TrialChecker Database Background Information

1. QCTN

The Queensland Clinical Trials Network Inc. (QCTN) is:

- an association of Queensland based, clinical research related entities
- independent and not for profit
- funded by both its members and a Queensland Government grant

QCTN's mission is to be instrumental in developing Queensland's capabilities to support the clinical development of new medicines and treatments and will facilitate:

- the undertaking of clinical trials and related services in Queensland, Australia, in an environment that stimulates clinical trial professionalism and cooperation
- adherence to national and international ethical, quality and regulatory standards
- public awareness of clinical trials
- attraction of national and international interest to Queensland

QCTN itself does not conduct clinical trials, but its members do.

2. TrialChecker

Patients and volunteers are treated in the context of a clinical trial by qualified clinicians and clinical research nurses in clinical trials centres. A clinical trial centre can be a hospital department, a medical centre or a centre specialised in early phase clinical trials (phase I/II). The clinicians and research nurses in QCTN Member clinical trial centres across Queensland are eligible users of TrialChecker.

Prior to enrolment of a person (subject) into a trial, the clinician or research nurse needs to make sure that the person is eligible for participation. One of the typical exclusion criteria is if a person is already included in another ongoing trial or has very recently completed involvement in a trial. The current practice is that the person is questioned by the clinician or research nurse as to whether or not he/she is participating in another ongoing trial. However, in the absence of a TrialChecker Database, there is no independent way of verifying whether or not the person's response is in conflict with the requirements of the (new) trial suggested by the clinician or research nurse.

Clinical trial centres must be members of QCTN to use TrialChecker and nominated staff members must be registered with QCTN for authorised and secure access to the database. QCTN's role is to administer the TrialChecker database. There is no fee to QCTN members for using the database.

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3. Purpose

The primary purpose of the TrialChecker database is:

- To safeguard the safety of volunteers and patients by avoiding inappropriate participation in multiple trials simultaneously or too frequently
- To safeguard investigators or clinical research organisations by providing another level of checking the eligibility of the volunteer or patient prior to trial participation
- To increase awareness of clinical trials with the general public

As a consequence of TrialChecker, information and data collected will provide an opportunity to generate periodical statistics on clinical trial participation rates.

4. Process

The following description illustrates the basic process of using the TrialChecker Database. The term *subject* is used in the remainder of this document to refer to either a healthy volunteer or a patient.

Set-up stage

1. The clinical trial centre (CTC) registers with QCTN for secure access to the database. QCTN Membership is subject to application and review by the membership committee.
2. QCTN provides the database login details to the official contact person in the CTC
3. Additional login details for other personnel in the CTC can be requested by the official CTC contact person.

Pre-screening stage

1. The research nurse sees a subject who might be eligible for clinical trial participation
2. The research nurse gets the subject's consent to check and/or enter his/her details against the details stored in the TrialChecker Database
3. The research nurse logs on to the Member-only section of the QCTN website

Subject enrolment (randomisation) stage

1. Assuming a subject is eligible for the trial, the research nurse will consent the subject for the clinical trial resulting in a signed informed consent form (for involvement in the trial)
2. The research nurse logs on to the Member-only section of the QCTN website
3. The research nurse enters new, or updates existing key identifiers for the subject and/or the clinical trial
    - *If a subject participated in a trial previously or concurrently, the basic characteristics of that trial (from any CTC) will be displayed for the purpose of assisting in checking the eligibility of the subjects' inclusion in the new trial.*

Withdrawal stage

A clinical trial centre and/or a subject may apply to withdraw details from the TrialChecker database at any time.

Informed Consent

The research nurse needs to record in the TrialChecker Database that the clinical trial informed consent was obtained in order for the subject to be linked to the trial. If no Informed Consent is registered, 'subject-trial linkage' cannot occur.

Disclaimer

All users of TrialChecker are aware that using this facility is only part of the process of ascertaining a subject's suitability for trial inclusion / exclusion and should not be solely relied upon.