expectation

Q: Describe the timings of product/service customization: date you can deliver the product/service and key milestones to keep track of the progress.

A:

C:

3.6: Overread services (if applicable)

Q: Describe how an overread service may be incorporated into your product.

A:

C:

Q: How are overread services managed for quality?

A:

C:

Category 4

Device supply and provisioning, import & export

In this section topics around supply chain and manufacturing planning cycles are covered including the qualification process for 3rd party vendors. The emphasis lies on product approvals, regulations as well as processes in place to ensure monitoring, tracking and recovery of devices in use.



[4.1: Supply chain and manufacturing planning cycles](#)

Q: Describe your production and planning cycle time or window:

A:

C:

Q: How do you manage risks in your supply chain?

A:

C:

[4.2: Life Cycle Management, Product planning and phase-out cycles](#)

Q: How do you manage product phase-outs with your customers?

A:

C:

Q: How do you manage product phase out if such products are in long-term clinical research or care implementations that outlast the phase-out time?

A:

C:

[4.3: Qualification process for 3rd party vendors](#)

Q: Provide your SOP or process description for vendor qualification and oversight:

A:

C:

4.4: Clarification if 3rd party or own device

Q: How are any devices/services developed by third parties and used in your product ensured to be appropriate and predictably available?

A:

C:

4.5: Process for kitting, labelling and reconciling unique device identifiers

Q: If applicable, provide your SOPs for kitting, labelling, and device identifier registration / reconciliation:

A:

C:

Q: How do you oversee any outsourced kitting and distribution processes?

A:

C:

4.6: Process for order/re-order management, emergency orders, inventory storage, facility registrations

Q: Describe the ordering and reordering process for normal orders and emergency orders separately:

A:

C:

Q: Describe your inventory management, providing relevant SOPs, and the facilities in which inventory is stored:

A:

C:

[4.7: Processes for monitoring distribution and recovery](#)

Q: How do you ensure security and reliability for product deliveries to sites?

A:

C:

Q: What is the process for recovering a product after its use has concluded?

A:

C:

[4.7.1: Import/Export Plan Execution](#)

Q: In which countries are you licensed to import or export your products?

A:

C:

Q: Please detail the experience of countries where you have deployed your device detailing shipping/logistics arrangements:

A:

C:

[4.7.2: Tracking & Tracing](#)

Q: What are your procedures for responding to shipping errors or missing shipments? Do you have any Supply Chain Mgmt Experts involved?

A:

C:

4.7.3: Response to reported errors or out-of-spec kits

Q: What are your procedures for responding to kit configuration errors reported by clinical site staff, participants, or study teams?

A:

C:

4.7.4: Recovery and hardware/software cleaning for reuse

Q: Describe the process for recovering devices/kits and preparing them for redeployment?

A:

C:

Q: How do you ensure that data is purged from the device?

A:

C:

Q: What documentation do you share with sponsors for devices that will be reused?

A:

C:

4.8: Regulatory Compliance

Q: Provide a summary and documents for the approvals, medical device status, and intended use statement for all applicable geographic areas:

A:

C:

Q: Provide any other relevant documentation of testing/compliance by professional standards:

A:

C:

4.9: Return/destroy devices

Q: Please specify how devices at the end of the study will be handled.

A:

C:

Category 5

Account provisioning

This section provides questions related to the user account management, security mechanisms and related timelines at study closeout.



5.1: User account management

Q: What are your account setup procedures? What documentation do you distribute to support it?

A:

C:

Q: What is your process for cleaning up accounts that are no longer necessary?

A:

C:

Q: Who has access and authority to add new or edit existing user accounts?

A:

C:

Q: Do accounts maintain unique IDs that obscure the name of the patient?

A:

C:

5.2: User security model and access

Q: What is your user security model, including specific relevant protocols?

A:

C:

Q: What are your key user types (e.g., patients, administrators, site managers, researchers)?

A:

C:

Q: What is your approach to role-based access control (RBAC), i.e., your process for granting permissions to data or sections that are aligned with the needs of a user?

A:

C:

5.3: Account management

Q: Do you have the ability to manage accounts in batches?

A:

C:

Q: What are the on-site requirements, if any, for account provisioning/management?

A:

C:

Q: What are your processes and protocols for communicating with patients directly or indirectly (i.e., through site admins) to address user account setup or access issues (e.g., password reset)?

A:

C:

Category 6

Study specific materials (investigators) /
design / usability

This category contains selected questions about ICFs, manuals for study coordinators in place and instructions for use. Moreover, this part covers the topics of usability reports, lessons learnt and feedback data from previous activities.



6.1: Study documents

6.1.1: Instructions for use

Q: Provide a copy of the instructions for use:

A:

C:

6.1.2: Manuals for study coordinators

Q: Provide a copy of manuals for study coordinators

A:

C:

6.1.3: Study Operations Manual template

Q: Please provide a study operations manual (if different from above)

A:

C:

6.1.4: Template introduction deck for Site Investigator meetings

Q: Please provide a copy, if available

A:

C:

6.2.: Usability report detailing feedback from users (HCPs and specific patient group) in their ability to use the product

Q: Please provide formal reports from usability studies or any recognized standards that were designed around these.

A:

C:

6.2.1: Report of previous deployments/studies ensuring usability

Q: Please provide an overview from previous clinical studies detailing any usability assessments/ issues/learnings.

A:

C:

6.3: Data quality check

Q: How do you ensure high quality data capture?

A:

C:

Q: How does your product help trial participants comply with the protocol?

A:

C:

6.3.1: Feedback mechanism to site of any data quality issues (e.g., patients wearing sensors, identify incorrect sensor placement)

Q: Do you have a mechanism in place to provide feedback to sites to ensure high quality data capture?

A:

C:

Category 7

Live trial support for stakeholders

In this section questions around the helpdesk, support levels and training of staff are covered. Questions tend to outline SLAs in place and the handling of feedback/complaints.



7.1: Helpdesk availability

Q: Describe your helpdesk levels (L1/L2/L3 support) and operational model/metrics including availability times:

A:

C:

Q: How do you manage and document appropriate training for helpdesk staff?

A:

C:

7.1.1: Languages available for helpdesk

Q: Which languages are currently available for front-line support?

A:

C:

Q: How long does it take to enable front-line support in a new language?

A:

C:

7.2: Support process for site staff, patients, study team, sponsors and inspectors

Q: What support do you provide if your service experiences down-time?

A:

C:

Q: What support do you provide if a hardware component fails during a clinical trial?

A:

C:

7.3: Service Level Agreements

Q: Provide your service level agreement template for user support services:

A:

C:

7.4: Process for handling & managing complaints

Q: What is your process for receiving, managing, responding to, and tracking complaints and other feedback?

A:

C:

Q: How do you archive and make complaints received during a study available to a sponsor or, if needed, an inspector?

A:

C:

7.5: Process for managing information and activities related to adverse events

Q: How do you manage information that may be directly or indirectly related to adverse events?

A:

C:

Q: If adverse event-related information appears in your product or system, describe your procedure to respond to such an event:

A:

C:

7.6: Documentation - EULA, warranty

Q: Provide a copy of your end-user license agreement and the process for obtaining EULA agreement/consent:

A:

C:

Provide a copy of your warranty:

A:

C:

Category 8

Trial closeout activities

This part covers in detail the topics of data collection and transfer as well as processes on query resolutions and the management of devices at trial closeout.



8.1: Data transfer as per data transfer specifications document - delivery specs including timing, format, support, etc.

Q: Do you have a generic template of your data transfer specifications which can be shared? Please provide.

A:

C:

Q: What is your process for resolving queries during reconciliation of the clinical database with your database?

A:

C:

8.2: Data retention / future use policy - including HIPAA-related or DPIA. related (based on your region) secondary data use rights referenced in vendor's corporate privacy policy, the study's patient consent forms, platform EULA's, etc.

Q: What's your data retention policy? Please provide overview of how data collected during the study will be retained in your system:

A:

C:

Q: Please provide an overview of how any data collected will be used by the vendor:

A:

C:

8.3: Timelines

Q: Provide any available statistics on time to provision accounts and close accounts after study closeout.

A:

C:

Category 9

(GxP) Data handling / processing
and data flow

This section compiles questions around data management, technologies and tools involved in data flows as well as review processes.



9.1: Overview Data Management

Q: Provide a data flow schematic, including the sources (and countries) of your data collection:

A:

C:

Q: Provide your data transfer specifications and secure transfer method description

A:

C:

9.2: What type, level and volume of data is collected, and how is it protected (suggest adapting to GDPR/ HIPAA as needed):

Q: Specifically, how do you handle any personally identifiable information (PII), person-generated health data (PGHD) or personal health information (PHI)?

A:

C:

Q: What are your procedures and documentation related to patient informed consent?

A:

C:

Q: What methods of de-identification and encryption are you using (in any device, transfer or cloud environment) to ensure the privacy and security of patient data

A:

C:

Q: Describe your data governance principles (accurate, complete and verifiable), e.g., Golden Source (one version of the truth) and distribution model:

A:

C:

Q: Describe your Quality Risk Management (incl.GDPR, IEC 62304 & 82304, as well as applicable FDA guidance, ICH guidelines, the Five Safes, etc)

A:

C:

Q: What are your archiving and business continuity arrangements?

A:

C:

Q: How do you provide archival data to investigators or sponsors, provide process timelines if possible:

A:

C:

[9.3: Technologies and tools](#)

Q: Describe the technologies and tools used in data flows and processes:

A:

C:

Q: In particular, please comment on any manual vs. automatic elements:

A:

C:

Q: Also, please comment on cloud vs. on premise technology

A:

C:

9.4: Data attributes

Q: Describe the data interoperability standards you follow:

A:

C:

Q: Describe your protocol for handling critical data elements and metadata:

A:

C:

Q: Please provide a copy of your current Privacy Policy:

A:

C:

9.5: Data review mechanisms

Q: Describe your audit trail and event log functionalities

A:

C:

9.6: Interim Database Lock

Q: Please provide specifics on how you manage the interim database lock:

A:

C:

Q: Please clarify on how you manage the resolution of issues to enable a database lock (raw data and derived endpoints):

A:

C:

9.7: Data and de-identification and encryption

Q: What methods of de-identification and encryption are you using to ensure the privacy and security of patient data?

A:

C:

9.8: Additional US compliance considerations

NOTE: This assessment can be extended and tailored to your specific needs

Q: How are you specifically handling and managing PHI in compliance with HIPAA?

A:

C:

Q: Do you use any unique coded ID's for participants?

A:

C:

Q: Do you use randomized master keys for the study and users in your security model?

A:

C:

Q: What is your user access and security model overall for who can access study data based on where it is being stored and how is it being used?

A:

C:

Q: What is your process and policy for sharing data, as allowed per informed consent, IRB approval, EULAs, etc. with other study members or 3rd parties?

A:

C:

Q: How is data transferred in these circumstances?

A:

C:

Q: Under HIPAA, are you designated as a Covered Entity or do you otherwise have a BAA in place with one as needed?

A:

C:

Q: How are you able to comply with the 21st Century Cures Act with regard to incremental consent requirements and data accessibility in the US?

A:

C:

9.9: GDPR Compliance

Q: Please confirm that you are in compliance with all GDPR requirements, in particular for personal data of EU residents regardless of your company's location.

A:

C:

Please address the following checklist (see below)

Q: Lawful basis & transparency: information audit to cover data, processing and access; legal justification; privacy policy; informed consent

A:

C:

Q: Data security: data protection design; policies and procedures around (i) data encryption and anonymization, (ii) internal compliance/security, (iii) data protection impact assessment as defined by the GDPR, and (iv) data breach notification

A:

C:

Q: Accountability & governance: List the relevant roles that apply to your organization. compliance officer; 3rd party agreements; EU representatives; data protection officer

A:

C:

Category 10

Device and Data (sensors + raw data) algorithm accessibility for review

In this section, topics like integration into third-party platforms, handling of data streams/personally identifiable information, specifics from algorithms as medical device to version control are covered.



10.1: Integration of device and/or algorithms with third-party trial or care management platform

Q: How do you support integration of your products into third-party platforms?

A:

C:

10.2: Control over merging PII with sensor ID or sensor data:

Q: Does your product handle or require personally identifiable information?

A:

C:

10.3: Use of data from sensors whether or not overseen by regulatory bodies (i.e., accelerometers)

Q: How are data not reviewed by regulators used or rendered?

A:

C:

10.4: Known patient demographics or geographies that may affect measurement

Q: Please provide information about any patient demographics that would affect the assessments:

A:

C:

10.5: Sensor annotation data availability - high uncertainty periods annotated

Q: How are data streams annotated if they were acquired under conditions for which the device is not approved (ex. Low-perfusion oxygenation or high-motion heart rate from PPG)

A:

C:

10.6: Compute location for transforming data into parameters

Q: Which data are processed on the device/mobile phone, and which are transformed off the device?

A:

C:

10.7: Algorithm registration as a medical device

Q: Does the device + algorithm have medical device certification? Please provide relevant certification:

A:

C:

10.8: Modularity of algorithms

Q: Which algorithms are available as part of a third-party integration (API or SDK)?

A:

C:

10.9: Algorithm version control

Q: For any part of your product not covered by ISO 13485 and/or ISO 62304 how do you control algorithm and technology versioning and version release?

A:

C:

Category 11

Interoperability / Integration

This category deals with the specifics around data interoperability standards and regulations, data formats used and accessible and information about data transfer specifications. If you are using third-party devices or data, there is a collection of additional questions included.



If you are using third-party devices or data, please answer the following questions

11.1: Device-level integration

Q: Describe your product's framework for connecting to third party systems (API, SDK) and data flow

A:

C:

11.2: Dependencies for accurate function i.e., calibrations

Q: How is your product calibrated and where is calibration information stored and/or retrieved, even if it is run by a third-party application

A:

C:

11.3: Assumption of regulated function (medical device display, SaMD, etc)

Q: Does a third-party application need to fulfil a regulated function (medical device display, SaMD data transformation, etc)

A:

C:

11.4: Data sources in addition to primary data being generated (EMRs, etc.)

Q: Which external data sources does your product use, and how do you verify that those data are high-quality?

A:

C:

Category 12

Validation/ Clinical Relevance/ standard of documentation to showcase

In this section, questions cover the topics around your evidence profile, relevant studies and reports and publications.



12.1: Evidence Profile (Dossier)

Q: Detail intended use, class of device (where appropriate)

A:

C:

Q: Describe setting (e.g., clinic vs home based; instrumented test vs continuous monitoring, etc)

A:

C:

Q: Describe the demographics and the specific context of use and patient population on which your product has been tested in thus far

A:

C:

12.2: Usability studies

<https://www.cmu.edu/teaching/assessment/basics/formative-summative.html>

Q: Please provide reports from relevant user and usability studies

A:

C:

12.3: Verification/validation studies

Q: Please detail verification, analytical validation, clinical validation that your devices have been through.

A:

C:

Q: Provide comparison against ground truth/gold standard wherever possible.

A:

C:

Q: For any novel parameters and/or outcomes, provide the evidence of parameter/outcome stability, sensitivity, and specificity in relevant patient populations

A:

C:

[12.4: Algorithm implementation](#)

Q: Provide all possible detail on processes to extract endpoints from raw data

A:

C:

[12.5: Special conditions](#)

Q: Which demographics has your device been validated in (e.g., paediatrics, pregnant women)?

A:

C:

Q: How generalizable is this to broader populations and / or this project i.e., what are the consequences of your inclusion/exclusion criteria?

A:

C:

12.6: Intended Use: showcase evidence, Proof of Concept, relevant publication

Q: If you are aware of published, high-quality, independent validation studies using your product, please provide references to those studies

A:

C:

Category 13

Cybersecurity

In this part, topics regarding cybersecurity of the product and/or service processes are covered including intrusion detection, access management and security patching as well as IT training management and compliance.



13.1: Cybersecurity overview

Q: Describe your key measures and processes

A:

C:

13.1.1: Vulnerability / Penetration

Q: What is your threat test policy?

A:

C:

Q: What data leakage controls are in place?

A:

C:

Q: What is your anti-virus protection for your product and/or service?

A:

C:

13.1.2: Intrusion detection

Q: What are your monitoring practices?

A:

C:

Q: What are your log file arrangements?

A:

C:

13.2: Privileged access management

Q: Describe your access policies:

A:

C:

Q: Describe your password policies:

A:

C:

13.3: Security patching

Q: Describe your patch management and remediation policy:

A:

C:

GLOSSARY

Ref. DiMe's Playbook for Inspo & Definition: <https://playbook.dimesociety.org/tools/glossary/>

- **Endpoint:** Event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial.
- **EULA:** End User License Agreement. It is a legally binding agreement between the owner of a product and the end user. It gives the user the right to use the product.
- **GDPR:** [General Data Protection Regulation in Europe](#). Protection of natural persons with regard to the processing of personal data and on the free movement of such data
- **GxP:** good practice quality guidelines and regulations
- **ISO:** The International Organization for Standardization is an international nongovernmental organization made up of national standards bodies; it develops and publishes a wide range of proprietary, industrial, and commercial standards and is composed of representatives from various national standards organizations.
- **Product:** platform / device / algorithm / service
- **QMS:** Quality Management System
- **RBAC:** Role-Based Access Control
- **Summative vs Formative evidence:** <https://www.cmu.edu/teaching/assessment/basics/formative-summative.html>





DIGITAL HEALTH VENDOR ASSESSMENT
FOR CLINICAL TRIALS