



831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP2 – TECH

## D2.7 Technology support system

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### Document History

Version	Date	Description
V0.0	17.10.2022	First structuring
V0.1	15.02.2023	Include information from partners
V0.3	14.03.2023	Chapters filled, screenshots of final implementation
V0.4	15.03.2023	Remove C&P content, further details on implementation
V0.5	20.03.2023	All sections filled – further modifications after internal review
V0.6	12.06.2023	Clearer distinction between RADIAL knowledge base (KB) and Dashboard login, Information and Process Flow
V0.7	17.07.2023	Added KB structure details, info/process flow for tickets
V0.8	12.09.2023	Updates
V0.9	13.09.2023	Adaptations
V1.0	14.09.2023	Finalisation

## Abstract

The technology support system within Trials@Home comprises all support aspects that are required to enable a barrier-free participation in the project's clinical trial called RADIAL. Due to the high number of stakeholders as well as separate roles (participant, site, CRA) present in the study, the support system consists of a number of different already available solutions provided by the project partners that need to be integrated or coordinated and arranged to enable an optimised workflow.

This deliverable aims to give an overview of the already available solutions, their features and their scope. Furthermore, this deliverable describes how the available solutions can be channelled into one helpdesk system.

To provide additional support, the helpdesk system will not only provide manuals with additional information but must also allow to request information from experts. The requirements for such a system are described in this deliverable and the final implementation chosen for this task is presented. In short, the eventually implemented helpdesk system will be a combination of a Wiki-like information resource and a ticketing system that allows to create topic-specific tickets that will make sure that the requests reach the appropriate agent fast.

## Methods

The adequate choice of a helpdesk system overarching all already available solutions requires a stock-check of the existing support systems to identify their capabilities, scopes, and limitations.

### General Requirements

The general requirements for a technology support system addressing the needs of a large trial like RADIAL are:

- Centralised repository of information
- Ability to contact persons with additional knowledge on specific aspects (customer support and service)
- Answers to frequently asked questions (FAQs)
- Adaptability and extensibility (Content management system [CMS])
- Possibility to define different roles with different permissions for access to the helpdesk system, e.g.
  - content creator
  - ticket agent
  - administrator

### Specific Requirements

The requirements specifically for the RADIAL trial are:

- Bundling information and knowledge from multiple channels into one helpdesk system
- Know-how and training material exchange (eLearning)
- Restricted access to learning material, i.e., additional password protection of the website, to avoid general availability

### Available Solutions

This section describes all training and support solutions provided by the stakeholders of Trials@Home and thereby gives an overview of all aspects that need to be covered by or integrated into the final technology support system.

#### eClinical Health ClinPal Platform

App: The ClinPal Platform / App is used as Electronic Data Capture (EDC) system, eDiary, electronic patient-reported outcome (ePRO). Additionally, it is also used for onboarding of subjects, subject identification verification (IDAS), and e-consent and e-signatures for part B sites.

App User Access: All applicable project team members, site staff and subjects must have access to the portal in order to have access to the functionalities as described above.

Manual and Training: A manual and training for the portal will be provided at the start of the clinical project or when new features become available.

### **Julius Clinical Study Team Portal**

Julius Clinical Microsoft Teams Study Portal, called Teams Study Portal, is set up for the RADIAL project by Julius Clinical to externally share project related documents between Julius Clinical, consortium partners (including sponsor) and local partners.

All applicable project team members must have access to the Teams Study Portal in order to have access to applicable procedures and templates used in the clinical project. Specific Teams channel access is granted based upon the role of staff in the project.

Access can be requested through the Julius Clinical Clinical Trial Assistant (CTA).

User accounts and proper accesses are checked by the Julius Clinical CTA regularly, at least on a quarterly basis.

### **Signant Health RTSM System**

The Randomisation and Trial Supply Management (RTSM) system of Signant Health is used for the RADIAL project. The RTSM system is used for randomisation of the subjects at part A sites, Investigational Product (IP) kit(s) shipment to sites and subjects, and IP kit(s) accountability.

User Access: All applicable site staff and all applicable project team members (including CRAs) must have access to the portal in order to arrange (site staff) / have access to information about (project team) the subject randomisation and Investigational Product (IP) shipment, accountability, return and destruction.

Staff user access: The CRA should send the required information (name, email address, sites) to the Julius Clinical CTA. The Julius Clinical CTA will request the access to the RTSM system by sending an email to Signant Health.

Project team members user access: The Julius Clinical CTA will request the access to the RTSM system by sending an email to Signant Health. Signant Health will provide the access to the RTSM system. Signant Health will send the Username and Password via email. The email will also contain the URL link to access the IRT login home page.

The Julius Clinical CTAs will maintain an overview of all users that have access to the RTSM system. The RTSM system can also be accessed via the Signant Health Mobile App available in the iOS App Store and Android Play Store.

System Manual and Training: The Signant Health IRT System User Manual provides step-by-step instructions for navigating through the various features and functionalities of the system. It is located under the 'Question Mark link' at the top of the page. Click on 'Help Documentation'. Training will be provided by the CRA during the Site Initiation Visit (SIV).

Signant Health provides navigational training for site personnel through an interactive tutorial, which is available from the information bar in the RTSM system upon initial login. It is located under the 'Question Mark link' at the top of the page. Click on 'System Training'.

System Features: The transactions available in the RTSM system are Screening, Rescreening, Enrolment, Randomisation, Study Visit, Deactivation, Drug Shipment Receipt, Lost or Damaged Study Drug, Quarantine Kit, Initiate Accountability, Edit Accountability, Site Destruction, DTP Shipment Receipt and DTP Lost or Damaged Kit.

After successful completion of a site transaction, the Site User will receive a notification by e-mail confirming the data recorded and the information returned by the RTSM system.

Features available for site staff include:

- Trigger initial and resupplies of IP kit(s) shipments automatically
- Send automatic IP kit(s) Shipment Request Notifications (expected arrival date of the shipment)

- Acknowledge receipt of IP kit(s) on site
- Document status of IP kit(s) (Lost, Damaged, Quarantined)
- Assignment of IP kit(s) to subjects
  - o Subject enrolment for part B site, upon completion of the transaction IP kit(s) to be included in the Direct To Patient (DTP) shipment from the central pharmacy to the subject
  - o Subject randomisation for part A sites, upon completion of the transaction the system will confirm the IP kit(s) to be dispensed by the site to the subject (hybrid arm visit 6 via courier)
- Document subject discontinuation (screen failure, end of treatment, end of study)
- IP kit(s) accountability on stock level for each site
- IP kit(s) accountability on subject level, including return of IP kit(s) to the site by subjects
- Confirm Destruction of IP kit(s) at a site level for part A sites

Subject screening and rescreening information are integrated in ClinPal's RTSM system. Features available to the project team include:

- Reports that provide detailed information regarding the Drug Accountability and Destruction

## **Cerba Trova Portal**

For the RADIAL study, Cerba Research is used as a central laboratory provider. The online portal or Cerba Research Lab is called Cerba Trova, and it is used for the HbA1c lab samples of the subjects.

User Access: Relevant site staff and relevant project team members (including CRAs) must have access to the Cerba Trova portal in order to access the HbA1c results of the subjects.

Site staff user access: The CRA should complete the Cerba Trova Access Request Form and send the completed form to the Julius Clinical CTA. The Julius Clinical CTA will request the access by sending the completed form to Cerba Research.

Project team members user access: The Julius Clinical CTA should complete the Cerba Trova Access Request Form. The Julius Clinical CTA will request the access by sending the completed form to Cerba Research.

Cerba Research will provide the access to Cerba Trova portal. The portal can be accessed via the Cerba research website and then click the 'Cerba Research' on the right top corner of the webpage. The Julius Clinical CTAs will maintain an overview of all users that have access to the Cerba Trova portal.

Manual and Training: The manual for Cerba Trova is available in

- LifeSphere eTMF > TMF > Laboratory > Central Lab Manual and Updates
- Teams Study Portal UMCU Internal Team > Project Procedures > Manuals
- the ISF.

Training will be provided by the CRA during the Site Initiation Visit (SIV).

Portal Features: Features available to the project team and applicable site staff may include:

- Lab results
- Respond to lab queries (site staff only)
- Alert values, data clarification issues and inclusion/exclusion checks
- Investigator Study Documentation (e.g., Central Laboratory Manual, Instruction Leaflet)

## **AARDEX MEMS**

The MEMS Mobile application provides medication adherence functionalities in general and has been adapted for the use in the RADIAL study. For the RADIAL study the app is used to connect to the Mallya add-on for insulin pens and retrieve its data. The data is transferred to MEMS Adherence Software (MEMS AS), which provides real-time, user-friendly adherence dashboards.

## **ValidSign**

ValidSign provides solutions for automating a document e-signing process, which are used for the sign-off processes within Trials@Home. Automating the workflow for e-signing saves time, and

reduces cost and delays, but most importantly strengthens legal compliance.

## MyProjectPlaza

For file sharing within Trials@Home the SharePoint solution MyProjectPlaza provided by *Iygarture* is used. This comprises administrative information as well as presentations and deliverables to secure reproducible documentation a reliable collaborative workflow.

## Evaluation and Comparison

Table 1 provides an overview of all available online portals and their access requirements for site staff, patient, and clinical research assistance (CRAs).

*Table 1 Overview of online portals and access.*

Portal	Site Staff		Patient		CRA	
	Access required	Platform	Access required	Platform	Access required	Platform
<i>eClinical Health ClinPal</i>	yes	Desktop (online)	Yes	Desktop (online): ICF process, viewing data and App	No	
<i>Julius Clinical Study Team Portal</i>	No	N/A	No	N/A	yes	Desktop (online)
<i>Signant Health RTSM System</i>	Yes	Desktop (online)	No	N/A	yes	Desktop (online)
<i>Cerba Trova</i>	Yes	Desktop (online): Physician will receive an email with HbA1c values.	No	N/A	No	N/A
<i>MEMS app</i>	No	N/A	Yes	App: Download through Appstore or automatic download through ClinPal when ClinPal and MEMS are installed; MEMS can be automatically launched in ClinPal	No	N/A
<i>MEMS AS portal</i>	Yes	Desktop (online)	No	N/A	No	N/A
<i>ValidSign</i>	No	N/A	No	N/A	No	Process will be guided by CTAs
<i>MRN Sharefile folder</i>	Yes	Desktop (online)	No	N/A	No	N/A
<i>My ProjectPlaza</i>	No	N/A	No	N/A	No	N/A

## Results

### Implemented Helpdesk System

The multichannel support system was implemented based on the UVdesk (<https://www.uvdesk.com>) helpdesk system, an open-source helpdesk solution.

UVdesk provides a fully functional project package, which was configured to the needs of the RADIAL trial by FH JOANNEUM and provides:

- the helpdesk knowledge base for CRAs and site staff,
- a backend access to modify and continuously extend the knowledge base, and
- a dashboard for ticket agents to manage support requests.

The implemented RADIAL helpdesk knowledge base is available at <https://radial-helpdesk.fh-joanneum.at/> for users. As requested, the access to the site is password protected, so the knowledge base is not publicly available. Username and password are needed to proceed to the knowledgebase (see Figure 1).



Figure 1: Login credentials are required for access to the RADIAL website.

Figure 2 shows the start page of the implemented RADIAL helpdesk system after the initial login. Users can search for any information they are looking for and related articles containing the search key words in their meta data will be suggested.

The structure shown in Figure 2 was discussed and agreed upon by all stakeholders – it aims at providing a layout that enables visitors to find the adequate topic for their purpose on the first level shown as tiles. Visitors can then quickly browse through the folders in a self-service manner. Folder topics are:

- Frequently asked questions (FAQs),
- General info
- Vendors
- Site/CRA training
- Patient Training, and
- Other categories.

Folders comprise multiple categories, which themselves comprise multiple articles. Of course, an article can be linked to several folders and categories if this is useful.

## Explore the knowledge base

Check out our knowledge base to see if your question has already been answered.

 <p>FAQs 5 Categories 24 Articles</p>	 <p>General Info 2 Categories 10 Articles</p>	 <p>Vendors 10 Categories 32 Articles</p>
 <p>Site/CRA Training 3 Categories 17 Articles</p>	 <p>Patient Training 2 Categories 27 Articles</p>	 <p>Other Categories 16 Categories 33 Articles</p>

**Did not find what you were looking for? Use our search!**

Figure 2: Start page of the RADIAL helpdesk knowledge base.

Furthermore, the 'Contact Us' button will redirect the user to a contact form where visitors can create a new ticket and request individual support. Via the contact form (see Figure 3) the type of request can be chosen to filter the request beforehand – additionally, the site ID needs to be entered in the message.

### Create Ticket Request

Name\*

*Enter your name*

Email\*

*Enter your email*

Type\*

*Choose ticket type*

Subject\*

*Ticket subject*

Message\* 

← → **B** *I*

Site ID: < PUT YOUR SITE ID HERE >

*Ticket content*

[Add Attachment](#)

[CREATE TICKET](#)

### Create Ticket Request

Name\*

*Enter your name*

Email\*

*Enter your email*

Type\*

Select type

- Account creation
- ClinPal App
- ClinPal Dashboard
- Devices
- General Support
- MEMS AS
- Onboarding
- RTSM and logistics
- Telehealth

*Ticket content*

[Add Attachment](#)

[CREATE TICKET](#)

Figure 3: Contact form. Ticket type and site ID are required for additional context.

The implemented RADIAL helpdesk dashboard for managing knowledge base content and handling ticket requests is available to registered users at <https://radial-helpdesk.fh-joanneum.at/en/member/login>. Figure 4 shows the login screen to the RADIAL helpdesk dashboard.

With the helpdesk dashboard, as shown in Figure 5, contents and users of the knowledge base can be managed. Support agents with the respective permissions (or privileges) can add and organize folders, categories, and articles. If their status is 'Published' they will be displayed on the front-end helpdesk knowledge base (i.e., Figure 2); 'Draft' status articles can be used for internal communication.

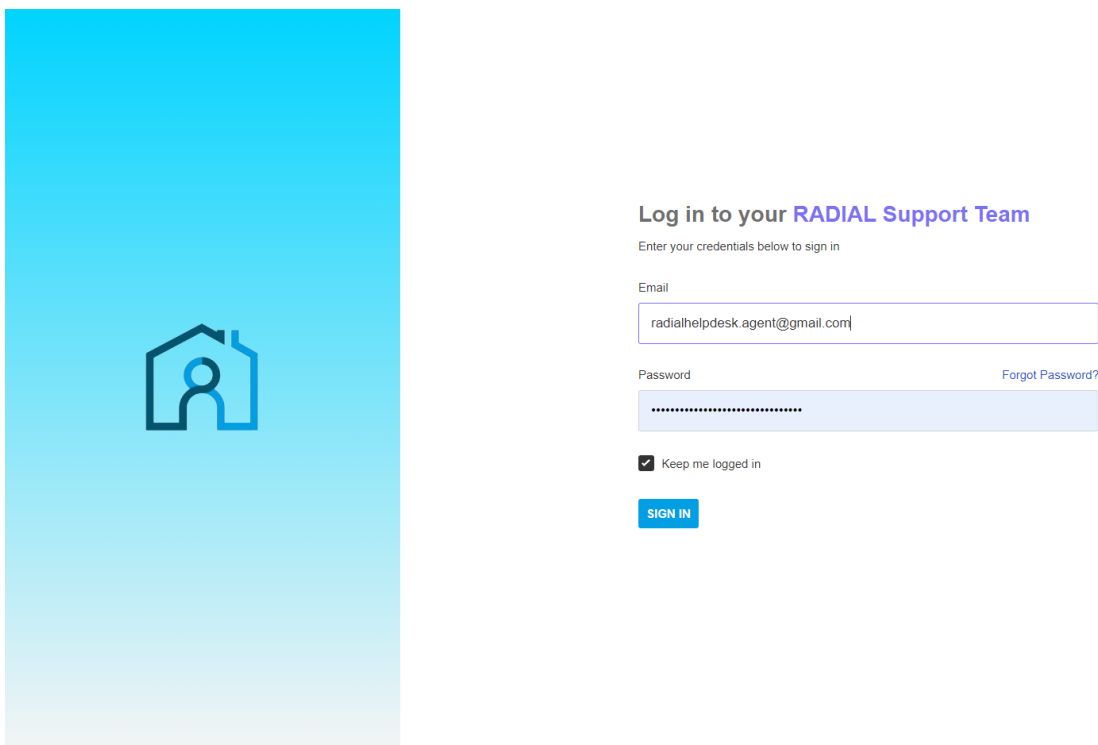


Figure 4 Login to the knowledge base content, user and ticket management dashboard.

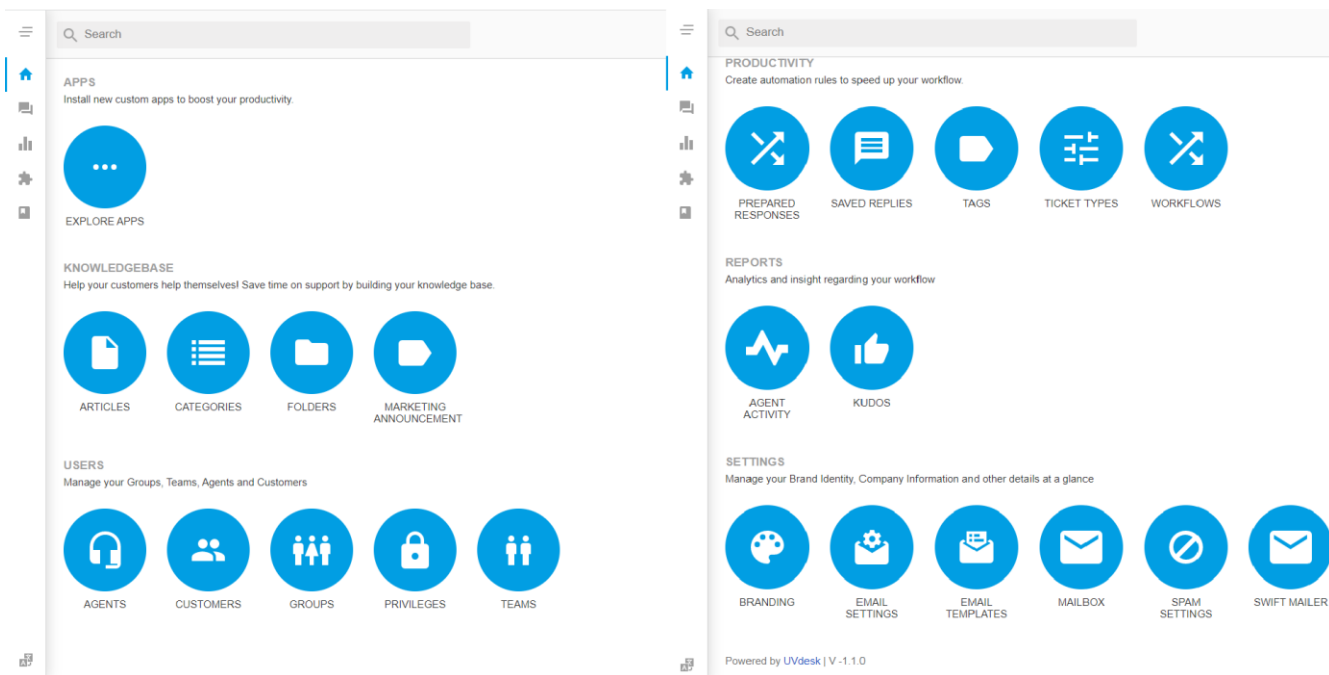


Figure 5 Dashboard for content and user management of the helpdesk system.



## User Roles

Five different user roles have been defined. If necessary, the following list can be extended. Notice that the list starts with the least privileged role and ends with the role with all permissions – a higher number therefore means that the role has all permissions of a role with a lower number plus the additional description provided for the role.

1. Content Creator: Content Creators can only modify the knowledge base. They can create and modify folders and articles and can link them to categories. Currently, CRAs and technical support staff collaborate as content creators.
2. Site/CRAs: Clinical Research Assistants (CRAs), i.e., clinical site support staff using the knowledge base, can create and edit tickets with different ticket types.
3. Ticket Agent: Site support staff/CRAs also act as Ticket Agents. Ticket Agents have no restrictions on how they can handle tickets. In addition to the CRA's permissions, Ticket Agents can reply on tickets, change the responsible person or move tickets to other teams.
4. Administrator: Administrators can add or remove users of any kind and modify the roles and permissions of existing users. Administrator rights are currently only granted to technical support staff on FHJ side.
5. Account Owner: This is the first user existing in the helpdesk system after its creation, i.e., a developer from FHJ. The Account Owner has admin rights but is the only account that cannot be deleted.

## Availability

As mentioned above, the implemented RADIAL helpdesk knowledge base is available at <https://radial-helpdesk.fh-joanneum.at/> for all users. As the link suggests, the website was certified for secure communication using *https*. A backup of the server content, i.e., the knowledge base and the ticket system, is created on a daily basis.

The system generally provides additional access for customers, i.e., users that request support by creating tickets; however, it was decided to omit this additional level for the support system for RADIAL. This reduces the administrative overhead by eliminating the need for customers to create an additional account. The restricted access to the content of the site required for RADIAL is regulated via the additional password protection of the entire site, as described above (see *Implemented Helpdesk System*). Registered users can log in to the system, which will forward them to the overview dashboard. Here, the users can modify the content as defined by their permissions (see *User Roles*).

## Information and Process Flow

Study participants contact the clinical site support staff or CRAs directly. If a participant's question cannot be answered directly, clinical site support staff and CRAs can browse the knowledge base to find the information in specific training materials. They could also use the knowledge base search bar, shown in Figure 2 (bottom).

If the information they are looking for is not available in the knowledgebase, the clinical site support staff or CRAs create a ticket at the RADIAL helpdesk (see Figure 3). Ticket Agents are then responsible for managing the ticket requests via the helpdesk ticketing dashboard, which is shown in Figure 6.

The Ticket Agents – if unable to answer a specific request – can contact key members of the Trials@Home consortium or request information from vendor ticketing systems or other contacts by adding them as collaborators to a ticket. Since the helpdesk system uses a mail service in the background, answers from external collaborators to a collaboration invitation are automatically merged into the ticket process and the answer is forwarded to all involved parties. As shown in Figure 7 a direct communication between CRAs or sites and vendors is possible – this may be necessary in urgent cases; the standard workflow, however, is from left to right. Of course, in these cases the issues, tracked by the vendor in their internal systems, should be reported back to our internal ticketing system to have the learnings and in case extend the FAQs in the knowledge base (KB).

The entire information flow of the RADIAL helpdesk is visualized in Figure 7. Additional Figure 8 displays a decision tree how to respond to newly created tickets.

- In case of a new ticket generation by a site or CRA member all tickets agents in the project are notified via email.
- The ticket agents available or responsible according to the coverage plan either assigning the ticket in the ticketing system to themselves or, in case someone else is more expert regarding the concrete issue, assign the ticket to another agent in the system.
- The ticket agents should be aware of the content available in the KB and in case point the ticket creator to the available content and help.
- If the information is NOT in the KB, the ticket agent will i) bring the issue to the weekly helpdesk scrum and RADIAL core study team meeting or ii) involve core study team members which were part of the protocol design, technology setup, UAT etc. and may contact the technology provider for help. The technology provider will create a ticket in their internal system and solve the issue together with the site and the patient. For documentation, as soon the third-party vendor is closing the ticket, he will inform the RADIAL helpdesk team to close and document the ticket on their side.
- For improving the process as well as the KB documentation, in the weekly helpdesk scrums it will be discussed if, based on the ticket issues, the KB can be extended or improved.

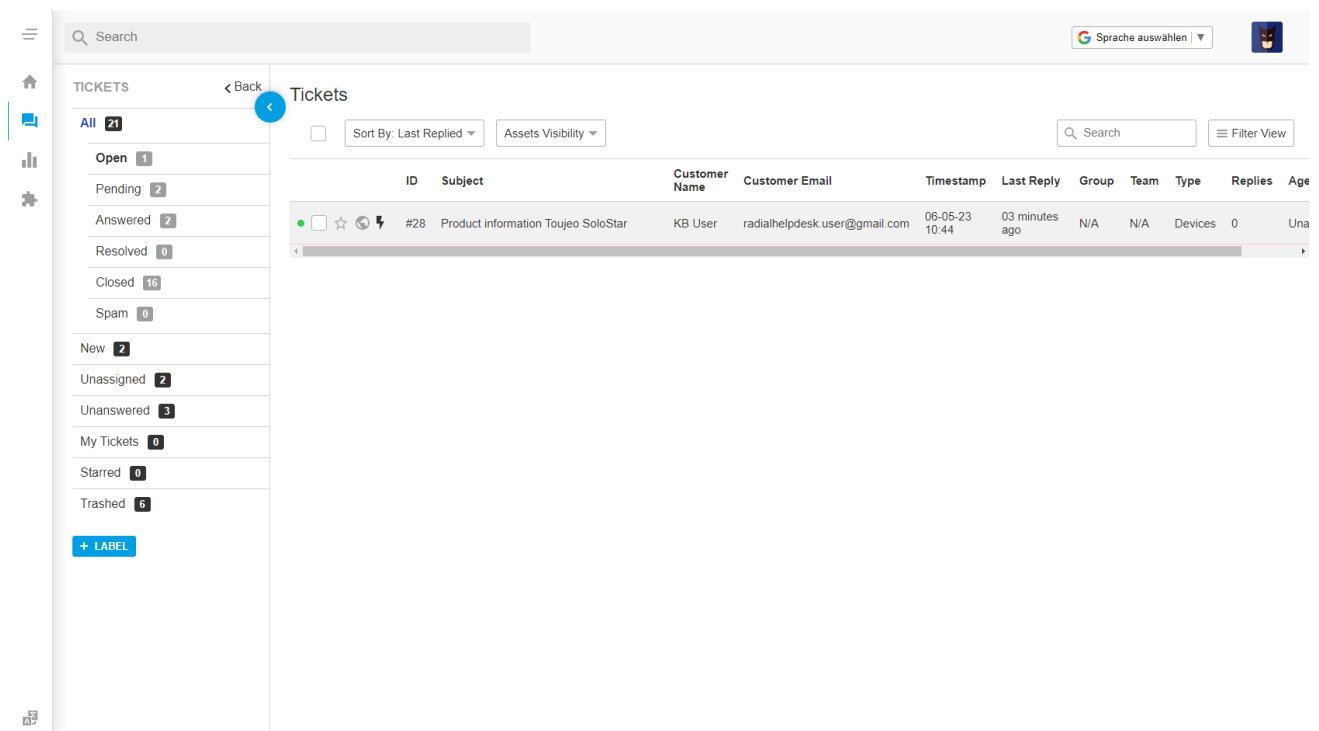


Figure 6 RADIAL helpdesk ticketing dashboard.

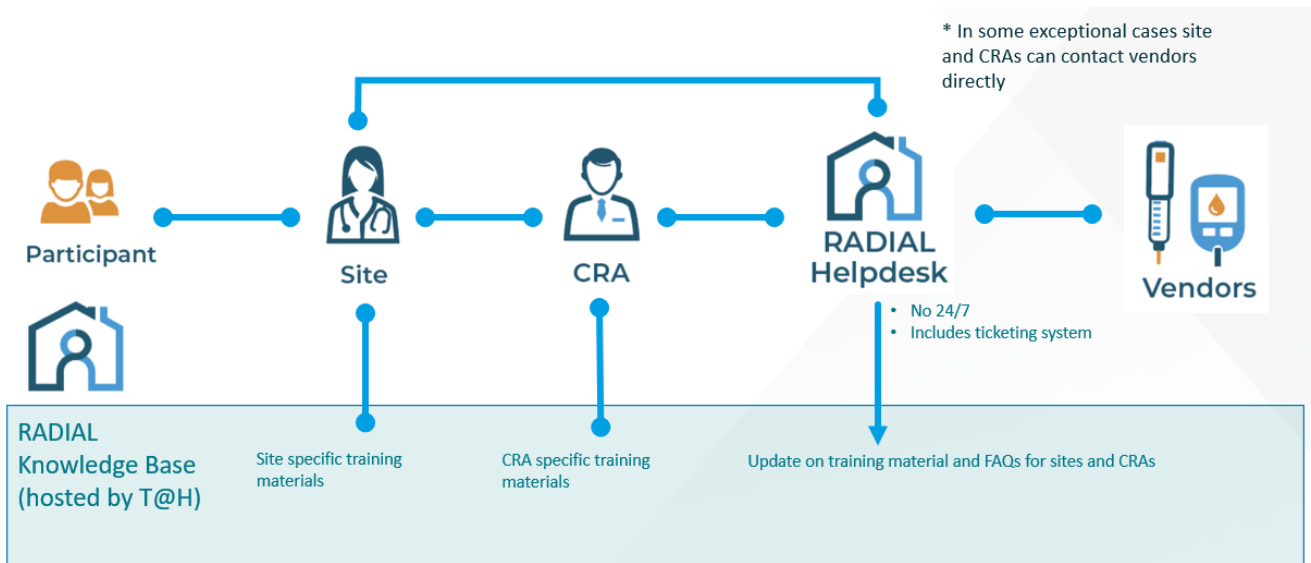


Figure 7 RADIAL helpdesk information and process flow.

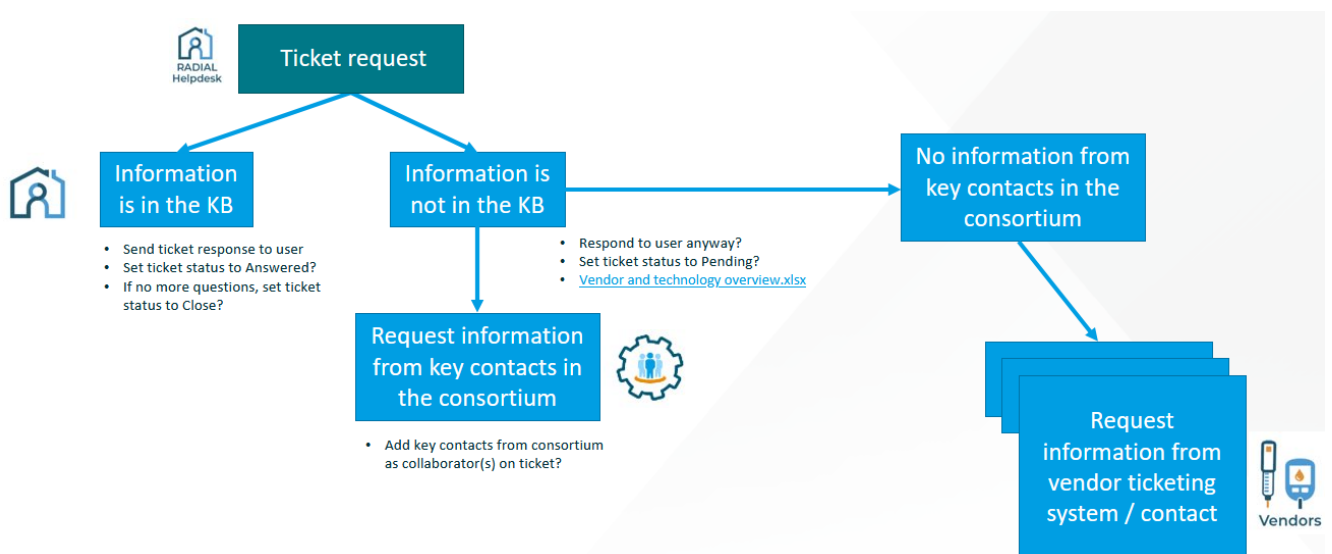


Figure 8 Decision tree for ticket requests

## Coverage Plan and Organization

To provide a consistent helpdesk coverage during workdays and working hours and to improve the process as well as record the lessons learned, the following process has been agreed on.

- 1) A coverage plan with 3 timeslots between 9 am CET and 6 pm CET, in which the currently six ticket agents cover slots in a weekly schedule, was created. Two agents fill every slot to guarantee backups in case of vacations etc. OOO dates are communicated in the plan before to act when needed.
- 2) We scheduled a weekly scrum meeting between all ticket agents to discuss urgent matters and share experience. In case we see a shortage on coverage due to too many incoming tickets, we can therefore react in time to bringing new agents to the team.
- 3) One assigned member of the ticket agents is taking part in the weekly core study team meetings to inform the core study team about current issues regarding tickets or performance.
- 4) We started a 24h chat channel in MS Teams where fast help or absence of agents can be communicated between the agents.
- 5) We will prepare monthly database (DB) exports and provide help desk usage and ticket statistics to improve the process (information like total number of tickets, average age of tickets, tickets per site and country, type of tickets, frequent search terms in the KB)
- 6) We provided a list where we track problems internally to extend the FAQ section in the KB or the materials in general in short time.

## SLA Overview

<b>Technology</b>	<b>Vendor</b>	<b>site support</b>	<b>helpdesk operating hours</b>	<b>monitoring hours</b>
Clinpal	eClinical Health	no	The Platform is monitored 7x24 hours and engineers are on call.	The Platform is monitored 7x24 hours and engineers are on call.
RTSM	SignantHealth	yes	telephone support business hours Monday-Friday 8 till 22 GMT; will provide electronic support through issue tracking system	uptime percentage 99.9%
Telehealth	Virtrial / SignantHealth	yes	<like above>	<like above>
MEMS	AARDEX	no	24h a day	24/7, 365 days a year
Remote Recruitment	Investis Digital	no	24/7/365 client support; Response to all inquiries within 15 (fifteen) minutes	24/7/365 security monitoring

## Conclusion

The helpdesk system for the RADIAL trial provides a knowledge base and a ticket system for support request, both of which are password protected.

When requesting support, a topic as well as the site ID must be specified – this helps to sort out erroneous requests on the one hand and allows to provide more specific answers on the other hand. The content of the system is backed up continuously to avoid loss of data. The provided system therefore complies with all requested functionalities.

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