

ANZCTR DATA COMPLETENESS AUDITS

General methodology

Each year, a random sample of studies registered on the ANZCTR in the previous calendar year is extracted from the ANZCTR database into a Microsoft Excel spreadsheet. Trials are selected using a computerised random selection method within R software.

A copy of the spreadsheet is given to ANZCTR staff members to audit. Each auditor reviews assigned data fields for completeness and quality, and marks them as either 'Complete' or 'Incomplete' per below

- **Complete:** Indicates that the input for a data field satisfactorily met the criteria required for Primary Registries in the WHO Registry Network (<http://www.who.int/ictip/network/primary/en/>) and ANZCTR-specific requirements detailed in the ANZCTR's "Data Item Definition/Explanation" document (<http://www.anzctr.org.au/docs/ANZCTR%20Data%20field%20explanation.pdf?t=586>).
- **Incomplete:** Indicates that the input for a data field did not satisfactorily meet the WHO and ANZCTR requirements. For incomplete entries auditors were required to add a reason why the field was deemed incomplete.

Once complete, the number of data field entries labelled as 'Incomplete' and the reason the field failed to meet requirements is discussed by ANZCTR staff members. Where discrepancies are identified, the issues are resolved by consensus discussion. If an agreement cannot be reached the ANZCTR Project Manager is consulted and a final decision made.

Results

Results of the previous three audits are summarised below.

| Year | Date completed | # audited (% trials registered that year) | # fields audited | # Complete (%) | # Incomplete (%) |
|------|----------------|---|------------------|----------------|------------------|
| 2016 | 22/05/2017 | 87 (5%) | 10,377 | 10,303 (99.3%) | 74 (0.7%) |
| 2017 | 23/05/2018 | 83 (5%) | 9,985 | 9,916 (99.3%) | 69 (0.7%) |
| 2018 | 09/09/2019 | 200 (10%) | 27,222 | 26,971 (99.1%) | 251 (0.9%) |

