Same-day registration on the ISRCTN registry

ISRCTN can offer same-day registration of urgent COVID-19 clinical trials after NIHR triage, given the right preparations.

ISRCTN prioritises the registration of study records that have imminent recruitment start dates or are urgent for other reasons (e.g. the lack of a registration number is holding up a journal's acceptance of a manuscript), provided trialists give the minimally required information.

The box lists the conditions normally required for speedy registration of studies submitted using the ISRCTN submission form. These are based on the most common issues trialists experience. The attached notes include the way ISRCTN can make allowance for missing information in urgent cases.

Ten steps to same-day registration on ISRCTN

1. Submit the registration record to ISRCTN before 3 p.m.
2. If not paying online that day, confirm the source of payment.
3. For online submissions, follow the pop-up instructions.
4. Provide the WHO minimum dataset (or say when available)
5. Send ISRCTN third party confirmation of the study's existence.
6. Provide IRAS and CPMS numbers if applicable.
7. Supply outcome measures in the correct format
8. Give ISRCTN the key points for a plain English summary.
9. Say whether the study is asking participants to volunteer.
10. Send ISRCTN a copy of the IRAS form before or at registration.

Normal requirements for same day registration

1. **Submit the registration record before 3 pm**.
    - Later submission may be possible if you warn ISRCTN staff and have a trialist available to answer queries.
2. **Send confirmation from DHSC or NIHR** if the fee is to be covered by the DHSC allocation
3. If using the online submission form, **follow the pop-up instructions** for each field. These describe
    - the information required,
    - the correct format and
    - the fields to be left blank
4. **Supply all items of the WHO minimum dataset** (page 21 of https://apps.who.int/iris/bitstream/handle/10665/274994/9789241514743-eng.pdf) **OR explain why any item is not yet available** (e.g. where ethics approval is still pending).
    - *The minimum dataset includes a **data sharing plan**. This should be considered before submission.*
    - *If necessary, a **'not known' statement** may be used, e.g. "The data sharing plans for the current study are unknown and will be made available at a later date".*
5. Provide a third-party **confirmation of the study's existence**
    - *e.g. ethics approval document or confirmation letter from a funder or sponsor. This can't be submitted in the web form. It can be sent to info@isrctn.com following receipt of the submission number.*
    - *For studies submitted via CPMS, ISRCTN doesn't require separate confirmation. It states that the NIHR confirms the trial's existence.*
6. Give **IRAS and CPMS numbers** if applicable
    - *These can be added to the protocol/serial number fields. ISRCTN reports to the NIHR all UK registrations, with their IRAS and CPMS numbers, monthly to keep CPMS up to date.*

7. Put the **outcome measures in the correct format**
    - *Each outcome measure should include the variable measured, the method of measurement and the timepoints or duration of measurement.*
8. Prepare for **the plain English summary**
    - *ISRCTN has developed a generic introduction to COVID-19 and can write most of the summary from information provided in the rest of the record. The trialist is asked for a specific statement why the intervention or observation is being studied in COVID-19 (for the 'Background and study aims' section); and any potential risks or benefits of participating in the study (including any known adverse events and how these will be identified and managed).*
    - *The plain English summary is not part of the WHO minimum dataset, but it is displayed prominently on the public view of ISRCTN and in Be Part of Research.*
9. **Will the study recruit by seeking participants to volunteer?**
    - *Should all study sites be public during recruitment? If not, sites can be hidden from public view on Be Part of Research.*
    - *Explain this in the intervention field and plain English summary.*

Communication before submission

Compared with trialist-submitted study records, submissions uploaded from the CPMS data feed tend to have information missing.

ISRCTN has standard questions it sends to these applicants. ISRCTN can send the questions in advance if it has the trialist's contact details.

Alternatively, a central HRA or NIHR point of contact could distribute guidance based on these questions. ISRCTN could quickly provide this guidance.

ISRCTN welcomes an advance copy of the IRAS form

Trialists can speed up same-day registration by sending the IRAS form to info@isrctn.com before or at the same time as applying for registration.