831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP2 – TECH

D2.2 Detailed list of Quality assessment criteria and assessment procedures

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Document History

Version	Date	Description
V2.0	25 August 2020	Improved version of deliverable report for deliverable D2.2 Detailed list of quality assessment criteria and assessment procedures
V1.0	10 July 2020	First draft of deliverable report for deliverable D2.2 Detailed list of quality assessment criteria and assessment procedures

Abstract

This report describes the development of the quality criteria and assessment procedures for the quality assessment of the technologies for the pan-European pilot study. The final set of quality criteria and assessment procedures to be used are presented. This report can be adjusted based on ESP and ExBo feedback.

Methods

Objective 1: Defining the quality criteria for the quality assessment of the technologies resulting from Task 2.1.1 (Technology Scan)

To come to a set of quality criteria for the assessment of technologies for the pilot study, a stepwise approach was taken. Prior to the start of the development of the quality criteria, all members in the Quality stream were asked to assign themselves to one or more Basic Building Block(s) (BBB) that best fit their expertise and interest, and that they would be responsible for developing the quality criteria for. Subsequently, the following steps were taken:

1. **Desk research and literature review**
   In this first step, all members of the Quality stream were asked to perform a literature review for their BBB, to identify existing quality criteria and frameworks for the quality assessment of RDCT technologies that are already published in the scientific and grey literature. Furthermore, members were asked to provide quality criteria and frameworks they use in their own organizations and based on their expert opinion. This resulted in the first long list of quality criteria.

2. **De-duplication and re-organization**
   In the second step, the UMCU team reviewed the long list and performed a first and preliminary general clean-up of the long list. Duplicate criteria were removed, criteria were reorganized to find the best BBB fit, and where necessary, the members of the Quality stream were asked to provide more comprehensive descriptions of their criteria, to provide the information sources for their criteria, and to review the clean-up that was performed by the UMCU team.

3. **Delphi-survey**
   After the clean-up of the long list, a 3-round Delphi survey was set up. The aim of the Delphi survey was to assess the importance of all criteria, to ask for clarification on all criteria, and to add any missing criteria in 3 subsequent rounds. All Trials@Home consortium members were invited to participate in all survey rounds:

   I. In the first round, all criteria on the long list were presented to the participants, who were asked to rate the level of importance of all criteria on a 9-point Likert scale (RAND methodology). The importance rating was assessed according to the following rules that represented both the importance (through the median score) and the consensus around the importance (through the Interquartile Range [IQR]) of the criteria:

      - If the median rating was 7-9, and the IQR was =<1.5, the criteria were included;
      - If the median rating was 1-6, and the IQR was =<1.5, the criteria were excluded;
      - If the median rating was 4-9, and the IQR was >1.5, or the criteria were newly added, the criteria were included in the subsequent Delphi round for another rating.

      Furthermore, in this first survey, participants were able to ask for clarification on existing criteria, and to add any additional criteria that were not yet included in the long list. Criteria that were added in this stage, were presented in the second survey to undergo the same rating and assessment as described in this survey.

   II. In the second round, the criteria that had not reached consensus around their importance in the first survey, were presented again and assessed for importance and consensus using the same

methodology as was used in the first round. Newly added criteria were also presented and rated and assessed in the same way.

III. In the third round, the criteria (original and newly added) that had not reached consensus around their importance in the first and second round, were presented again and assessed for importance and consensus using the following rules:

- If the median rating was 8-9, and the IQR was =<2, the criteria were included;
- If the median rating was 1-7, the criteria were excluded;
- If the median rating was 8-9, and the IQR was >2, the criteria were presented to the BBB teams (step 4).

4. BBB alignment

After the Delphi survey, a reduced list of final quality criteria was produced, along with a short list of criteria that did not reach consensus around their importance in the 3 rounds of the Delphi survey. In this fourth step, both these final and 'doubtful' criteria were presented to the respective BBB teams that consist of subject matter experts from all work packages. These teams were assigned 3 tasks in order to finalize the set of quality criteria:

I. Make a decision about the doubtful criteria and label these as 'must have' criteria, 'nice to have' criteria, or not needed (exclude) criteria;

II. Match the criteria to the correct building block activities (as defined in the BBB definitions and activities working group);

III. Put forward names of people willing to assess the quality of the technologies gathered through the technology scan (Task 2.2.1), the internal and external RFI, and the open call results.

Objective 2: Defining the assessment procedures for the quality assessment of the technologies resulting from Task 2.1.1 (Technology Scan)

After the finalization of the quality criteria, a focused group discussion with the Quality stream members was organized. In this session, all attendees were asked to provide information on their experiences and setting-specific procedures to assess and select technologies for clinical trials based on pre-defined criteria. This input was used to develop an assessment protocol, which subsequently was optimized through group discussion until consensus was reached.

During the development of the quality criteria and assessment procedures, continuous feedback was requested and incorporated from the WP2 TECH members at the bi-weekly work package meetings, and was extensively discussed during the WP2 TECH virtual "F2F" meeting in April 2020.

Next steps: ESP and ExBo consultation

As a next step, the ESP and ExBo will provide feedback on the completeness, feasibility, development methodology and transparency of the quality criteria and assessment procedures. This input will be used to make any improvements and finalize the quality criteria and assessment procedures to be used for the assessment of the technologies resulting from the technology scan, the internal and external RFI, and the planned open call.

Results

Objective 1: Defining the quality criteria for the quality assessment of the technologies resulting from Task 2.1.1 (Technology Scan)

The number of quality criteria generated in the various steps as previously described, is shown in Figure 1 (total numbers and numbers per BBB). A total number of 328 quality criteria were initially generated through the first desk research (step 1), after the clean-up (step 2: i.e. removing duplicates), 221 criteria were included in the Delphi survey (step 3). This survey was completed by 64 experts. In the three Delphi rounds 33 criteria were added by participants and 112 criteria removed resulting in 142 criteria. The BBB-teams (step 4) removed another 5 criteria, which resulted in a final list of 137 criteria. Appendix 1 shows all quality criteria per BBB, including their related BBB activities and weight.

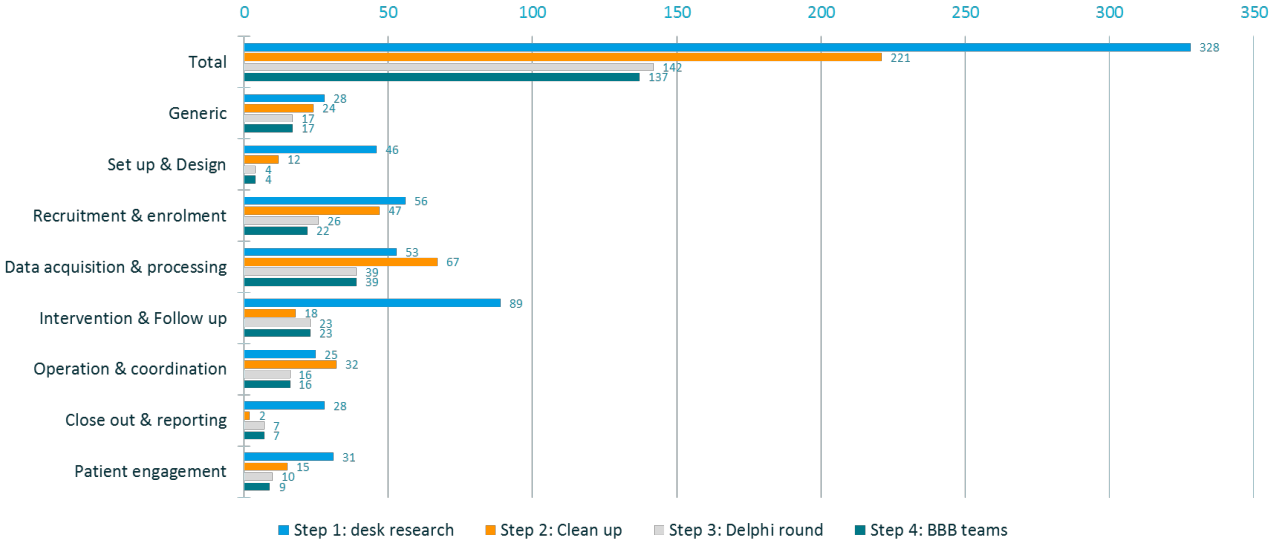

Figure 1. Number of quality criteria generated per step

Objective 2: Defining the assessment procedures for the quality assessment of the technologies resulting from Task 2.1.1 (Technology Scan)

In the (Quality stream) focus group discussion (n=9 participants), consensus was reached about a stepwise quality assessment procedure consisting of 6 steps. The systematic approach is described in detail below and visually represented by Figure 2.

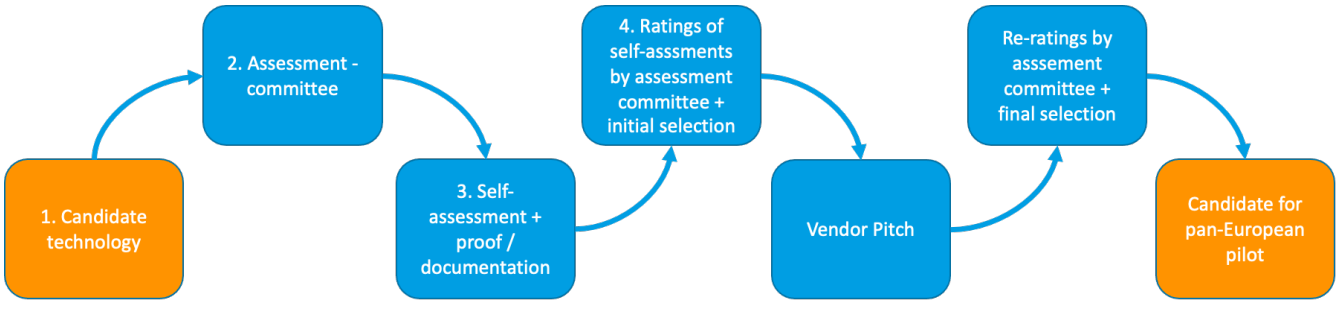

Figure 2. Assessment procedure for quality assessment of technologies

Step 1. Pre-selection of candidate technologies

Candidate technologies are identified through a broad technology scan and through the internal and external Request for Information procedures. In these procedures, technologies are categorized in Basic Building Blocks (BBB) categories by the Scanning team based on key functionalities within those building blocks, which are called activities. The proposed technology requirements (as set by the BBB assembly teams) will guide which technological functionalities are needed and consequently have to be assessed. For each of these functionalities (e.g. e-consent), the Scanning team provides a list of technologies/providers that meet these technological focus points. These functionalities were then reviewed by the basic building block subgroups, which compared the technologies with their visions for their respective basic building blocks. Finally, the list of technologies was presented to the ExBo in order to get feedback from the entire consortium on the collection of found technologies.

Step 2. Establish a specialized assessment committee

Based on the type of technology (BBB), a five person specialized assessment committee will be established from a list of candidates (Appendix 2) to assess the specific technologies for that BBB. The candidates are volunteers with various backgrounds (clinical/methodological, technology, legal). Each committee (one for each building block =8) is led by an academic lead, supplemented by 2 clinical methodological/building block experts, 1 technology expert (either pharma / non-pharma) and 1 legal expert (either pharma/ non pharma). Each of the committee member is asked to indicate and disclose conflict of interest for each of the candidate technologies assessed in that committee. An assessment committee can only be established if none of the members has a conflict of interest.

Step 3. Self-assessment by vendors/technology providers

A custom-made (tailored set of quality criteria based on the specific building block / building block activity) digital self-assessment form is sent to the vendor/technology provider. This form contains questions addressing: 1. General information of the technology and the vendor/technology provider; 2. Generic quality criteria; 3. Quality criteria relevant to the specific technology, based on the relevant BBB and specific activities within that BBB. The form is sent as an online survey, with a provisional time-frame of 3 weeks to return. For each of the questions, the vendor/technology provider is requested to provide as much documentation as possible to support their claim (e.g. certificates, SOPs, procedures).

Step 4. Initial selection of technologies

The assessment committee will receive the self-assessment portfolio of each vendor/technology provider, which includes the results of the self-assessment form and all related documentation, by e-mail. Each member of the assessment committee is asked to rate the degree to which all relevant quality criteria are met (based on the provided self-assessment and documentation) in a separate assessment form. The ratings from the committee members will be combined and summarized by the committee lead. In a subsequent conference meeting, the portfolios and ratings will be discussed. After the discussion, each committee member will be asked to provide a top 3 (with 3, 2, 1 points respectively) and invited to provide argumentation. The three vendors/technology providers with the highest total scores (sum of scores of all committee members) will be selected for step 5.

Step 5. Vendor/technology provider pitch

The three selected vendor/technology providers will be invited to pitch their technologies and to subsequently answer any questions from the committee in a conference meeting. After the meeting, all committee members will fill in the same assessment form and amend their previous rating of the vendor/technology provider based on the pitch and Q&A.

Step 6. Final selection

The ratings from all committee members will be combined and summarized again by the committee lead, and subsequently discussed in another conference meeting. The ratings from all committee members will be combined and summarized again by the committee lead, and subsequently discussed in another conference meeting. After the discussion, each committee member will be asked to provide a top 3 (with 3, 2, 1 points respectively) and invited to provide argumentation. The vendor/technology provider with the highest sum scores will be nominated as candidate technology for the pan-European pilot study.

Coordination

The coordination of the technology assessment steps are coordinated by UMCU and FH Joanneum. The

assessment procedure will be supported by the Trials@Home project management office (PMO), who will support in the set-up and maintenance of a secured cloud-based database for the storage of all data coming out of the quality assessment procedures. Depending on the type of technology (BBB and related BBB activities) that will be assessed, this database is used to:

- select committee members based on their expertise;
- generate a customized online self-assessment form;
- generate a customized assessment form for committee members;
- schedule vendor/technology provider pitch sessions;
- store, analyse and display assessment results.

The mechanism used to on-board the technologies (goods/works/services, sub-contracting, third parties etc…) will adhere to the relevant grant agreement articles.

Conclusion

The described quality criteria and assessment procedures may be adjusted based on input from ESP and ExBo, after which they will be implemented for use for the assessment of the results of the technology scan, and the results of the internal and external RFI.

Repository for primary data

Data will be stored in the secure cloud-based database that will be set-up and maintained in close collaboration with PMO.

Appendices

Appendix 1. Detailed list of quality assessment criteria

Generic

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
1	Technology/system is compliant with applicable privacy and safety standards and regulations, such as FDA, GDPR, MDR, ISO.	NA	NA	NA	1
2	Technology allows multiple simultaneous accesses and edits from multiple locations (web/cloud-based access)	NA	NA	NA	1
3	Technology has strong password requirements (e.g. two-factor authentication, does not allow to save password on device).	NA	NA	NA	1
4	Unauthorized log-in attempts are limited and recorded	NA	NA	NA	1
5	Technology enables automatic log-off for long, idle periods (e.g. at least 15 minutes)	NA	NA	NA	1
6	Technology enables protection of records to enable their accurate and ready retrieval throughout the records retention period	NA	NA	NA	1
7	Technology enables restriction of user access to data with different levels of access permission	NA	NA	NA	1
8	Technology systematically considered human factors in the development of the device user interface (such as task/function analyses, user studies, prototype tests and mock-up reviews)	NA	NA	NA	1
9	The technology production units are tested under actual or simulated use conditions	NA	NA	NA	1
10	The system interface is at least in the local language (of the specific country, and approved by EC) and in English.	NA	NA	NA	1
11	Technology (visual information, language, design) is appropriate for the target audience	NA	NA	NA	1
12	Technology should allow participants to select preferred way of communication (phone, email etc.)	NA	NA	NA	1
13	Technology has adequate hardware quality: inconspicuous, small and noise-less, sufficient battery life (on full charge), charging time is short, includes country-specific electrical fittings/voltages, water resistant technology.	NA	NA	NA	1
14	Technology provider has a business continuity plan	NA	NA	NA	1
15	Technology manufacturer provides sufficient (e-)training tools such as user manual or instructional videos for the technology users	NA	NA	NA	1
16	Technology updates are seemless (without interruption of functionalities)	NA	NA	NA	1
17	Technology vendor maintains operational services related to tech equipment: a tracking system of distribution of the product, from which reports can be pulled by users/sponsor; delivery of devices to patients; replacement of defective devices	NA	NA	NA	0,5

BBB: Set up & design

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
18	Technology is able to share documents with potential sites to analyze site feasibility	Operational Feasibility Assessment and Selection	Site Feasibility Documentation Database		1
19	Technology is able to perform and track online Investigator/Site Staff Training	Site start-up			1
20	Technology is able to track pre study visits	Site start-up	Study Start-up Data Repository		0,5
21	Technology enables automated site/patient payments	Study Payments Management	Study Reimbursement & Payments System		0,5

BBB: Rectruitment & enrollment

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
22	Information materials given during informant consent process are accessible to participants.	Obtaining informed consent	Participant education		1
23	Technology allows PI oversight with regards to coordination and management of the informed consent procedure	Obtaining informed consent	Documentation management		1

24	Participant has access to the informed consent application and his/her signed consent form (not only members of the research team)	Obtaining informed consent			1
25	Technology verifies the authenticity of the informed consent document	Obtaining informed consent	Clinical monitoring		1
26	Technology allows the investigator to contact the participant directly	Obtaining informed consent	Patient-HCP interaction and communication		1
27	Technology allows the participant to contact the investigator directly	Obtaining informed consent	Patient-HCP interaction and communication		1
28	Technology saves information during the process (not only after completing steps)	Obtaining informed consent	Management of study-generated data		0,5
29	Technology allows adequate access for external monitors to check the informed consent procedure	Obtaining informed consent	Clinical monitoring		1
30	Technology evaluates/tracks metrics (i.e. time-of-use schedule, approval deadlines, number of findings during monitoring, revocation rate)	Obtaining informed consent	Performance Monitoring		0,5
31	Technology allows participant to choose the format/media for receiving a copy of the signed consent form	Obtaining informed consent			0,5
32	Technology has the possibility of signing with electronic signature	Obtaining informed consent	System approval facilitation		1
33	Technology has an official certificate for signing with electronic signature	Obtaining informed consent	System approval facilitation		1
34	Technology is adapted to use by low literate participants	Obtaining informed consent	Creation of ICF	Participant education	1
35	Technology is adapted/adaptable to use by participants with special needs (i.e. vision problems)	Obtaining informed consent	Creation of ICF	Patient technology enablement	1
36	Technology allows investigator/participant to change language	Obtaining informed consent	Creation of ICF	Patient technology enablement	1
37	Technology offers the possibility of re-consent after amendments to the protocol	Obtaining informed consent	Documentation management		1
38	In case of amendments and re-consent, the technology highlights relevant changes for participants for quick and easy identification of changes	Obtaining informed consent	Creation of ICF		1
39	Technology includes validated methods to verify inclusion and exclusion criteria of a subject for trial participation	Screening			1
40	The enrollment data allow for daily visualization of enrollment statistics such as eligibility and enrollment rates, stratified numbers and proportions	Performance monitoring			1
41	Steps from eligibility to enrollment for each subject are recorded in such a way that none of the eligible subjects (enrolled and not-enrolled) is lost in the data registration	Management of study-generated data			1
42	Technology includes a portal or landing page with outreach to patients via social media, technology platform	Participant outreach	Participant outreach	Pre-screening	1
43	Technology is able to setup recruitment plan based on add-on variables during the study (e.g. high percentage of non-recruiting sites; high drop out rate)	Pre-screening	Pre-screening	Management of study-generated data	0,5

BBB: Data acquisition & processing

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
44	Technology is able to classify each data point (participant identification, endpoint or safety-related data)	Management of study-generated data			1
45	Technology allows integration of third party generated or maintained critical data (e.g. central laboratories, electronic health records, ePROs) to be integrated into the database	Management of study-generated data	eCRF and system query design		1
46	Technology safeguards that recording of a clinical observation is made at the same time as when the observation occurred or after it occurred (data entry for future not allowed). If real-time recording is not possible, the chronology of events is recorded, with pre-defined maximum delay	Clinical data repository management	Gathering and management of real-life data		1
47	Technology safeguards records to be retained and maintained for a period of time specified in the country-specific overseeing authorities and regulations (e.g. EMA; GCP)	Data reconcilliation & Query management	Gathering and management of real-life data		1
48	Technology safeguards records are available for country-specific regulatory inspections during the study	Data reconcilliation & Query management	Gathering and management of real-life data		1
49	Technology safeguards records are independently preserved at clinical site and/or some other designated site (e.g. technology provider)	Management of study-generated data	Data reconcilliation & Query management		1
50	Technology safeguards data generated is easily accessible for retrieval throughout the records retention period	Management of study-generated data	Data reconcilliation & Query management		0,5

51	Technology that needs calibration has calibration procedures in place to document when potential calibration errors are identified and how the calibration issue was resolved	Gathering and management of real-life data			1
52	Validation of data collection/measurements has been done in a controlled environment (the laboratory or clinic) and a real-world environment	Gathering and management of real-life data			1
53	If algorithms are used, the process by which the algorithm was developed is published or otherwise made freely available	Management of study-generated data	Gathering and management of real-life data	Clinical data repository management	0,5
54	The technology includes a system to collect and preserve clinical data which is pre-managed and validated according to SOP (Standard Operation Procedures)	Clinical data repository management	Gathering and management of real-life data		1
55	The technology is able to discern invalid or altered records	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	1
56	Technology generates electronic data that meets the same or better data quality and integrity as traditional/paper records	Data transformation & standardization	Data analysis		1
57	Technology allows collection of sufficient contextual information to understand the outcome data captured by mobile technologies while avoiding the collection of intrusive data	Gathering and management of real-life data	Data transformation & standardization		1
58	Technology allows collection of metadata indicating source of the data and a UTC time stamp	Clinical data repository management	Gathering and management of real-life data		1
59	Technology safeguards data monitoring occurs in an automated, centralized fashion so that discovery of irregular data calibration errors, can be flagged and investigated	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	1
60	Technology uses Electronic Prompts, Flags, and Data Quality Checks in the eCRF	Data transformation & standardization	Data analysis		1
61	Technology provides the possibility for clinical investigator to review and electronically sign the completed eCRF for each subject	eCRF and system query design	Gathering and management of real-life data		1
62	Technology provides the possibility for clinical investigator to be masked to specific data in the eCRF	eCRF and system query design	Management of study-generated data		0,5
63	Technology allows automated de-duplication, filtering, and parsing of data	Data reconcilliation & Query management	eCRF and system query design	Data transformation & standardization	1
64	Technology ensures that quality of data captured by mobile technologies is monitored centrally through automated processes	Clinical data repository management	Gathering and management of real-life data	eCRF and system query design	1
65	Technology automatically transfers individual participant data to a central server or other data gathering platform for the trial	Gathering and management of real-life data	Clinical data repository management		1
66	Technology includes a data transfer plan that specifically guides how data from participant, to data warehouse, to data monitoring and programming, to archiving must flow	Data reconcilliation & Query management	Clinical data repository management		1
67	Technology allows to demonstrate that the data have not been corrupted following creation	Gathering and management of real-life data	Management of study-generated data		1
68	Technology safeguards presence of data element identifiers	Data transformation & standardization	Clinical data repository management	Gathering and management of real-life data	0,5
69	Technology ensures secure, computer-generated, time-stamped, electronic audit trails of users' actions and changes to data	Data transformation & standardization	Management of study-generated data	Clinical data repository management	1
70	Technology ensures audit trails can not be overridden	Data transformation & standardization	Management of study-generated data	Database lock	1
71	Data elements are in line with clinical interchange standards such as CDISC (Clinical Data Interchange Standards Consortium)	Data transformation & standardization	Management of study-generated data		1
72	Technology restricts users' access to data so they cannot tamper with them	Management of study-generated data	Clinical data repository management	Data reconcilliation & Query management	1
73	Technology has includes a robust, risk-based data security system	Data transformation & standardization	Management of study-generated data	Data reconcilliation & Query management	1
74	Technology has limited amount of data stored on a mobile device	Clinical data repository management	Gathering and management of real-life data	Management of study-generated data	0,5
75	Technology includes "Certificate Pinning" software on the mobile technology and on the server (Internet security mechanism which allows websites to resist impersonation by attackers using misissued or otherwise fraudulent digital certificates)	Clinical data repository management	Gathering and management of real-life data	Management of study-generated data	0,5

76	Technology has data security measures in place such as data encryption, checksums and tokenization in place	Data transformation & standardization	Data reconcilliation & Query management	Management of study-generated data	1
77	Technology includes services such as backups and disaster recovery arrangements in service level agreements with outsourced electronic service vendors	Management of study-generated data	Clinical data repository management	Data reconcilliation & Query management	1
78	Devices into or onto which data are stored are "scrubbed" at a proscribed time interval by the app/programmer.	Data reconcilliation & Query management	Clinical data repository management	Gathering and management of real-life data	1
79	Technology uses a secure network encryption certificate, such as Secure Sockets Layer (SSL) or Transport Layer Security (TLS), and transmit data wirelessly over Hypertext Transfer	Data reconcilliation & Query management	eCRF and system query design		1
80	Technology uses a protocol Secure (HTTPS), or similar secure file transfer protocol such as SFTP (Secure File Transfer Protocol)	Data reconcilliation & Query management	eCRF and system query design		1
81	Technology includes firmware that maintains data equivalence	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	0,5
82	Firmware that ensures data security is optimized	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	1

BBB: Intervention & Follow-up

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
83	Technology has measures in place to ensure that trial participants receive the correct IMP / that only trial participants in the right study arm receive the IMP	IMP supply & re-supply	Home health visits	Clinic visits	1
84	Technology is able to identify IMP errors	IMP supply & re-supply	IMP adherence monitoring		1
85	Technology is able to manage packaging and labeling requirements	IMP supply & re-supply	IMP adherence monitoring		1
86	Technology provides a planning tool for study supplies demand and production according to study design and requirements	IMP supply & re-supply			0,5
87	Technology is able to track study drug to pharmacy (or depot) and a patient home or work, to send confirmation that the drug was delivered and to identify potential shortage	IMP supply & re-supply	IMP adherence monitoring	Self-intervention & self-monitoring	1
88	Technology allows participants to schedule IMP deliveries through an online portal or app	IMP supply & re-supply	IMP adherence monitoring	Self-intervention & self-monitoring	1
89	Technology to ensure IMP chain of custody is maintained and documented throughout the process	IMP supply & re-supply	IMP adherence monitoring		1
90	Technology to allow IMP accountability management (recording of doses taken, missed, unused, etc.)	IMP adherence monitoring	Home health visits	Clinic visits	1
91	Technology can incorporate SOPs for the accountability of the supply chain	IMP supply & re-supply			1
92	Technology complies with local laws and regulations regarding direct-to-patient shipping of IMP	IMP supply & re-supply	Home health visits		1
93	Technology allows ongoing safety evaluation and reporting	Home health visits	Telemedicine visits	Self-intervention & self-monitoring	1
94	Technology allows participants to clearly identify and differentiate how to proceed in case of a vital emergency (ask for urgent local medical care) or reporting a serious adverse event through the (mobile) technology	Self-intervention & self-monitoring	Telemedicine visits	Clinic visits	1
95	Technology is able to deliver health services at a distance, real-time or asynchronously	Home health visits	Telemedicine visits	Patient-HCP interaction and communication	1
96	Technology allows patients and physicians to communicate in real-time while maintaining GDPR compliance	Telemedicine visits			1
97	Technology speed, resource usage and response time are sufficient.	Telemedicine visits	Self-intervention & self-monitoring	Home health visits	1
98	Technology permits providers to share patient information with a practitioner in another location	Telemedicine visits	Home health visits	Clinic visits	1
99	Technology allows caregivers to remotely help subjects to better manage interventions/medications	Telemedicine visits	Home health visits		1
100	Technology allows remote caregivers to remotely monitor patients at home by using mobile (medical/consumer) devices to collect data (e.g. blood sugar, blood pressure etc.)	Self-intervention & self-monitoring	Telemedicine visits		1
101	Technology allows site staff and remote monitors to communicate	Telemedicine visits	Home health visits	Clinic visits	1
102	Technology allows not only to identify and monitor deviations (e.g. IP errors, temperature excursions; safety) but also to send triggered notification/alert to site staff and/or monitor (ideally can be defined whom would get notification)	Telemedicine visits	Home health visits	IMP adherence monitoring	1

103	Technology is able to track home visits/telemedicine activities (i.e. staff involved, collected data, completed assessments)	Telemedicine visits	Home health visits		1
104	Technology allows scheduling of appointments and activities	Telemedicine visits	Home health visits	Clinic visits	0,5
105	Technology includes overview of expected activities to be completed at each defined timepoints as reference for patients	Self-intervention & self-monitoring	Home health visits	Telemedicine visits	

BBB: Operations & Coordination

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
106	Technology allows managing the timeline of study (e.g. regulatory complete)	Study oversight	Regulatory Management	Performance monitoring	1
107	Technology allows managing clinical trial contract information (contract timeline, stakeholders, negotiations, etc.)	Study oversight	Documentation management	Inspection facilitation	1
108	Technology allows managing all documents generated during clinical trials, separated by department	Documentation management	Clinical monitoring	Inspection facilitation	1
109	Technology allows identifying a protocol deviation/violation	Manage Protocol and GCP deviations	Safety Management	Inspection facilitation	1
110	Technology allows managing communication with a site or other organization	Vendor management (if other organization are vendors)	Study oversight		0,5
111	Technology allows managing information about interventional product, vendor or sponsor	Vendor management	Study oversight		0,5
112	Technology allow tracking and reporting of Green Light Approvals/Site Activations	Regulatory Management	Performance monitoring	Clinical monitoring	1
113	Technology allows managing patient schedule automatically and displayed in calendar form through the patient management function	Study oversight			1
114	Technology allows managing information about site visit status and results	Operational analytics	Clinical monitoring	Documentation management	1
115	Technology allows managing information related to site-specific SAE	Safety management	Operational analytics	Manage Protocol and GCP deviations	1
116	Technology provides clinical trial management functions related to medical devices from external organizations	Vendor Management	System approval facilitation		1
117	Technology allows managing the clinical drug import and export	Regulatory Management	Study oversight	Documentation management	1
118	Technology allows managing the biomaterial obtained during clinical trials	Vendor Management	Study oversight		1
119	Technology supports SOP management, training and automatic notification by the unit	Inspection facilitation	Documentation management	Study oversight	1
120	Technology provides management functions for tasks to be performed by each user.	Clinical monitoring			0,5
121	Technology allows managing the timeline of study (e.g. regulatory complete)	Study oversight	Regulatory Management	Performance monitoring	0,5

BBB: Close out & Reporting

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
122	Technology enables effective storage, management, and tracking of electronic documents	Archiving			1
123	Technology allows to retrieve, display and re-configure systems parameters and choices made at implementation	Decommissioning			1
124	Technology enables generation of automated medical review summaries based on pre-defined parameters	Producing study report	Publishing of clinical study results	Scientific dissemination of study results	0,5
125	Technology enables generation of automated Clinical study report sections based on pre-defined parameters	Producing study report	Publishing of clinical study results	Scientific dissemination of study results	0,5
126	Technology enables data transfers, archiving, decommissioning of user accounts etc	Decommissioning			1
127	Technology enables creation of CSR appendices from electronic tool (deviations, list of staff (PI and SubI) and others potentially	Archiving			0,5
128	Technology enables tracking and reporting of Close-Out Visits	Study oversight	Operational analytics	Clinical monitoring	1

BBB: Patient engagement

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
129	Technology provides information about the condition, the trial and the IMP	Educational Engagement	Disease Self-management		0,5
130	Technology enables the patient to start communication and collaboration with provider through the technology platform	Interactive Engagement	Disease Self-management	Safety Monitoring	0,5

131	Technology allows user input and contains prompts (reminders, sharing options, notifications, etc.)	Interactive Engagement	Disease Self-management		1
132	Technology enables that data are available online (almost) immediately	Management of study-generated data	Management of study-generated data	Gathering and management of real-life data	1
133	Technology provides rapid feedback available to patient	Educational Engagement	Disease Self-management	Gathering and management of real-life data	1
134	Technology allows to look at trends in patient engagement	Operational Analytics	Patient Adherance		0,5
135	Technology allows providing acknowledgment or thanks for patient participation.	Interactive Engagement			1
136	Technology is able to provide reminders/alerts about scheduled medication, testing, appointments, activities etc.	Interactive Engagement	Patient Adherance	Disease Self-management	1
137	Technology is able to record/track health information and to display and summarize it for patient	Educational Engagement	Disease Self-management	Patient Adherence	1

Appendix 2. Assessment committee member list (preliminary)

Academic leads		
Jaap Trappenburg	UMCU	
Arnela Haagmans - Suman	UMCU	
Hans Reitsma	UMCU	
Patricia Bruijning	UMCU	
Jeroen de Bruin	Joanneum	
Sten Hanke	Joanneum	
Robert Rehb	Joanneum	
Jaime Fons,	Fisabio	
Lina Perez Breva	Fisabio	
Javier Diez-Domingo	Fisabio	
Clinical trial / BBB-specfic experts		
Rebecca Jackson	Janssen	Patient engagement
Eric Houtman	JCR	
Gary Friedman	Pfizer	Set-up & design
Yonni Shem-Tov	TEVA	
Lampros Mpaltadoros	CERTH	Data acquisition & processing
Loulietta Lazarou	CERTH	Data acquisition & processing
Thanos Stavropoulos	CERTH	Data acquisition & processing
Tanja Keiper	MERCK	Recruitment & Enrollment
Cinzia Molendini	Themrn	Intervention & follow-up
David Dronneau	Sanofi	Intervention & follow-up
Nina Reyes	Covance	Operations & Coordination
Kasia Cieślak	Janssen	Operations & Coordination
Technical experts		
Jeroen de Bruin	Joanneum	
Rob Luscombe	Janssen	
Legal experts		
To be defined		