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Center of Excellence – Remote Decentralised Clinical Trials

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D2.8 Updated summary and detailed report with recommendations for integrated technologies to be used in RDCT and hybrid approaches, based on pilot findings

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1. Abstract

This report provides a comprehensive summary of the integrated technologies deployed in the RADIAL pilot trial and offers practical recommendations for their application in future Decentralized Clinical Trials (DCTs) and hybrid trial designs. Drawing from operational insights, validation documentation, and implementation learnings, the report outlines the selection, qualification, deployment, and post-go-live management of the RADIAL technology package. The solution combined a central platform (Clinpal) with a suite of components that were integrated to varying degrees, or operated as stand-alone tools. These included eConsent and telemedicine capabilities, a participant-facing mobile application (RADIAL app), Bluetooth-enabled glucometers and insulin smart caps, a randomization and trial supply management system (RTSM), an electronic medication adherence platform (MEMS), and a recruitment and pre-screening website. Each component was assessed against predefined quality, usability, and compliance criteria to ensure regulatory alignment, operational feasibility, and scalability.

While the technologies successfully supported trial decentralization and improved participant accessibility and oversight, the pilot also revealed critical challenges, particularly in areas of interoperability, real-world usability, and support structures. The findings highlight that effective technology deployment in DCTs depends not only on technical performance, but also on robust governance, user readiness, and integrated planning.

The report concludes with targeted recommendations to guide the adoption and scaling of integrated technologies in future decentralized and hybrid studies, contributing to the evolution of participant-centric, digitally enabled clinical research.

2. Introduction

The RADIAL study, conducted within the framework of the EU-funded Trials@Home project, served as a pan-European pilot to explore the feasibility, utility, and regulatory acceptability of integrated digital technologies in supporting DCTs. Through a three-arm design—Conventional, Hybrid, and Remote—the trial systematically evaluated the performance of a multi-component technology package across varying levels of decentralization. This report presents an updated summary and recommendations regarding the technologies deployed in RADIAL, with the aim of informing their future application in DCT and hybrid clinical trial designs. It consolidates key lessons learned, assesses the suitability and scalability of selected digital solutions, and provides guidance for their sustainable implementation in future trials.

The technologies examined include core components such as the main platform, which encompassed the electronic data capture (EDC), eConsent, telemedicine and a participant-facing mobile app, which together enabled digitalization of trial operations across participants, sites, sponsors, and vendors. The analysis draws on evidence from the technology selection and qualification process, system validation and integration activities, post-go-live change management, and operational feedback captured throughout the trial lifecycle.

This report is intended for stakeholders involved in the design, procurement, oversight, and operationalization of DCT technologies, including project leads, data managers, technology vendors, regulators, and sponsors. It seeks to provide both strategic guidance and practical insights for DCT design and execution.

The report is structured to follow the lifecycle of the technology implementation – starting with selection, integration, and validation, followed by an analysis of operational performance and concluding with practical recommendations and next steps for future deployments.

3. Overview of the Technology Package in the Pilot

The RADIAL pilot implemented a modular and interoperable technology package to support end-to-end activities trial across its three arms - Conventional, Hybrid, Remote. The technology stack was designed to enable decentralized capabilities such as remote consent, home-based data collection, and direct-to-patient drug delivery, while ensuring compliance with GCP, GDPR, and national regulations in the five participating EU countries: Germany, Italy, the Netherlands, Poland, and the United Kingdom.

3.1 Technology Components and Integration

Each technology component served a defined purpose and while some tools were embedded within the main platform, others were integrated through APIs or file-based exchanges, and a few operated independently with manual data reconciliation. The table below summarizes the key components, their core functions, and level of integration.

Component	Functionality	Integration Type
Main Platform – Clinpal	Served as the EDC and central orchestrator for eConsent, ePRO, telemedicine, site/patient dashboards, drug shipments, and lab results.	Core system, hub for most integrations (API and native modules).
eConsent System	Enabled electronic consent using QES, automated identity verification, and multimedia content. Accessible via RADIAL App and Clinpal.	Embedded in Clinpal, no additional integration required.
Telemedicine Platform	Enabled secure video consultations (Remote & Hybrid arms), particularly for consent, safety assessments, and follow-ups.	Integrated with Clinpal, web-based embedding and scheduling sync.
Mobile App (RADIAL app)	Provided access to trial tasks, reminders, ePROs, secure messaging, barcode scanning for lab samples, and training content.	Partially integrated, bidirectional data flow with Clinpal via API.
Connected Devices:	Collected insulin dosing and glucose data. Mallya data passed through MEMS App; glucometer via Bluetooth to the app.	Indirect integration via middleware (MEMS App), some manual data reconciliation.
• *Mallya® Smart Cap*		
• *Bluetooth Glucometer*		
MEMS App & Adherence Platform	Tracked medication adherence and provided visualizations to study teams. Summary data linked to participant profiles.	Stand-alone, summary data imported to Clinpal via data transfers.
RTSM System	Managed randomization, drug allocation, and shipment triggers.	Integrated with Clinpal through automated data exchange and logic triggers.
Logistics System	Processed prescriptions, shipping addresses, and coordinated study material delivery.	Connected to RTSM, no integration with Clinpal.
Lab Portal	Captured central lab results (e.g., HbA1c) and uploaded data into Clinpal.	Data entry performed by clinical site personnel
Learning Management System (LMS)	Delivered training to sites and participants. Training completion status integrated with go-live readiness.	Integrated with Clinpal and the RADIAL App.
Study Website (Pre-Screener)	Hosted eligibility screener for public-facing participant recruitment.	Stand-alone.

3.2 Integration Approach

The RADIAL technology package followed a hub-and-spoke model, with the main platform (Clinpal) acting as

the central orchestrator for communication between the various technology components. Integration was achieved through a combination of API connections, secure file exchanges, and manual workflows where full automation was not feasible. Interoperability was a key focus, particularly for components handling patient-reported data and device outputs.

Each integrated component was selected based on its technical capability, regulatory compliance status, language support, and alignment with the patient population needs. Customizations were implemented as needed to ensure each technology component fit seamlessly within RADIAL's operational workflows and the distinct requirements of each arm.

3.3 Deployment Across Study Arms

- **Conventional Arm:**
  Employed limited digital tools, with most activities conducted on-site. EDC and RTSM components were active, with telemedicine and eConsent not used.
- **Hybrid Arm:**
  Combined on-site visits with selected remote activities. Telemedicine, eConsent, and the RADIAL app were introduced, with moderate device integration.
- **Remote Arm:**
  Delivered a near-fully decentralized experience. Participants completed consent, visits, training, and reporting remotely. The arm utilized the full technology stack, including eConsent, telemedicine, treatment adherence device, glucometer, the RADIAL mobile app, RTSM, direct-to-patient IMP shipment and home nursing.

3.4 Rationale and Objectives

The technology package was designed to:

- Validate decentralized workflows in a GCP-compliant and patient-centric manner.
- Assess integration feasibility of multiple systems in a pan-European trial.
- Provide learnings for scalable adoption of digital solutions in future DCTs.
- Compare operational performance and participant engagement across arms.

The RADIAL pilot served as a testbed for these objectives, enabling structured evaluation of what worked well, what needed refinement, and what could be recommended for broader implementation in future hybrid or decentralized trials.

4. Technology Selection and Qualification Process

The selection and qualification of the technology package for the RADIAL pilot trial followed a structured, multi-phase process to ensure that all solutions met rigorous standards for quality, regulatory compliance, usability, and suitability for a decentralized or hybrid trial design. This process combined internal consortium activities, public calls, and formalized assessment methodologies to identify, evaluate, and qualify technologies for use across all trial phases and Basic Building Block activities (BBBs).

4.1 Process Overview

Technology identification and evaluation were conducted through a **three-phase approach**:

1. **RFI Conceptualization Phase:**
   Both internal and public Requests for Information (RFI) were developed to gather relevant data on potential vendors and solutions. In parallel, a **technology scan** was conducted to identify and map

commercially available technologies against trial requirements. This phase also included the drafting of a comprehensive list of technology quality and functionality criteria based on literature review, regulatory requirements, and expert stakeholder input.

2. **RFI Submission and Data Collection:**
   This phase involved two parallel streams:
   - Internal RADIAL partners submitted candidate technologies directly.
   - A public RFI call invited external organizations to submit technology proposals aligned with BBB needs.

Vendors completed structured self-assessments against the defined criteria and submitted supporting documentation—such as certifications, screenshots, process diagrams, and sample outputs.

3. **Evaluation and Qualification:**
   A detailed review was carried out by assessment committees comprising internal experts and independent stakeholders (including the IMI Scientific and Ethical Advisory Board). The evaluation considered:
   - Alignment with predefined 137 quality criteria.
   - Suitability for the assigned BBB.
   - Vendor response quality and documentation.
   - Demonstrated ability to scale, integrate, and operate in a pan-EU clinical environment.

Technologies pre-selected from internal Trials@Home partners were reviewed with equal scrutiny.

4.2 Quality Assessment Criteria

The **137 criteria** formed the cornerstone of the qualification process. They covered seven thematic domains:

- **Regulatory Compliance:** Adherence to GCP, GDPR, ISO standards, and data privacy principles.
- **Security & Access Control:** Password policies, audit trails, role-based access, encryption.
- **Data Integrity & Reliability:** Validation procedures, record retention, system auditability.
- **Usability & Accessibility:** Language support, accessibility features, hardware requirements, localization.
- **Integration & Interoperability:** Compatibility, API readiness, metadata exchange standards.
- **Operational Functionality:** Task tracking, IMP logistics, site communication, remote visit tracking.
- **Patient-Centric Features:** Alerts, reminders, communication tools, e-consent, access to signed forms.

These criteria were assessed not only for compliance but also for RADIAL-specific relevance, distinguishing between universally important DCT features and features that were uniquely impactful for this pilot trial setup.

4.3 Evaluation Tools and Scoring

Each technology submission was scored using structured templates:

- A weighted scoring system was applied to differentiate “essential,” “important,” and “desirable” features.
- Comments and qualitative assessments were gathered to flag strengths, weaknesses, and areas of concern.
- Where needed, vendors were invited to give live presentations or demonstrations to support evaluation and allow direct Q&A with assessors.

Findings were consolidated into vendor scorecards and reviewed during joint decision-making sessions with governance oversight.

4.4 Integration with Compliance and Risk Planning

The qualification process was designed to feed directly into the Compliance Plan and User Acceptance Testing (UAT) Strategy:

- Only vendors who met minimum thresholds across all relevant criteria were onboarded.
- The evaluation records (including scoring templates, assessor team comments, and supporting documentation) were retained as part of the validation package.
- Risk assessments were initiated early, and a corresponding mitigation strategy was documented in the risk management plan.

While this process was followed for all external solutions, not all vendors underwent full qualification. Technologies that had been successfully validated within the past two years by any Trials@Home consortium member were accepted without repeating the full qualification cycle. In these cases, prior validation was deemed sufficient based on documented compliance and evidence of functional deployment. However, this pragmatic approach also introduced a risk: previous qualifications may not have fully aligned with RADIAL's specific use cases, and workflows. These gaps were acknowledged but not formally mitigated, reflecting a conscious trade-off in favour of efficiency, given the limited time and budget available during the pilot preparation phase.

4.5 Outcome

The selection process resulted in a cohesive and purpose-built technology package that reflected both strategic innovation (e.g., inclusion of Mallya adherence sensors and a site/patient app) and practical operability across multiple sites and countries. By leveraging a modular design anchored by a central platform (Clinpal), the technology ecosystem supported both a centralized coordination and a decentralized delivery model.

Despite time and budget constraints, the structured approach to selection and qualification laid a strong foundation for execution, risk awareness, and adaptive learning.

5. Analysis of Technology Performance in the Pilot

The RADIAL pilot offered a valuable opportunity to assess the performance of a multi-component, integrated technology package in a real-world, multi-country setting using a hybrid and decentralized clinical trial model. Conducted across five European countries, the trial tested how digital technologies performed under routine operational conditions—evaluating their feasibility, reliability, usability, and acceptability by participants, investigators, and site staff.

This section provides a performance overview of the key technology components, drawing on data from UAT, helpdesk logs, system performance metrics, and qualitative feedback gathered throughout the study.

5.1 Overall System Functionality

The integrated technology platform—centred around the Clinpal EDC and participant management environment—demonstrated high reliability across the three trial arms (Conventional, Hybrid, and Remote). Most components were successfully integrated via secure APIs or web-based modules, allowing:

- Real-time data entry and synchronization,
- Centralized participant status tracking,
- Role-based access for investigators, site staff, participants and monitors.

No major system outages or critical compliance issues were reported in production. System availability met the expected and defined uptime targets (>95%), and most helpdesk tickets were resolved within agreed SLAs.

5.2 Performance of Key Technology Components

Technology Component	Role in Trial	Performance Summary
Clinpal Platform (EDC, eConsent, RADIAL App)	Core participant and site management, eConsent, visit scheduling, and data capture	The platform was stable and integrated effectively with other systems. While minor usability and functionality issues were identified during production use, these were resolved promptly. Updates were typically deployed during weekends or after hours to avoid disruption to site or participant activities. In addition, all system updates were communicated to users in advance. The absence of major incidents and the sustained use of the system across arms indicate acceptable usability and system performance.
Telemedicine Platform	Remote consultations and site visits	Successfully enabled remote investigator-participant interactions. Initial setup required production testing due to live connectivity constraints. No critical issues during go-live.
Mallya Smart Cap Device	Used for insulin pen monitoring and dose adherence tracking.	The device demonstrated promising accuracy in recording injection events. However, Bluetooth connectivity issues were observed, particularly in the BYOD context, requiring additional support for successful pairing and data transfer. Integration with the platform via the MEMS App worked as expected, enabling summary adherence data to be available to study teams.
Bluetooth-Enabled Glucometers	Self-monitoring of blood glucose	Data syncing and visualization generally met expectations. However, the Bring Your Own Device (BYOD) approach introduced variability in smartphone compatibility and Bluetooth connectivity, leading to technical issues in some cases. Additional onboarding support and troubleshooting guidance were often needed.
Home Visit Coordination Tools	Logistics for nurses and direct-to-patient activities	Coordination of home visits between the site/PI, home nurse and IMP vendor were managed via weekly calls between the clinical operations team, home nurse vendor and DtP IMP vendor. Manual tracking via a spreadsheet was implemented when logistic challenges caused a delay to the first hybrid home visit. Overall, 53 hybrid home visits were successfully completed and entered into EDC.

5.3 Integration and Data Flow

A key enabler of success in the RADIAL pilot was the ability to maintain consistent, accurate data flow across multiple interconnected systems. Ensuring traceability, auditability, and near real-time access to participant data across platforms was essential for operational oversight and regulatory compliance.

Key observations include:

- Data flow between eConsent, visit scheduling, the RADIAL app, and the EDC system (Clinpal) was largely seamless, supporting smooth coordination of trial activities and reducing manual reconciliation.
- Audit trails for informed consent were compliant with regulatory requirements, providing a clear record of signature events and user identities.
- Frequent syncing issues were observed with third-party devices, particularly due to Bluetooth

connectivity problems in the BYOD setup. These problems were often hard to troubleshoot remotely. As a result, a manual workaround was introduced to allow participants to enter their data via the app to maintain data continuity.

While the modular platform architecture allowed for easy identification of affected components, in some cases involving Bluetooth connectivity, technical fixes were not feasible within the trial timeframe. This highlights the need for rigorous compatibility testing, improved connectivity planning, and potentially rethinking the BYOD strategy—which, although selected for budgetary reasons, proved challenging in ensuring consistent device performance and user experience.

5.4 Risk-Based UAT and Dry Run Impact

Given the evolving specifications and project time constraints, the pilot adopted a risk-based UAT approach. UAT was conducted effort-by-effort, with technologies only included in the integrated Dry Run once they had reached a defined maturity threshold. This phased approach:

- Allowed testing of critical patient journeys in a near-live environment.
- Reduced the risk of blocking deployment due to isolated component delays.
- Was validated by the fact that no critical production issues emerged post go-live.

In cases where technologies required live testing in the production environment (e.g., Telemedicine), a two-phase release model was followed. Only after successful testing with restricted access was full go-live authorized.

5.5 Observed Challenges and Mitigations

Despite the overall success of the RADIAL technology package, several operational challenges emerged during implementation and live use. These challenges stemmed from technical limitations, user variability, and the realities of deploying multiple fully or partially integrated components in a real-world setting. The table below summarizes key issues encountered during the pilot and the mitigation strategies applied to address them in a timely and pragmatic manner.

Challenge	Description	Mitigation Strategy
Live integration testing constraints	Some integrations (e.g., telehealth) could not be fully validated in the dev environment	Applied phased go-live approach with restricted production testing.
Data synchronization across devices	Syncing lags for device-generated data, especially from Bluetooth-enabled devices in a BYOD context. These delays impacted data visibility and monitoring timelines.	Enhanced participant onboarding support, connectivity troubleshooting guides, and access to live support were provided. A manual data entry option was also introduced as a fallback in persistent cases.
User familiarity with the technology components	Variations in digital literacy among participants affected comfort and confidence when using tools like eConsent, especially since some technologies were only used once during the trial. Initial training alone was not always sufficient.	Delivered simple instructions and training materials. Participants also received ongoing support from CRAs, the tech support team. In some cases, real-time support was offered to address issues as they arose and reinforce technology use where needed.

5.6 Conclusions on Performance

The technology package implemented in the RADIAL pilot successfully supported the operational delivery of a hybrid and decentralized clinical trial across multiple European countries. While the system met its core objectives and enabled the conduct of key decentralized processes, several practical challenges were

encountered—particularly around device connectivity, BYOD variability, and participant familiarity with digital tools.

Despite these limitations, the overall performance of the platform was stable, and many technical issues were mitigated through phased deployment, targeted user support, and structured governance. The pilot demonstrated that with a modular and well-orchestrated approach, digital trial components can be effectively deployed at scale—provided there is adequate planning for integration, testing, and contingency support.

These findings highlight the critical role of early system validation, interoperability planning, and ongoing risk management in ensuring the reliability and user experience of decentralized trial technologies.

6. Post-Go-Live Management and Support

Following the production release, robust governance mechanisms were activated to ensure the stability, compliance, and ongoing performance of the deployed technology package. This phase focused on issue tracking, change management, and user support, all of which were essential for minimizing disruptions and enabling a seamless participant and site experience throughout the trial.

6.1 Governance Structure and Monitoring Activities

Post-go-live operations were coordinated through weekly governance meetings involving representatives from the technology team, operations, data management, and quality assurance. These meetings ensured:

- Timely identification, assessment and resolution of issues
- Prioritization of Change Requests (CRs) and bug/hot fixes
- Oversight of user feedback and system/documentation enhancements

All issues were logged in a centralized system and triaged based on impact, urgency, and risk. The governance team maintained full traceability of open and resolved items, including justification for any deferred fixes.

6.2 Helpdesk Monitoring and Issue Resolution

A centralized helpdesk ticketing system captured user-reported problems and technical incidents from both study teams and participants. Key observations include:

- Most tickets were resolved within target timelines.
- Common queries related to device pairing, login issues, and consent document access.
- System-level problems were minimal and resolved through backend configuration updates or user guidance.

Helpdesk findings were reviewed weekly to identify systemic issues or patterns warranting broader fixes or updates.

6.3 Knowledge Base (KB) and User Empowerment

To complement direct support, a comprehensive Knowledge Base (KB) was developed, specifically tailored to the RADIAL technology environment. It included:

- Step-by-step guidance documents,
- Visual walkthroughs and quick-reference materials,
- FAQs and troubleshooting guides aligned with the most common helpdesk issues.

The KB was regularly updated based on ticket trends, system changes, and user feedback, allowing users to resolve common issues independently and improving support scalability.

6.4 Change Management and Improvements

Over the course of the post-go-live phase, the governance team logged and implemented:

- 13 CRs – primarily for country-specific translations and usability improvements
- 3 bug fixes – addressing minor system behaviours that did not impact data integrity
- 6 formal change logs – tracking changes made to system behaviour and user-facing features.

Change requests were assessed based on whether they addressed critical bugs, usability enhancements, or study-specific refinements. All changes underwent risk assessment and validation prior to deployment.

6.5 Communication with Sites and Users

To ensure transparency and minimize disruptions:

- Planned outages and maintenance windows were proactively communicated to sites
- Users were notified of system enhancements or known issues via site newsletters or in-app alerts
- Updates to training materials or KB entries were highlighted for end users.

This structured communication approach fostered trust, reduced frustration, and supported the adoption of new system features.

6.6 Lessons Learned for Future Deployments

The post-go-live phase yielded several operational insights:

- A phased release approach, where necessary, allowed live testing of critical components without compromising trial timelines.
- A responsive governance structure with short decision cycles facilitated timely resolution of technical and operational issues.
- Empowering users through self-service resources such as the KB, quick guides, and FAQs helped to keep dependency on the helpdesk low and contributed to higher user satisfaction.

Overall, the post-go-live management framework in RADIAL demonstrated a strong model for supporting hybrid and remote trials, ensuring system robustness and enabling proactive adaptation to user needs.

7. Summary of Findings and Recommendations

This section summarizes the key observations from the implementation and evaluation of the integrated technology package used in the RADIAL pilot and outlines strategic recommendations for future Remote Decentralized Clinical Trials (RDCTs) and hybrid approaches.

7.1 Key Findings

1. Risk-Based UAT Strategy Enabled Controlled Deployment

- The UAT framework was structured across multiple efforts, allowing component-level validation followed by integrated workflow testing.
- A phased release strategy was adopted, particularly for technologies that could not be fully validated in test environments (e.g., telemedicine), enabling restricted production testing before full go-live.

2. Compliance and Validation Were Adequately Addressed

- The technologies selected met core regulatory expectations (e.g., GCP, GDPR, 21CFR Part 11), supported by risk-based assessments.
- While formal qualification was not repeated for consortium-pre-validated technologies, supporting

documentation and prior validation history were considered sufficient for onboarding.

- A Risk Management Plan was used to track risk assessments and mitigation strategies, especially for novel components.

3. Clear Alignment with Decentralized Trial Objectives

- The solution covered all major DCT building blocks: eConsent, ePRO, remote visits, training, IMP distribution, participant support, and adherence tracking.
- Integration with the central platform (Clinpal) enabled coordination across modules and streamlined oversight, even across five EU countries with varying regulatory contexts.

4. Technology Readiness Was Strong, but Integration Remained a Challenge

- Most components were commercially available and proven in real-world healthcare or research settings.
- However, combining them into RADIAL's modular architecture introduced integration challenges, especially in data handoffs and multi-language implementations.
- Third-party devices used under a BYOD model created syncing and connectivity challenges that impacted data completeness and required fallback options.

5. Effective Post-Go-Live Governance Supported Stability

- A responsive, multi-stakeholder governance structure enabled timely triage of incidents, change requests, and user feedback.
- A RADIAL-specific Knowledge Base and structured communications (e.g., proactive alerts, updates) improved user empowerment and kept helpdesk load low.
- All changes were tracked, risk-assessed, and implemented without disrupting trial continuity, aided by careful scheduling of updates (e.g., after hours or weekends).

7.2 Recommendations for Future DCT/Hybrid Setups

Technology Selection

- Retain the multi-step evaluation and quality criteria process from RADIAL, with clearly defined "essential," "important," and "desirable" categories.
- Extend the qualification strategy to distinguish between fully qualified and previously validated technologies but ensure reassessment where use-case or deployment context differs.
- Include early usability assessments involving both patients and site staff to account for diverse digital literacy levels and accessibility needs.
- Where budget allows, consider avoiding high-risk BYOD strategies for critical connected devices; if BYOD is pursued, require stringent compatibility pre-checks and clear fallback options.

Testing and Validation

- Maintain the modular UAT strategy used in RADIAL, ensuring each technology is validated individually and in integrated flows.
- Retain the phased go-live model, especially for platforms (e.g., telemedicine) where live connectivity and data security can only be fully tested in production.
- Allocate additional time and resources to validate multi-language content, especially in interactive modules like eConsent.

Data and System Governance

- Continue robust documentation of UAT outcomes, deviations, dry-run results, and change control logs to ensure audit-readiness.
- Implement live data flow mapping covering device data, external lab portals, and middleware apps, with explicit traceability for each transfer point.
- Designate a cross-functional compliance lead to monitor alignment with GCP, GDPR, and country-specific digital health requirements.

Support and Maintenance

- Retain the RADIAL post-go-live governance model, including:
  - Weekly issue triage with IT, data, and operations.
  - Risk-based prioritization of bug/hot fixes and enhancements.
- Maintain and actively update a study-specific knowledge base to support end-users, aligned with ticket patterns and feedback.
- Where feasible, use dashboards to automate visibility into ticket trends, open change requests, and usage statistics, aiding continuous improvement.

Participant and Site Experience

- Embed inclusive design early: test with real users from target populations, including those with low digital literacy, vision impairments, and language diversity.
- Empower participants with multiple communication preferences (SMS, app, email), flexible re-consent tools, and reminders.
- Ensure self-service functions (e.g., document retrieval, appointment rescheduling, health summaries) are intuitive and multilingual.
- Provide onboarding support beyond digital tutorials—via phone, live chat, or site staff facilitation when necessary.

Data Integration and Interoperability

- Prioritize technologies with proven API capabilities and EDC-readiness, reducing dependency on manual data reconciliation.
- Establish shared integration guidelines and data mapping templates across vendors to align on standards like CDISC and HL7.
- Create centralized data aggregation layers that support real-time ingestion and facilitate cross-system monitoring.

8. Abbreviations

Term	Definition
API	Application Programming Interface. A set of protocols and tools for building software applications and enabling system integration.
CDISC	Clinical Data Interchange Standards Consortium. A global standards development organization that provides data standards to streamline clinical research and enable data sharing.

Clinpal	The Electronic Data Capture (EDC) system used in the RADIAL trial, offering integrated support for eConsent, ePRO, and participant tracking.
CR (Change Request)	A formal request to modify or enhance a system, often logged post-go-live to address usability, translation, or functional issues.
DCT (Decentralized Clinical Trial)	A clinical trial that uses digital tools and remote processes to conduct study activities without requiring participants to visit a central trial site.
eConsent	Electronic Informed Consent. A digital process through which participants review and sign informed consent forms.
ePRO	Electronic Patient-Reported Outcomes. Digital capture of participants' health status or responses directly through an electronic system.
EDC (Electronic Data Capture)	Software used to collect, manage, and store clinical trial data in electronic format.
EMA	European Medicines Agency. The regulatory authority for evaluation and supervision of medicinal products in the EU.
FDA 21 CFR Part 11	U.S. regulation establishing requirements for electronic records and electronic signatures to ensure they are trustworthy and equivalent to paper records.
GDPR	General Data Protection Regulation. A regulation in EU law on data protection and privacy for individuals within the European Union.
GCP (Good Clinical Practice)	An international quality standard for designing, conducting, recording, and reporting trials involving human participants.
IMP	Investigational Medicinal Product. A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial.
ISO	International Organization for Standardization. An independent body developing international standards, including those for information security and medical device software.
KB (Knowledge Base)	A centralized digital repository of documentation, FAQs, guidance materials, and training content to support system users.

MEMs	Medication Adherence Software (dashboard, analytical solutions, monitoring)
RADIAL	The Trials@Home pilot study implementing a hybrid DCT model across three trial arms: Conventional, Hybrid, and Remote.
RDCT	Remote Decentralized Clinical Trial. A clinical trial where study activities are conducted remotely using digital and mobile health technologies.
SOP	Standard Operating Procedure. A set of step-by-step instructions compiled to help workers carry out routine operations.
UAT (User Acceptance Testing)	A validation process where end users test whether a system meets business and functional requirements and is ready for production deployment.

9. Appendix

Quality Criteria

BBB Group	Nr.	Criterion
Generic	1	Technology/system is compliant with applicable privacy and safety standards and regulations, such as FDA, GDPR, MDR, ISO.
	2	Technology allows multiple simultaneous accesses and edits from multiple locations (web/cloud-based access) locations (web/cloud-based access).
	3	Technology has strong password requirements (e.g. two-factor authentication, does not allow to save password on device).
	4	Unauthorized log-in attempts are limited and recorded.
		Technology enables automatic log-off for long, idle periods (e.g. at least 15 minutes).
	6	Technology enables protection of records to enable their accurate and ready retrieval throughout the records retention period.
	7	Technology enables restriction of user access to data with different levels of access permission.
	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).
	9	The technology production units are tested under actual or simulated use conditions.
	10	The system interface is at least in the local language (of the specific country, and approved by EC) and in English.
	11	Technology (visual information, language, design) is appropriate for the target audience
	12	Technology should allow participants to select preferred way of communication (phone, email etc.).
	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.
	14	Technology provider has a business continuity plan.
	15	Technology manufacturer provides sufficient (e-) training tools such as user manual or instructional videos for the technology users.
	16	Technology updates are seemless (without interruption of functionalities).
	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.
Set-up & Design	18	Technology is able to share documents with potential sites to analyze site feasibility.
	19	Technology is able to perform and track online Investigator/Site Staff Training.
	20	Technology is able to track pre study visits.
	21	Technology enables automated site/patient payments.
Recruitment & Enrolment	22	Information materials given during informant consent process are accessible to participants.
	23	Technology allows PI oversight with regards to coordination and management of the informed consent procedure.

	24	Participant has access to the informed consent application and his/her signed consent form (not only members of the research team).
	25	Technology verifies the authenticity of the informed consent document.
	26	Technology allows the investigator to contact the participant directly.
	27	Technology allows the participant to contact the investigator directly.
	28	Technology saves information during the process (not only after completing steps).
	29	Technology allows adequate access for external monitors to check the informed consent procedure.
	30	Technology evaluates/tracks metrics (i.e. time-of-use schedule, approval deadlines, number of findings during monitoring, revocation rate).
	31	Technology allows participant to choose the format/media for receiving a copy of the signed consent form.
	32	Technology has the possibility of signing with electronic signature
	33	Technology has an official certificate for signing with electronic signature
	34	Technology is adapted to use by low literate participants
	35	Technology is adapted/adaptable to use by participants with special needs (i.e. vision problems)
	36	Technology allows investigator/participant to change language
	37	Technology offers the possibility of re-consent after amendments to the protocol
	38	In case of amendments and re-consent, the technology highlights relevant changes for participants for quick and easy identification of changes
	39	Technology includes validated methods to verify inclusion and exclusion criteria of a subject for trial participation
	40	The enrollment data allow for daily visualization of enrollment statistics such as eligibility and enrollment rates, stratified numbers and proportions
	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
	42	Technology includes a portal or landing page with outreach to patients via social media, technology platform

	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)
Data Acquisition & Processing	44	Technology is able to classify each data point (participant identification, endpoint or safety-related data).
	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.
	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.
	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)
	48	Technology safeguards records are available for country-specific regulatory inspections during the study
	49	Technology safeguards records are independently preserved at clinical site and/or some other designated site (e.g. technology provider)
	50	Technology safeguards data generated is easily accessible for retrieval throughout the records retention period
	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
	52	Validation of data collection/measurements has been done in a controlled environment (the laboratory or clinic) and a real-world environment
	53	If algorithms are used, the process by which the algorithm was developed is published or otherwise made freely available
	54	The technology includes a system to collect and preserve clinical data which is pre-managed and validated according to SOP (Standard Operation Procedures)
	55	The technology is able to discern invalid or altered records
	56	Technology generates electronic data that meets the same or better data quality and integrity as traditional/paper records

	57	Technology allows collection of sufficient contextual information to understand the outcome data captured by mobile technologies while avoiding the collection of intrusive data
	58	Technology allows collection of metadata indicating source of the data and a UTC time stamp
	59	Technology safeguards data monitoring occurs in an automated, centralized fashion so that discovery of irregular data calibration errors, can be flagged and investigated
	60	Technology uses Electronic Prompts, Flags, and Data Quality Checks in the eCRF
	61	Technology provides the possibility for clinical investigator to review and electronically sign the completed eCRF for each subject
	62	Technology provides the possibility for clinical investigator to be masked to specific data in the eCRF
	63	Technology allows automated de-duplication, filtering, and parsing of data
	64	Technology ensures that quality of data captured by mobile technologies is monitored centrally through automated processes
	65	Technology automatically transfers individual participant data to a central server or other data gathering platform for the trial
	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
	67	Technology allows to demonstrate that the data have not been corrupted following creation
	68	Technology safeguards presence of data element identifiers
	69	Technology ensures secure, computer-generated, time-stamped, electronic audit trails of users' actions and changes to data.
	70	Technology ensures audit trails can not be overridden.
	71	Data elements are in line with clinical interchange standards such as CDISC (Clinical Data Interchange Standards Consortium).
	72	Technology restricts users' access to data so they cannot tamper with them.
	73	Technology has includes a robust, risk-based data security system
	74	Technology has limited amount of data stored on a mobile device

	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)
	76	Technology has data security measures in place such as data encryption, checksums and tokenization in place
	77	Technology includes services such as backups and disaster recovery arrangements in service level agreements with outsourced electronic service vendors
	78	Devices into or onto which data are stored are "scrubbed" at a proscribed time interval by the app/programmer.
	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
	80	Technology uses a protocol Secure (HTTPS), or similar secure file transfer protocol such as SFTP (Secure File Transfer Protocol)
	81	Technology includes firmware that maintains data equivalence
	82	Firmware that ensures data security is optimized
Intervention & Follow-up	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
	84	Technology is able to identify IMP errors
	85	Technology is able to manage packaging and labeling requirements
	86	Technology provides a planning tool for study supplies demand and production according to study design and requirements
	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
	88	Technology allows participants to schedule IMP deliveries through an online portal or app

	89	Technology to ensure IMP chain of custody is maintained and documented throughout the process
	90	Technology to allow IMP accountability management (recording of doses taken, missed, unused, etc.)
	91	Technology can incorporate SOPs for the accountability of the supply chain
	92	Technology complies with local laws and regulations regarding direct-to-patient shipping of IMP
	93	Technology allows ongoing safety evaluation and reporting
	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
	95	Technology is able to deliver health services at a distance, real-time or asynchronously
	96	Technology allows patients and physicians to communicate in real-time while maintaining GDPR compliance
	97	Technology speed, resource usage and response time are sufficient.
	98	Technology permits providers to share patient information with a practitioner in another location
	99	Technology allows caregivers to remotely help subjects to better manage interventions / medications
	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.)
	101	Technology allows site staff and remote monitors to communicate
	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)
	103	Technology is able to track home visits / telemedicine activities (i.e. staff involved, collected data, completed assessments)
	104	Technology allows scheduling of appointments and activities
	105	Technology includes overview of expected activities to be completed at each defined timepoints as reference for patients

]	106	Technology allows managing the timeline of study (e.g. regulatory complete)
	107	Technology allows managing clinical trial contract information (contract timeline, stakeholders, negotiations, etc.)
	108	Technology allows managing all documents generated during clinical trials, separated by department
	109	Technology allows identifying a protocol deviation/violation
	110	Technology allows managing communication with a site or other organization
	111	Technology allows managing information about interventional product, vendor or sponsor
	112	Technology allow tracking and reporting of Green Light Approvals/Site Activations
	113	Technology allows managing patient schedule automatically and displayed in calendar form through the patient management function
	114	Technology allows managing information about site visit status and results
	115	Technology allows managing information related to site-specific SAE
	116	Technology provides clinical trial management functions related to medical devices from external organizations
	117	Technology allows managing the clinical drug import and export
	118	Technology allows managing the biomaterial obtained during clinical trials
	119	Technology supports SOP management, training and automatic notification by the unit
	120	Technology provides management functions for tasks to be performed by each user.
	121	Technology allows managing the timeline of study (e.g. regulatory complete)

Close out & Reporting	122	Technology enables effective storage, management, and tracking of electronic documents
	123	Technology allows to retrieve, display and re-configure systems parameters and choices made at implementation
	124	Technology enables generation of automated medical review summaries based on pre-defined parameters
	125	Technology enables generation of automated Clinical study report sections based on pre-defined parameters
	126	Technology enables data transfers, archiving, decommissioning of user accounts etc
	127	Technology enables creation of CSR appendices from electronic tool (deviations, list of staff (PI and SubI) and others potentially
	128	Technology enables tracking and reporting of Close-Out Visits
Patient Engagement	129	Technology provides information about the condition, the trial and the IMP
	130	Technology enables the patient to start communication and collaboration with provider through the technology platform
	131	Technology allows user input and contains prompts (reminders, sharing options, notifications, etc.)
	132	Technology enables that data are available online (almost) immediately
	133	Technology provides rapid feedback available to patient
	134	Technology allows to look at trends in patient engagement
	135	Technology allows providing acknowledgment or thanks for patient participation.
	136	Technology is able to provide reminders/alerts about scheduled medication, testing, appointments, activities etc.
	137	Technology is able to record/track health information and to display and summarize it for patient

Vendor scorecard template – Example from bucket Patient Concierge & Helpdesk

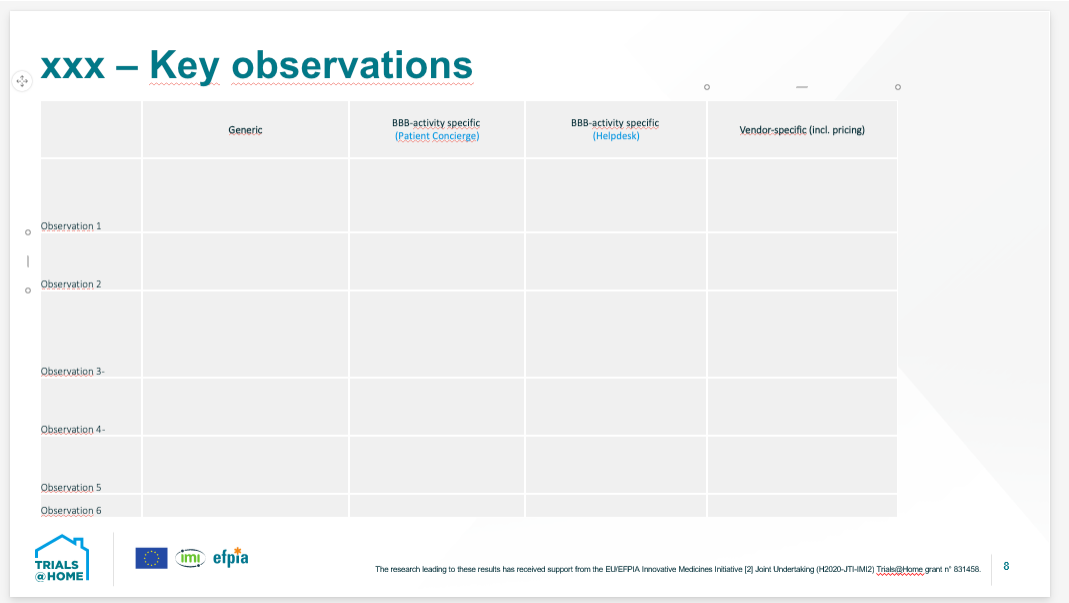

Figure 1: Vendor scorecard template – key observation collection

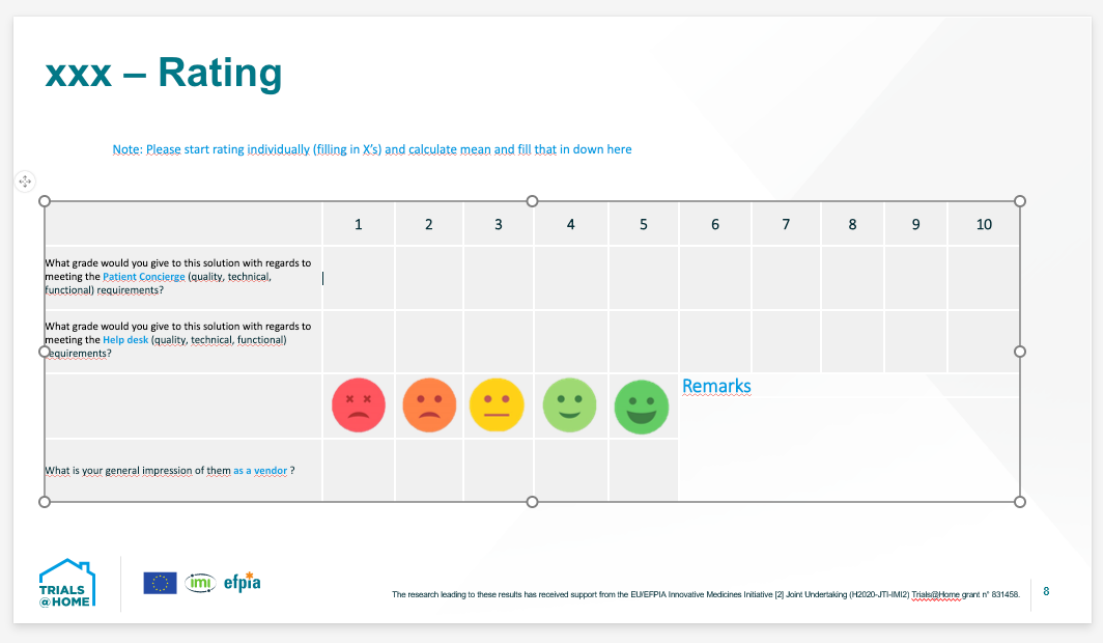

Figure 2: Vendor scorecard template – Rating template

Components and data flows

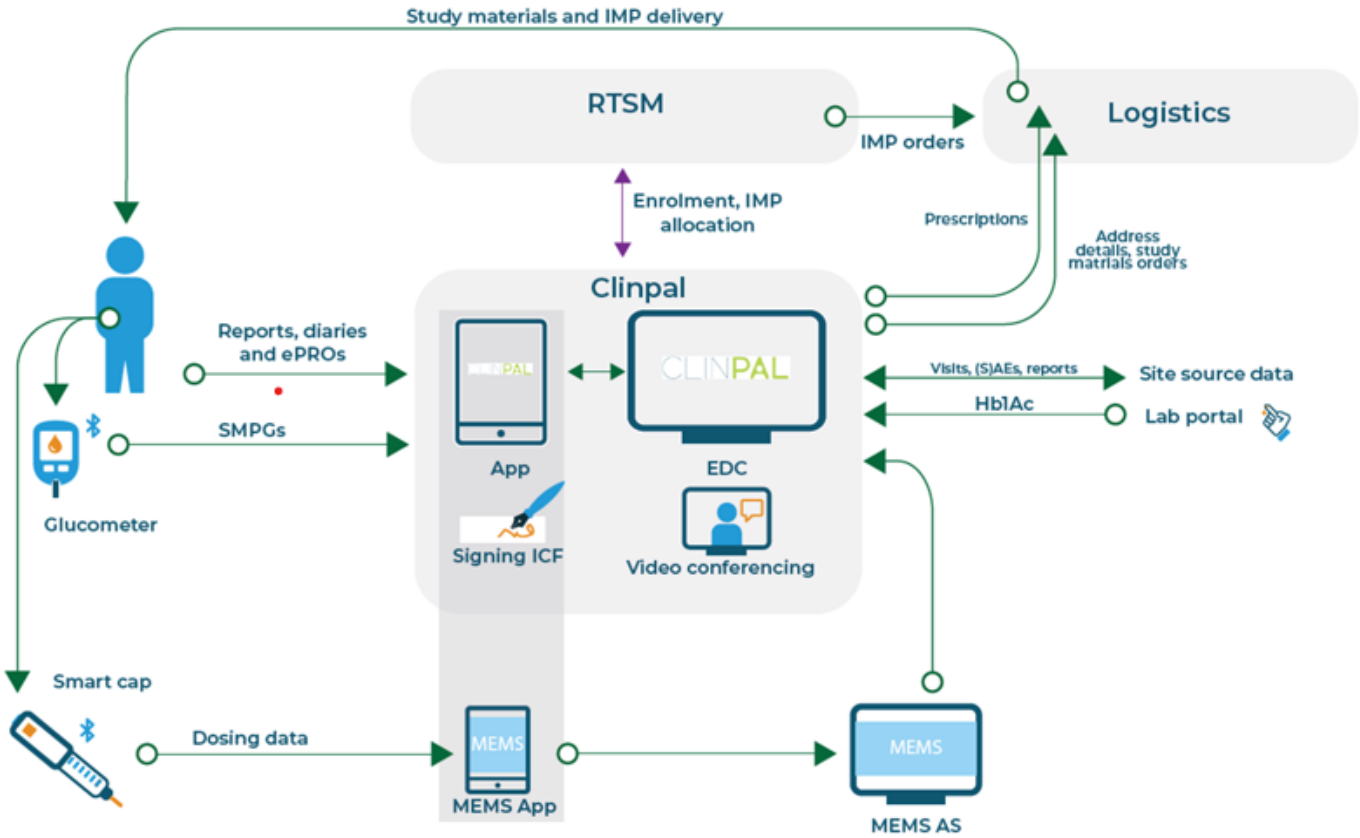

Figure 3: Technical components and data flows