

Identifying and contacting candidates for type 1 diabetes research using ADDRESS-2

Background

ADDRESS-2 participants have consented to be approached about participating in other type 1 diabetes (T1D) research studies. On joining, participants with new-onset T1D are good candidates for early intervention trials and unaffected siblings are candidates for prevention trials. Both are suited to aetiopathogenesis studies. With the passage of time, participants with T1D become suitable for studies for which a minimum duration of diabetes is required, for example, T1D of at least one year in duration (T1D > 12 m).

The principles under which approval may be granted to researchers requesting to use ADDRESS-2 to identify candidates for another type 1 diabetes (T1D) research study are described in the document, "Research access to the ADDRESS-2 resource". The document also describes the application and assessment processes. The aim is to support all NIHR CRN portfolio studies and other studies in receipt of NIHR funding that request to use the ADDRESS-2 database to identify candidates. To allow information to be provided in a staggered fashion to participants meeting the eligibility criteria for more than one study recruiting concurrently, studies are prioritised. The prioritisation criteria are described in the document, "ADDRESS-2 prioritisation criteria".

This document describes how candidates can be identified and contacted about studies for which they may be eligible. This is summarised in the flow diagram in Appendix 1, Referring ADDRESS-2 participants into other T1D studies.

Information provided to ADDRESS-2 sites about approved studies

Information about studies with approval to use ADDRESS-2 to identify candidates will be sent via email to the local research teams at ADDRESS-2 sites. This will happen before any participants are identified as candidates for the study.

Identification of candidates in ADDRESS-2

For studies recruiting people with T1D, the method of identification is dependent on the eligibility time frame post-diagnosis. The frequency of database searches will be agreed with the individual study team.

New-onset T1D <100 days post-diagnosis

ADDRESS-2 can be used like a network of participant identification centres (PICs) for studies recruiting people within 100 days of diagnosis, as shown in the flow diagram in Appendix 1 Referring ADDRESS-2 participants into other T1D studies.

The ADDRESS-2 protocol allows for studies requiring rapid recruitment post-diagnosis to be introduced to people newly diagnosed with T1D at the same time that ADDRESS-2 is introduced, and for recruitment to occur in parallel.

Separate PIC approval is not required for this because the recruitment pathway is described in the ADDRESS-2 protocol, which has been reviewed and approved by the NHS Research Ethics Committee and Research and Development departments giving NHS permission for the study.

The central ADDRESS-2 team at Imperial College will work with trial sites and neighbouring ADDRESS-2 sites to support the referral of candidates identified by ADDRESS-2 sites.

New and recent-onset T1D ≤ 12 months post-diagnosis

The central ADDRESS-2 team at Imperial College will run searches of the database to identify candidates for studies recruiting people with T1D ≤ 12 months post-diagnosis.

T1D > 12 months post-diagnosis

For studies recruiting people with T1D > 12 months post-diagnosis and recruiting in more than one of the 15 local branches of the NIHR Clinical Research Network (LCRN) the central ADDRESS-2 team will run searches of the database.

For studies recruiting people with T1D > 12 months post-diagnosis and recruiting in a single LCRN or ADDRESS-2 site, the LCRN or the site may run a search of their local section of the ADDRESS-2 database. Assistance can be requested from the central ADDRESS-2 team.

Unaffected siblings

The central ADDRESS-2 team at Imperial College will run searches of the database to identify candidates for studies recruiting unaffected siblings.

Contact notification sent to ADDRESS-2 sites and diabetes care physicians

When an ADDRESS-2 participant is matched to a study the ADDRESS-2 site research team and diabetes care physician will be informed via email and letter. The ADDRESS-2 id of the participant is sent via email and the name and date of birth of the participant via letter along with information about the study to which the participant has been matched.

For all studies with the exception of those recruiting people with T1D < 100 days post-diagnosis, contact notification will be sent 5 working days before contact is made with the participant about the study, so that the care physician and site principle investigator (PI) are forearmed with information about the study, which the participant may wish to discuss with them. ADDRESS-2 aims to empower patients, but pre-contact notification gives the care physician or PI the opportunity to explain why contact with the participant is considered to be inappropriate at that time.

Contact notification for studies recruiting people with T1D < 100 days post-diagnosis will be sent to diabetes care physicians and PIs in parallel with participant contact to prevent delays in offering research opportunities to candidates.

How candidates are contacted

Candidates can be contacted about approved studies by their local ADDRESS-2 site team, or if specific consent has been given, by the central ADDRESS-2 team. If the central team conducts the database search, the central team will ask site teams to contact candidates who have not consented to contact from the team at Imperial College London.

Participants consented or re-consented from October 2014 onwards are asked their willingness to be contacted via phone, letter, email or text (SMS).

Candidates may be provided with summary information about the study or the participant information sheets for the study, as agreed with the study team. Candidates are asked to give consent for their contact details to be passed to the study team so that the study team can contact them directly to explain more about the study.

Appendix 1 Referring ADDRESS-2 participants into other T1D studies

An ADDRESS-2 participant can be identified as a potential candidate for a T1D study, contacted about that study, and referred to the individual study team for further information via the routes shown in Figure 1.

Route 1: the ADDRESS-2 site acts like a Participant Identification Centre (PIC). The ADDRESS-2 protocol allows for studies requiring rapid recruitment post-diagnosis to be introduced to people newly diagnosed with T1D at the same time that ADDRESS-2 is introduced, and for recruitment to occur in parallel. Separate PIC approval is not required because the recruitment pathway is described in the ADDRESS-2 protocol (approved by ethics and R&D).

Route 2: the ADDRESS-2 team at the site or at Imperial College or the LCRN runs a search of the ADDRESS-2 database to identify candidates for a T1D study. Searches for people with T1D \leq 12 months duration, or recruiting in more than one LCRN, or recruiting unaffected siblings require prior approval of the Management Committee. The study coordinator must be informed of all searches.

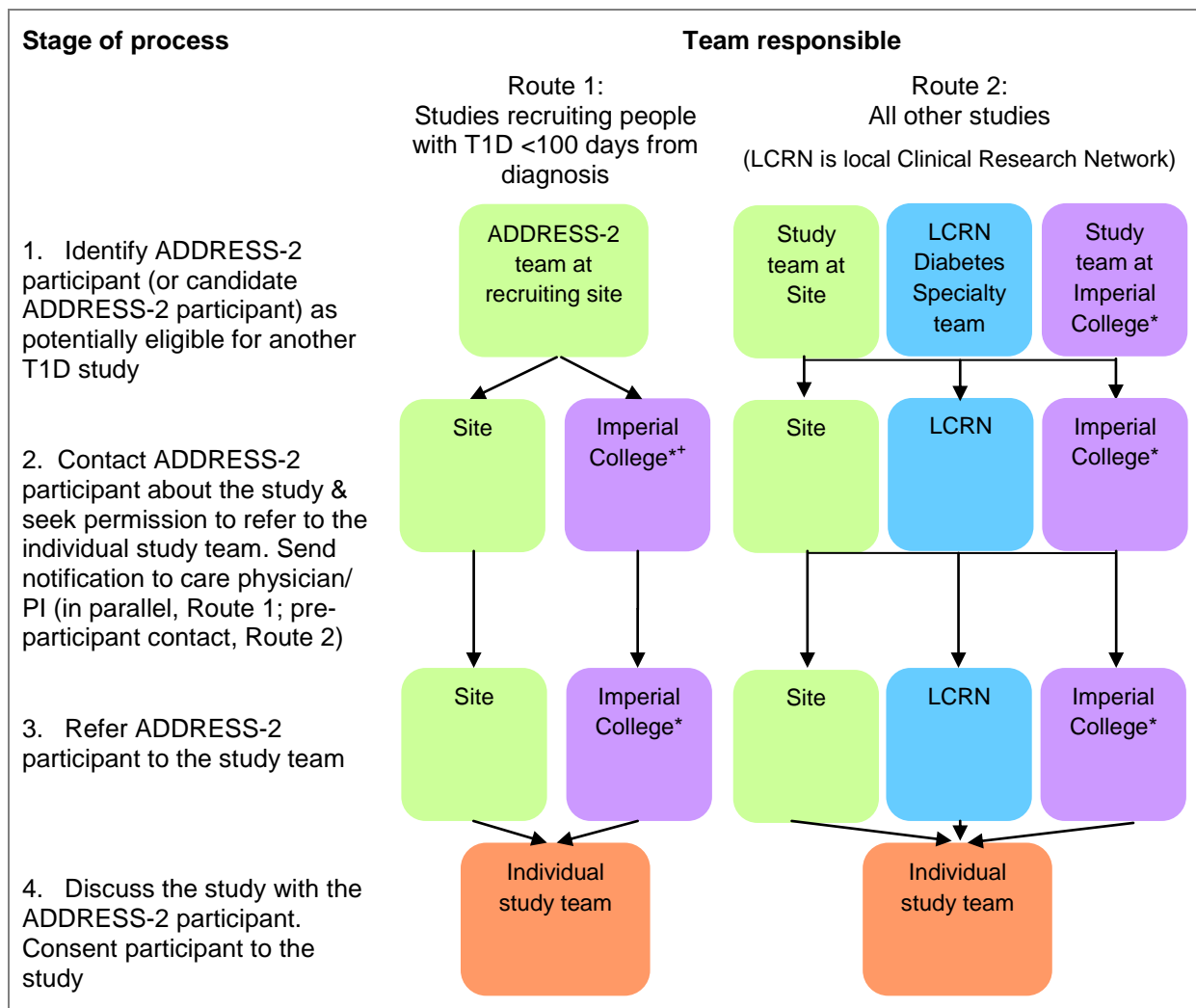


Figure 1. Routes of referral into other T1D research studies

* Participants who have given specific consent for this (consent forms implemented from 1st October 2014)

**For the team at Imperial College to contact the ADDRESS-2 participant, the site must telephone the ADDRESS-2 Coordination Centre to alert them that a new ADDRESS-2 participant may be eligible for another study.