

CLINICAL RESEARCH – CLINICAL TRIAL MANAGEMENT SYSTEM USER SUPPORT AND DOWNTIME PROCEDURE [®]

DOCUMENT SUMMARY/KEY POINTS

- The purpose is to outline the procedure for accessing user support, notification of planned and unplanned downtime and obtaining access to electronic documents stored in the SCHN Clinical Trial Management System (CTMS) in the event of unplanned downtime.
- The procedure must be followed by all personnel involved in the conduct of clinical research utilising the SCHN CTMS.

CHANGE SUMMARY

- Minor typographical changes.

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the conduct of clinical research utilising the SCHN CTMS.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1 st August 2021	Review Period: 3 years
Team Leader:	Clinical Trials Program Manager	Area/Dept: Kids Research

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Purpose/Scope

The purpose is to outline the procedure for accessing user support, notification of planned and unplanned downtime and obtaining access to electronic documents stored in the SCHN Clinical Trial Management System (CTMS) in the event of unplanned downtime.

Adherence to this procedure will ensure:

- Consistency, efficiency and quality control with regard to workflow processes for clinical research personnel related to SCHN CTMS support issues; and
- Business continuity contingencies in the event of planned or unplanned downtime affecting the SCHN CTMS.

This procedure must be followed by all personnel involved in the conduct of clinical research utilising the SCHN CTMS.

Background

SCHN undertakes a wide range of investigator, initiated, collaborative-group and commercially-sponsored clinical research, including clinical trials where SCHN may be either or both Sponsor and Site. A CTMS is a web-based application that aids in the operational, administrative, regulatory and financial management of a portfolio of clinical research.

The SCHN CTMS is provided by US-based software company, Bio-Optronics (<https://bio-optronics.com/ctms/>). The SCHN CTMS is hosted locally in the NSW-based Government Data Centre (GovDC) via eHealth (<http://www.ehealth.nsw.gov.au/>).

Requests for use of the SCHN CTMS can be lodged via email to the SCHN CTMS Administrator on SCHN-CTMS@health.nsw.gov.au.

Procedure

User Support

- If a user or group of users encounters an issue with using the SCHN CTMS, it is recommended that the user first notifies the responsible Team's CTMS Super User for trouble-shooting support;
- If the issue is unable to be rectified by the Team's CTMS Super User, the SCHN CTMS Administrator must be notified via email to SCHN-CTMS@health.nsw.gov.au;
- The SCHN CTMS Administrator will be responsible for confirming that the issue is reproducible (if feasible), identifying the likely source of the issue, confirming whether the issue has already been reported and if so, its current status;
- If the SCHN CTMS Administrator identifies that the likely source of the issue relates to the hosting service provider, eHealth, and has not yet been reported, the SCHN

Administrator will log a ticket with the NSW Health State Wide Service Desk (SWSD) cc:// the affected user(s);

- If the SCHN CTMS Administrator identifies that the likely source of the issue relates to the application service provider, Bio-Optronics, and has not yet been reported, the SCHN Administrator will log a ticket with the Bio-Optronics Help Desk via support@bio-optronics.com or 877-279-8377 cc:// the affected user(s);
- The SCHN CTMS Administrator will be responsible for periodic follow-up in relation to support requests to either eHealth or Bio-Optronics to ensure their prompt resolution, and relaying the outcome to the affected user(s);

Downtime

In the context of this procedure, downtime is defined as any time that the SCHN CTMS is not available for normal use by internal or external users of the system. Issues that affect only one user, a group of users and/or specific workstation(s) are not considered to be downtime.

Planned downtime is defined as a period of time within which the SCHN CTMS, or parts of it, are unavailable for normal use. Planned downtime will be notified in advance in order to enable advance planning to occur that minimises any disruption to operations and any inconvenience to users. Typical examples of planned downtime are the unavailability of system(s) due to upgrades and/or periodic maintenance.

Unplanned downtime is defined as a sudden event that results in the inability to access the SCHN CTMS, or parts of it, for normal use. Unplanned downtime occurs without prior notice and may be due to an event such as application failure, hardware failure, electricity outage or Network failure. The duration of system unavailability might initially be unknown.

Communication

Planned Downtime

- Planned downtime will occur outside of Sydney regular working days/hours to minimise disruption to users of the SCHN CTMS;
- Communication about a planned downtime relating will be sent out by either eHealth or Bio-Optronics (as applicable) via email to the SCHN CTMS Administrator, at least 14 days in advance to the planned downtime;
- The SCHN CTMS Administrator will be responsible for circulating notification of planned downtime that is scheduled to occur during Sydney regular working days/hours to all SCHN-based users of the CTMS.

Unplanned Downtime

- Once eHealth or Bio-Optronics have identified a downtime for the whole SCHN CTMS or its components, the SCHN CTMS Administrator will be notified directly via email to SCHN-CTMS@health.nsw.gov.au;
- The SCHN CTMS Administrator will circulate notifications of unplanned downtime occurring during Sydney regular working days/hours to all SCHN-based users of the CTMS; providing periodic updates (as appropriate), and notifying users when downtime has ended.

Actions

- In the event of a planned or unplanned downtime, the SCHN CTMS will not be accessible for use;
- Electronic documents or data stored in the SCHN CTMS that are deemed critical to business continuity should be:
 - Accessed in advance of a planned downtime in accordance with the notifications provided by the SCHN CTMS Administrator; or
 - In the event of unplanned downtime, requested for retrieval (most recent saved version) by the SCHN CTMS Administrator via the hosting service provider, eHealth's access to back-up records.

Post-Downtime Recovery

- Any electronic documents or data collected during downtime periods that would have normally be entered and/or uploaded into the SCHN CTMS must be actioned by the user(s) as soon as possible.

Abbreviations and Definitions

CTMS	Clinical Trials Management System
IT	Information Technology
NSW	New South Wales
PD	Policy Directive
SCHN	Sydney Children's Hospitals Network

Related Documents

1. SCHN Policy 2014-9045 – Health Care Records Management - <http://webapps.schn.health.nsw.gov.au/epolicy/policy/3274>
2. SCHN Procedure 2019-145 - Clinical Research – Record Keeping - <http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661>
3. Major Incident Management Lifecycle Process - <http://hseh.intranet.health.nsw.gov.au/it-support/major-incident-management>
4. eHealth ICT Broadcast Policy - http://intranet.hss.health.nsw.gov.au/_data/assets/pdf_file/0004/670207/eHealth-ICT-Broadcast-Policy.pdf

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