



## DATA QUALITY – guide for sites

The DCVAS database is a valuable resource for vasculitis research.

Please help us maintain high quality standards and reduce data queries to your site by following the guidance below.

### DATA COMPLETENESS / CLINICAL LOGIC

After you lock data at your site, the following items are checked for consistency and accuracy by our data team in Oxford. It is a good idea to use the review page to check data for this logic prior to locking data as it will save queries back to you.

- **Ensure clinical scenarios** selected on page 2 **are followed up in the corresponding section.** (e.g. if you select positive ANCA or positive biopsy, ensure a result is included in the autoantibodies or biopsy section OR if you select new onset of headache, please ensure you select the location of the headache in the neurology section, etc.)
- Ensure you use the correct units for your **laboratory** results. Select other and record if not standard.
- Check all fields are completed for **biopsy and imaging results** with **reference to the code list** (please check separate code lists for general and specific findings).
- If a patient has had **whole body scan** which shows inflammation, **mark the site** of the inflammation, rather than select whole body.
- If there has been a **change of diagnosis** between baseline and follow up, make sure you **state why**.

### DATA TIME POINTS– please be consistent with dates and record these as outlined below:

- **The screening date & study visit date refer to patient enrolment into the study.** (i.e. the screening date & study visit date **must be after your site joined the study**).
- **The screening date is the date that you assess a patient's eligibility for the study.** *This is not the date when you first see a patient who has been referred for clinical assessment.*
- **The visit date is the study entry date** – when you take **informed consent**, interview the patient and complete the baseline CRF. *This is not the date of a routine clinic visit.*
- **The assessment date is when your team first sees a patient for clinical assessment.**
- **Six month follow up is from date of diagnosis – not from the study visit date.**
- **Patients can be recruited retrospectively**, as long as a diagnosis was first made within the previous two years to study enrolment. In this case the clinical assessment date will be before the screening and visit date.

*e.g. A diagnosis of GPA is made on 1 January 2013. The patient is enrolled in the study on 30 August 2013 (study entry date). The baseline data is recorded with all relevant information up until diagnosis (1 January 2013) and the follow up data is relevant from 1 July 2013 or the nearest date after this where diagnosis has been confirmed. In this case both baseline and follow up date could be recorded at the one time when the patient enrolls in the study.*

Please email the data team if you have any questions

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