



# DIAMONDS Eligibility Guideline

---

## 1. DETERMINING ELIGIBILITY

### 1.1 Who

Staff trained on the DIAMONDS protocol may identify potentially eligible patients and obtain written consent in line with local policy.

Once written consent is obtained, a medically qualified doctor must confirm eligibility. Please note that the medically qualified doctor must have received training on the study and have been delegated this task on the study delegation log.

### 1.2 How

The medically qualified doctor confirming eligibility must sign the eligibility checklist to document this review and confirm that the patient is eligible for the study **AND** add a sticker which states the following into the medical notes:

*'This subject meets all the inclusion criteria and none of the exclusion criteria and is therefore eligible for entry into the DIAMONDS trial. Eligibility confirmed by <insert name of medically qualified doctor who confirmed eligibility>, recorded in notes by <insert name of healthcare professional>'*.

The signed paper eligibility checklist should be retained within the CRF.

### 1.3 Eligibility criteria

Patients will be eligible to participate in the study if they fulfil all the inclusion criteria and do not meet any exclusion criteria as listed in the protocol.

## 2. IF ELIGIBLE

If the patient has been determined as eligible to take part and this has been confirmed in writing on the eligibility checklist by a medically qualified doctor and the patient has provided written consent, staff delegated responsibility for recruitment/registration of patients may complete randomisation of the patient onto the trial using the randomisation system (see guideline). Remember to update the screening log.

## 3. IF INELIGIBLE

Update the screening log and record **all** reasons for ineligibility, retain all consent forms for screen failures.