**IVD Device manufacturer name:** Click or tap here to enter text.

**UK Responsible Person name (if applicable):** Click or tap here to enter text.

**IVD Device name:** Click or tap here to enter text.

Integrated Research Application System (IRAS) number: Click or tap here to enter text.

Clinical Trial Authorisation (CTA) application reference number: Click or tap here to enter text.

Intended purpose/use summary incl. intended users & environment: Click or tap here to enter text.

Investigational Medicinal Product (IMP), if applicable: Click or tap here to enter text.

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| **Please provide the following** | **Response** | **File name of documents provided** |
| **Specimen collection and results** | | |
| Brief description of specimen collection method. *(100 words max)*   * Submit the Instructions for Use (IFU) for the specimen collection device * Provide the MHRA registration reference of the device used for specimen collection | **Description**: Click or tap here to enter text.  **Specimen collection device(s) MHRA registration reference(s)**: Click or tap here to enter text. | IFU: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Brief description of specimen handling, storage and transportation from sample collection site to testing location. *(500 words max)* | **Description**: Click or tap here to enter text. | *Add a file for relevant supplementary content only* |
| Brief description how observed results and unexpected results are to be recorded and reported as part of the clinical trial, together with the aberrations of device performance whenever observed? *(300 words max)* | **Description**: Click or tap here to enter text. | *Add a file for relevant supplementary content only* |

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| **Assays and instruments** | | |
| Signed attestation on the device manufacturer’s letterheaded paper that the assays are the final design version that will be deployed in the clinical trial.  *Note: The attestation must become a controlled record in the manufacturer and sponsor quality management system.* | **Manufacturer attestation signed by:** Click or tap here to enter text.  **Manufacturer attestation signature date:** Click or tap to enter a date. | Signed attestation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Add a file of manufacturer’s attestation.* |
| List all instruments (e.g. by serial numbers or equipment reference) being used specifically for the clinical trial. | **List of instruments**: Click or tap here to enter text. | *Add a file for relevant supplementary content only* |
| Provide the validation summary report for each instrument being used in the clinical trial study  *Note: An installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) summary report may be submitted with a cover letter indicating qualification status of each instrument.* | **Has validation taken place on each instrument?** Choose an item.  **If not, provide the reason:**  Click or tap here to enter text. | Validation Summary Report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Submit valid certificates from the College of American Pathologists (CAP) / Clinical Laboratory Improvement Amendments (CLIA) or ISO 15189 accreditation for each laboratory where testing will be performed with the instruments aforementioned.    Confirm the date of expiry is in line with the clinical trial study duration | **Name of testing laboratory**: Click or tap here to enter text.  **CAP / CLIA certificate number:** Click or tap here to enter text.  **CAP / CLIA certificate expiry date:** Click or tap to enter a date.  **ISO 15189 certificate number:** Click or tap to enter a date.  **ISO 15189 certificate expiry date:** Click or tap to enter a date. | CAP/CLIA certificate(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ISO 15189 certificate(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Provide all certificates* |

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| **Clinical trial personnel** | | |
| List all investigators:   * Name * Institution * General Medical Council, General Dental Council, Nursing and Midwifery Council or equivalent registration for each investigator | **Lead/Chief/Principal Investigator name**: Click or tap here to enter text.  **Lead/Chief/Principal Investigator institution:** Click or tap here to enter text.  **Lead/Chief/Principal Investigator registration:** Click or tap here to enter text. | *Add a file listing all investigators (name, institution and applicable registrations) involved* |
| List of device users with their:   * Name * Organisation * Signed training attestation on laboratory letterheaded document that named personnel are competent to use the instruments for use in the clinical trial | **Laboratory attestation signed by:** Click or tap here to enter text.  **Laboratory attestation signature date:** Click or tap to enter a date. | List of all device users: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Add a file listing all device users (name, organisation).*  Signed attestation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Add a file of training attestation.* |
| The clinician or authorised medical person’s signature demonstrating evidence the risk management report has been reviewed for the IVD device including companion diagnostic devices. | **Signed by:**  Click or tap here to enter text.  **Job title of signature:**  Click or tap here to enter text.  **Signature date:**  Click or tap to enter a date. | Risk management report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Participant informed consent** | | |
| For DNA sequencing only, specific informed consent from patient must be sought.  Submit a copy of the informed consent form that is planned to be used highlighting the request to conduct DNA sequencing. | **Page number in the informed consent form where DNA sequencing consent is sought:**  Click or tap here to enter text. | Blank informed consent form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Accreditation** | | |
| For UK in-house developed tests, the UKAS accreditation schedule with the test name on the schedule. | **Page number in the UKAS accredited schedule where the test is named:**  Click or tap here to enter text. | UKAS accreditation schedule: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |