Medicines & Healthcare products
Regulatory Agency

GSK GCP Inspection Report

Inspection No: GCP 19494/37251014-0002

Published 22Dec2025

Contents

Inspection Summary

Inspection & Organisation Information	
Inspection Number	GCP 19494/37251014-0002
Purpose of Inspection	Statutory GCP Trial Specific Inspection
Type of Inspection	Hybrid
Organisation Inspected	GSK
Organisation Address	GSK HQ, 79 New Oxford Street, London. WC1A 1DG
Organisation Type	Commercial Sponsor
Dates of Inspection	19-23May2025 with a remote inspection day on the 13May2025
Lead Inspector	[redacted] GCP Inspector [redacted]
Accompanying Inspectors	[redacted] GCP Inspector [redacted] [redacted] GCP Inspector [redacted] [redacted] GLP Inspector [redacted]
Date of Closing Meeting	19Jun2025

Clinical Trial Selected for Review	
Protocol Reference	[redacted]
IRAS ID	[redacted]
Protocol Title	A Phase 3, randomized, placebo-controlled, [redacted]

Other Inspected Organisation - 01	
Name of Investigator	[redacted]
Organisation Inspected	Sherbourne Medical Centre
Organisation Address	40 Oxford St, Leamington Spa, Warwickshire. CV32 4RA
Organisation Type	GP Surgery

Dates of Inspection	08Sep2025 - 10Sep2025
Lead Inspector	[redacted] GCP Inspector[redacted]
Accompanying Inspectors	[redacted] GCP Inspector[redacted]
Date of Closing Meeting	10Sep2025

Other Inspected Organisation - 02	
Organisations Inspected	GSK Biological's Clinical Laboratory Sciences & GSK Vaccines
Organisation Addresses	GSK Biological's Clinical Laboratory Sciences, Wavre-Nord Noir Epine, Avenue Fleming 20, 1300 Wavre. Belgium GSK Vaccines, Rue de l'Institut 89, 1330 Rixensart. Belgium
Organisation Type	Delegated Service Provider
Dates of Inspection	30Sep, 1-2Oct2025
Lead Inspector	[redacted] GCP & GLP Inspector[redacted]
Accompanying Inspector	[redacted] GLP Inspector[redacted]
Date of Closing Meeting	02Oct2025

Inspection Report Version History (For Inspectorate Use Only)	
Inspection Report Date 01	22Dec2025
Response Receipt Date 01	29Jan2026
MHRA Review Date 01	12Feb2026

Inspection Close Date	12Feb2026

Relevant Background Information

At the previous MHRA GCP Inspection of GSK, two major findings were raised, related to the TMF and Archiving. Since the last inspection the Vaccines and Medicines organisation were combined into a single entity and a new electronic TMF system was introduced. The TMF system was part of a platform of solutions introduced across the clinical, regulatory, and quality functions. In addition to the implementation of the new platform of systems, [redacted]. Since the last inspection, GSK have also made several acquisitions.

The final clinical study report for the [redacted] trial was produced on the [redacted] The initial protocol was approved on the [redacted], first participant first visit was the [redacted] with the last participant last visit on the [redacted] Globally, [redacted] participants were screened, with [redacted] of those participants dosed and [redacted] participants completing the trial.

Sponsor Inspection Findings

INSTRUCTIONS TO INSPECTED ORGANISATION

Inspection responses and any subsequent clarifications should be completed in the fields provided for each Critical and Major graded finding. Please ensure there is a different row for each corrective and preventative action with the planned completion dates. Do not append any additional documentation or insert any file links. Please provide any other referenced documents as separate files.

No responses are required for Other graded findings. However, suitable evaluation, root cause, corrective actions and preventative actions should be generated with appropriate timelines by the inspected organisation. Evidence of the evaluation and subsequent actions including evidence of the completion of actions may be requested from the inspected organisation at any time including at future inspections.

No responses are required for Observations or Recommendations.

1. Critical Findings

There were **no Critical findings** identified during this inspection.

2. Major Findings

There were **2 Major findings** identified during this inspection related to Pharmacovigilance and Monitoring.

2.1. Pharmacovigilance

(1) A sponsor shall ensure that all relevant information about a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial in the United Kingdom and is fatal or life-threatening is—

(a)recorded; and

(b)reported as soon as possible to—

(i)the licensing authority …

(iii)the relevant ethics committee,

and in any event not later that 7 days after the sponsor was first aware of the reaction.

(2) A sponsor shall ensure that within 8 days of a report in accordance with paragraph (1)(b), any additional relevant information is sent to the persons or bodies listed in that paragraph.

(3) A sponsor shall ensure that a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial in the United Kingdom, other than those referred to in paragraph (1), is reported as soon as possible to—

(a)the licensing authority ...

(b)the relevant ethics committee,

UK Statutory Instrument 2004/1031 (as amended), Part 5, Regulation 33

The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
UK Statutory Instrument 2004/1031 (as amended), Schedule 1, Part 2, (4).

58: The IB as last amended and approved by the national competent authority or equivalent document (e.g. SmPC for marketed products) serves as the reference safety information for the assessment of the expectedness of any adverse reaction that might occur during the clinical trial.
Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial ('CT-1'), 2010/C 82/01

55. The RSI may change during the conduct of a clinical trial. This is typically a substantial amendment (24). For the purpose of SUSAR reporting the version of the RSI at the moment of occurrence of the SUSAR applies (25). Thus, a change of the RSI impacts on the number of adverse reactions to be reported as SUSARs. Regarding the applicable RSI for the purpose of the annual safety report, see section 8.
Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3') (2011/C172/01)

2.1.1. Finding Detail

The sponsor was unable to provide a data listing to demonstrate their compliance with statutory reporting timescales for SUSARs as per Regulation 33.

Pre-inspection request [redacted] required an [redacted] listing of all clinical trial SAE cases reported for the selected trial. Each case, either the initial or subsequent follow-up versions, were requested to be on an individual row in the listing. The sponsor explained that due to safety database system limitations it was not possible to provide the listing format requested. The sponsor was only able to provide a listing which showed the latest version of a case rather than all case versions. For cases with a single version where the event fulfilled the criteria for SUSAR reporting it was possible to assess compliance with the 7- or 15-day timelines. However, for cases with more than one version this was not possible as the status of an event may have changed over time, changing the requirement for expedited reporting and the "day 0". For example, a case may not have been considered "related" to IMP at its first version, and this detail may have been submitted by the investigator at a later case version, thereby adjusting the day 0 for 7-/15-day reporting.

In order to assess whether the sponsor had complied with Regulation 33 the inspector had to request narrative descriptions for each relevant case to order to verify that reporting of SUSARs had been conducted in accordance with the regulation. Two events were noted as having been submitted outside of the 7-/15-day timeframe as described in Finding **0.** It was not possible during this inspection to review conservative reporting, for example, when the investigator causality assessment was missing or not known.

The sponsor did provide the Regulatory Compliance Dashboard report (a [redacted] tool) with the aim of facilitating review during inspection however this report was not sufficient to demonstrate compliance:

- The listing did not include all case versions and did not include the most recent case version:

[redacted]	Included only case 0 (initial) to 5 whereas [redacted] showed most recent case version as 11.

[redacted]	Included only case 0 (initial) to 8 whereas [redacted] showed most recent case version as 14.
[redacted]	Included only case 0 (initial) to 8 whereas [redacted] showed most recent case version as 15.
[redacted]	Included only case 0 (initial) to 2 whereas [redacted] showed most recent case version as 15.

- The listing did not include cases from outside of the UK to enable review of reporting compliance.

The sponsor is required to develop a solution to enable review of compliance with regulation 33 at future inspections. This same finding was raised at a previous inspection (INSP GCP 19494/12271-0009 June 2015) however the corrective actions did not extend to finding a solution for this issue.

Inspected Organisation's Response - 01

[redacted]

[redacted]

Corrective Actions (s)	Due Date (DDMMMYYY)
[redacted]	

Preventative Action(s)	Due Date (DDMMMYYY)
[redacted]	

MHRA Review – 01

Response Accepted.

2.1.2. Finding Detail

The version of the RSI that was used to assess expectedness of cases could not be extracted from the system into a listing to facilitate review of compliance. The sponsor was required to populate the pre-request [redacted]) listing manually in preparation for the inspection. This introduced some confusion as the RSI was referred to as [redacted], which referred to the name given to the first autolistedness profile for the product (called as such because it was the RSI contained within IB [redacted] which was first approved in [redacted] This terminology had never been referred to in any MHRA communications previously, so it took some time to understand that this was the correct MHRA-approved version of the RSI.

Inspected Organisation's Response - 01

[redacted]

Corrective Actions (s)	Due Date (DDMMMYYY)
[redacted]	

Preventative Action(s)	Due Date (DDMMMYYY)
[redacted]	

MHRA Review – 01

Response Accepted.

2.1.3. Finding Detail

Two SUSAR cases were noted as having been submitted outside of the 7/15-day timeline.

- [redacted] Reportable by 22Nov2021 but not submitted until the 02Dec2021 (10 days rather than the required 7 days).
- [redacted]Reportable by 21Sep2021 but not submitted until the 12Oct2021 (21 days rather than the required 15 days).

Inspected Organisation's Response - 01

[redacted]

Corrective Actions (s)	Due Date (DDMMMYYY)
[redacted]	
Preventative Action(s)	**Due Date (DDMMMYYY)**

[redacted]

MHRA Review – 01

Response Accepted.

2.2. Monitoring

No person shall - (a) conduct a clinical trial; or (b) perform the functions of the sponsor of a clinical trial (whether that person is the sponsor or is acting under arrangements made with that sponsor), otherwise than in accordance with the conditions and principles of good clinical practice.
Subject to paragraph (5), the sponsor of a clinical trial shall put and keep in place arrangements for the purpose of ensuring that with regard to that trial the conditions and principles of good clinical practice are satisfied or adhered to.
UK Statutory Instrument 2004/1031 (as amended), regulation 28 (1 & 2)

(4) The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
(8) The investigator and sponsor shall consider all relevant guidance with respect to commencing and conducting a clinical trial.
UK Statutory Instrument 2004/1031 (as amended), Schedule 1, Part 2, (4, 8).

2.2.1. Finding Detail

Monitoring failed to identify under reporting of adverse events in the eCRF at Site [redacted] as per finding **5.1.1.**

Examples were noted where full SDV/SDR was recorded as completed by the monitor in the monitoring report; however, adverse events reported in the participant diary present in the source data worksheets at site were not identified by the monitor as not being reported in the eCRF:

- For participant [redacted] full SDR/SDV of Visit 2 and ConMeds (concomitant medication) was recorded by the monitor as completed at the monitoring visit on the 03Aug2021. The SDR/SDV failed to identify that an adverse event of [redacted] was recorded in the participant paper diary but was not entered into the eCRF by the site.

- For participant [redacted] full SDR/SDV of Visit 2, ConMeds, and the source preparing for [redacted] season was recorded by the monitor as completed at the monitoring visit on the 16Sep2021. The SDR/SDV failed to identify that [redacted] and [redacted] was recorded in the participant paper diary but was not entered into the eCRF by the site.

Inspected Organisation's Response - 01

[redacted]

Inspected Organisation's Response - 01

[redacted]

Corrective Actions (s)	Due Date (DDMMMYYY)
[redacted]	
Preventative Action(s)	**Due Date (DDMMMYYY)**
[redacted]	

MHRA Review – 01

Response Accepted.

3. Other Findings

There were **eight Other findings** identified during this inspection relating to Data Integrity Control Processes, Competent Authority, Data Management, Project/Trial Management, Serious Breach Reporting, Monitoring, Training and Statistics

3.1. Data Integrity Control Processes

3.1.1. Finding Detail

Unblinded data presented to the IDMC throughout the trial were stored on a web-based platform. It was not possible to confirm who had access to these data as no audit trail was available and therefore it was not possible to confirm it was securely stored and managed.

The IDMC charter stated the IDMC members would review the unblinded data at each meeting including but not limited to IMP exposure, safety, and efficacy. The sponsor confirmed that all unblinded data and documentation for the trial were maintained by the unblinded IDMC secretary using a web-based platform owned by the service provider [redacted] and that [redacted] did not have the capability to produce audit trail reports for this platform.

3.1.2. Finding Detail

The audit trail for the [redacted] IMP supplies system did not show trial level user access, and therefore it was not able to demonstrate that access had been suitability controlled in order to protect the blind. Additionally, the audit trail had not been in place during the entire trial (only activated in 2022 whereas FPFV was [redacted]), so overall the sponsor was unable to demonstrate who had had access to unblinded trial data in [redacted] and that such access was appropriate.

3.1.3. Finding Detail

Sponsor staff had data edit rights and could write to the eCRF, examples of this practice were noted in the protocol deviation form and the audit trail showed sponsor staff also wrote data in the eCRF field for the [redacted] . The eCRF is a data acquisition tool designed to record protocol required information to be reported by the investigator to the sponsor for each trial participant. Even with procedural and system controls to prevent the editing of investigator data, the sponsor having edit access to the eCRF increased the risk of inappropriate changes of investigator reported data.

3.1.4. Finding Detail

Information on who had edit access to investigator generated data such as audit trails or user logs were not required to be issued to sites at any point. Therefore, the investigator could not verify that the only personnel with such access were those that the investigator had delegated this activity to.

3.2. Competent Authority

3.2.1. Finding Detail

The Sponsor failed to notify the MHRA when they did not complete actions stated in the response to the Grounds for Non-Acceptance (GNA) letter in the initial CTA application.

In response to the initial CTA submission the MHRA issued a GNA with MHRA Comment 5-Pharmaceutical in the letter stating that the *'The labelling for the* [redacted] *should be amended to state that the nominal fill volume is* [redacted] As part of the response submitted by the sponsor to this comment in the GNA, the sponsor stated *'acknowledging the Agency's recommendation and seeking consistency across studies on this matter, the company is developing an approach for future studies so that the label will include the* [redacted] *nominal volume per dose (*[redacted]*) in the label of the product*.'

The sponsor confirmed that this requirement was not implemented for future studies as it was not logged in their regulatory system as a commitment and therefore it was not tracked to completion. The sponsor stated this GNA comment was not a local requirement in the UK and therefore the update to labelling was not implemented. Discussion with the MHRA Clinical Investigations and Trials (CIT) Team confirmed the expectation that if the sponsor chose not to change the labelling for future studies, this should have been communicated back to the MHRA.

3.3. Data Management

3.3.1. Finding Detail

There were no contemporaneous checks documented of cleaning activities leading to lock/data extraction undertaken for interim analysis [redacted] The actions to be confirmed as completed prior to database lock on the [redacted] were blank and the checklist instead made reference to a cleaning report [redacted] 23Dec2022 (the most recent version filed in the eTMF). This made some reference to activities in May 2022 in the "reports/confirmation of activities" section, but these appeared to have been entered retrospectively on the 18Aug2022. [redacted] of the [redacted] the version before the snapshot was taken for interim analysis, was blank.

3.3.2. Finding Detail

During interview sessions, the data management staff referred to trackers for the reconciliation and query resolution of laboratory data. A suitable copy of the tracker in relation to reconciliation of samples in scope (up to 11Apr2022) had not been retained to show that all the reconciliation issues had been resolved for these data.

3.4. Project/Trial Management

3.4.1. Finding Detail

The impact of protocol amendments on the study risk assessments were not adequately considered. For each protocol amendment, evidence of review of the impact on the study risk assessment was reviewed:

- For protocol amendment [redacted] there was a tab in the Operational Oversight Study Cockpit 23Feb2021, that contained an impact assessment on trial documents; however, it did not include specific prompts or evidence that the Risk Management Plan (RACT) or the Risk and Issue Management Log (RIM) in the Operational Oversight Study Cockpit 23Feb2021 were reviewed, and updates considered. It was noted that the first site had **not** been initiated at the time of this amendment.

- For protocol amendment [redacted] (approved in the UK on the [redacted]), the sponsor did not provide evidence of a review of the risk assessments associated with this protocol amendment. The sponsor did state a new risk was added to the Operational Oversight Study Cockpit related to protocol amendment [redacted] however, this risk was not created until the 23Feb2022.

- For protocol amendment [redacted], the sponsor provided the slides for the kick-off meeting for protocol amendment [redacted] These slides made no mention of the risk assessment, the RACT or the RIM.

- For protocol amendment [redacted], the sponsor provided the slides for the kick-off meeting for protocol amendment [redacted] these slides made no mention of the risk assessment, RACT or RIM.

The study was conducted following the sponsor's work instructions [redacted] and [redacted] The documents' section 4.3.1 required the Central Monitoring Lead (CML) to perform Study Risk Register review *"based on any new information and/or new learnings".* The sponsor stated a protocol amendment was intended to be considered as new information; however, this was not explicit, and as above, had not been documented as being performed.

It was noted that there was evidence of significant updates to the risk assessments based on protocol amendment [redacted]. It was also noted that the SOP [redacted] 08Jan2025 had content that covered important protocol amendments being a trigger for the RBQM strategy update.

3.5. Serious Breach Reporting

3.5.1. Finding Detail

The sponsor failed to follow the conditions set out when a serious breach was closed by the MHRA and did not notify a GCP inspector that the conditions would not be completed. On

the 20Dec2023, the sponsor notified the MHRA of a potential serious breach, [redacted] regarding a lack of temperature monitoring at site [redacted] When this serious breach was closed on the 08Apr2024, the sponsor were informed by the [redacted] GCP Inspector handling the serious breach at the time that the serious breach was considered closed on the condition that the CAPA was completed and CAPA effectiveness checks were put in place. The sponsor confirmed during the inspection that no CAPA effectiveness checks were completed and the rationale behind this was that the timing of detection of the issue was after the site had finished dosing on the study; however, this rationale was not communicated to the MHRA.

3.6. Monitoring

3.6.1. Finding Detail

A number of monitoring reports, both blinded and unblinded, were approved late in deviation from the [redacted](CRO) unblinded monitoring plan and the sponsor's monitoring SOPs:

- 13 of 256 (5%) unblinded monitoring visit reports were approved late. Reports should have been approved within 21 calendar days of the visit as per the [redacted] Unblinded Monitoring Plan (all versions). One SIV report took 50 days for approval from the visit date.

- 43 of the 672 (6%) blinded monitoring visit reports were approved late. Reports should have been approved 28 calendar days prior to the 24Jan2022, and then 21 calendar days after this point as per the sponsor's monitoring SOPs. Seven blinded monitoring visit reports took over 100 days to approve.

3.7. Training

3.7.1. Finding Detail

The training matrix for data management and statistical personnel did not cover the [redacted] current version is [redacted] effective 14Oct2020) or the [redacted](current version is [redacted] effective 21Apr2021).

3.8. Statistics

3.8.1. Finding Detail

The information contained within the headers for the [redacted] programs reviewed were not maintained as a form of version control. The dates within the program headers misaligned with dates in the operating systems or trackers (i.e. it appeared that the program had been updated, and the header not changed):

- Program [redacted] (program header 16Sep2021, operating system date 20Jul2022) and the associated [redacted] (program header 15Sep2021, operating system date 21Jul2022) in relation to the [redacted] analysis.

- For the final analysis the [redacted] version for the production program [redacted] was 27May2024, but the program header contained the date 29Apr2024.

3.9. Pharmacovigilance

3.9.1. Finding Detail

The Regulatory Compliance Dashboard was used by the sponsor to track compliance with the 7- or 15-day timelines for regulatory reporting. However, for events where the follow-up of cases triggered the 7-day timeline, the "report due on" date used a 15-day timeline rather than a 7 day timeline. There was no impact noted as all follow-ups were submitted to the MHRA within 7 days. However, the dashboard could give a false impression of compliance when used for oversight of regulatory compliance.

Observations and Recommendations

The following are observations and recommendations:

Record Keeping/Essential Documents

- The unblinded monitoring plan [redacted] signed by [redacted] on the [redacted] was not filed in the TMF until this was requested during the inspection.

IMP Management/Pharmacy

- Research Nurse [redacted] was given access to the [redacted] prior to completion of the site green light and IP release form. There was no impact identified as the system was not used until after site initiation.

Medical Writing

- The full data from the adjudication process (i.e. the data from the [redacted] eCRF) was not presented in the CSR as either a listing and/or PDFs. This meant that the assessments from each adjudicator and rationales were not available for regulatory assessors. This has been deemed an observation as it was not known whether regulatory assessors have requested to see this data or not.

CRF/Source Data

- For the event adjudication the second reviewer did not give sufficient explanation of why the case did not meet the protocol criteria for an [redacted]) for 6/156 cases. The second adjudicator stated that "does not meet the [redacted] case definition of the study" in response to the adjudication Question 16 "Please provide a rationale, as your assessment for [redacted] case definition is marked as No or Unable to Conclude"

Data Management

- The programme for checking that the primary endpoint data in the eCRF (and provided to the adjudication committee) had not been changed was considered “low risk” during

the assessment of programming risks by the sponsor. This is despite errors in this data potentially impacting the reliability of the trial.

- Unlike monitoring, there was no current process to link data management activities with the trial risk assessment processes and the Data Management Plan (DMP) for the trial made no reference to the Risk Management Plan (RMP). It was understood that this was being developed, and it was recommended that this was done to ensure all trial management activities are risk-based and proportionate as per the updated ICH GCP E6 R3 guidance.

- It was recommended that the use of [redacted] spreadsheets as "reports", particularly when cumulative through the trial, was reviewed to determine whether it was a suitable way to document that the quality of the data has reached the defined quality for an interim and final analysis. For example, this documentation was required to provide evidence that the activities in the database lock checklists had been successfully completed, or if not, what any outstanding data quality issues were (e.g. unresolved queries at the time of data extraction).

Other Inspected Organisation 01 Findings

INSTRUCTIONS TO INSPECTED ORGANISATION

If a separate response is provided by the inspected organisation and the Other Inspected Organisation 01, ensure this is clearly differentiated in the responses provided below.

Inspection responses and any subsequent clarifications should be completed in the fields provided for each Critical and Major graded finding. Please ensure there is a different row for each corrective and preventative action with the planned completion dates. Do not append any additional documentation or insert any file links. Please provide any other referenced documents as separate files.

No responses are required for Other graded findings. However, suitable evaluation, root cause, corrective actions and preventative actions should be generated with appropriate timelines by the inspected organisation. Evidence of the evaluation and subsequent actions including evidence of the completion of actions may be requested from the inspected organisation at any time including at future inspections.

No responses are required for Observations or Recommendations.

4. Critical Findings

There were **no Critical findings** identified during this inspection.

5. Major Findings

There was **one Major finding** identified during this inspection relating to CRF Data/Source Data.

5.1. CRF Data/Source Data

All clinical information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remains protected.
UK Statutory Instrument 2004/1031 (as amended), Schedule 1, Part 2 (9)

Adverse events, other than those to which paragraphs (1) to (3) apply, that are identified in the protocol as critical to evaluations of the safety of the trial shall be reported to the sponsor in accordance with the reporting requirements, including the time periods for such reporting, specified in that protocol.
UK Statutory Instrument 2004/1031 (as amended), Part 5, Regulation 32(5)

5.1.1. Finding Detail

Adverse events that occurred within the 30 days after dosing of the IMP were not reported by the investigator site in the eCRF in deviation from the protocol. 26 AEs across eight participants (24 participants reviewed) and their associated concomitant medication use

were not recorded in the eCRF despite being reported by the participant via the participant diary (paper). For example:

- Participant [redacted], dosed on the [redacted] reported an [redacted], and [redacted] as occurring within the first 30 days after dosing in their participant diary. The visit 2 source data worksheet showed that the research nurse had checked the 'diary and had marked 'No' for unsolicited AEs, but this was not reflective of the returned participant diary, and these data had not been entered into the eCRF.

- An AE of [redacted] was recorded in [redacted] participant diary as occurring within 30 days post-dosing. This was not recorded in the source data worksheets used by the site and was not added to the eCRF. It was also noted that the AE was not assessed by an investigator to determine if this met the criteria of an [redacted] as defined by the protocol and as required to identify the primary endpoint of the trial.

Inspected Organisation's Response - 01

[redacted]

Corrective Actions (s)	**Due Date (DDMMMYYY)**

[redacted]	
Preventative Action(s)	**Due Date (DDMMMYYY)**
[redacted]	

MHRA Review – 01

Response Accepted.

6. Other Findings

There was **one Other finding** identified during this inspection relating to Protocol Compliance.

6.1. Protocol Compliance

6.1.1. Finding Detail

Examples where participants were not observed for the 30 minutes after dosing (as mandated by the protocol) were noted:

- Participant [redacted] was dosed on the [redacted] with their second dose. The participant was dosed at 09:40. The participant was allowed to leave at 09:54. A note had been added to the source data worksheet that stated "subject had to leave" but this entry was not attributable or dated.

- Participant [redacted] was dosed with their second dose on the [redacted] The dose was delivered at 10:12, and the end time of the post vaccination observation was 10:35, i.e. 23 minutes after vaccination. There was no comment or note in the source data worksheet identifying the deviation.

Other Inspected Organisation 02 Findings

INSTRUCTIONS TO INSPECTED ORGANISATION

If a separate response is provided by the inspected organisation and the Other Inspected Organisation 02, ensure this is clearly differentiated in the responses provided below.

Inspection responses and any subsequent clarifications should be completed in the fields provided for each Critical and Major graded finding. Please ensure there is a different row for each corrective and preventative action with the planned completion dates. Do not append any additional documentation or insert any file links. Please provide any other referenced documents as separate files.

No responses are required for Other graded findings. However, suitable evaluation, root cause, corrective actions and preventative actions should be generated with appropriate timelines by the inspected organisation. Evidence of the evaluation and subsequent actions including evidence of the completion of actions may be requested from the inspected organisation at any time including at future inspections.

No responses are required for Observations or Recommendations.

7. Critical Findings

There were **no Critical findings** identified during this inspection.

8. Major Findings

There was **one Major finding** identified during this inspection relating to Record Keeping/Essential Documents.

8.1. Record Keeping/Essential Documents

(1) The sponsor shall keep a trial master file for a clinical trial. (2) The sponsor shall ensure that the trial master file is readily available at all reasonable times for inspection by the licensing authority or any person appointed by the sponsor to audit the arrangements for the trial. (3) The master file shall at all times contain the essential documents relating to that clinical trial. (4) The essential documents relating to a clinical trial are those which(a) enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and (b) show whether the trial is, or has been, conducted in accordance with the applicable requirements of Directive 2001/83/EC, the Directive, the GCP Directive and Commission Directive 2003/94/EC.
UK Statutory Instrument 2004/1031 (as amended), Regulation Part 31A

The necessary procedures to secure the quality of every aspect of the trial shall be complied with.
UK Statutory Instrument 2004/1031 (as amended), Schedule 1, Part 2, (4)

8.1.1. Finding Detail

Laboratory data and supporting information relating to polymerase chain reaction (PCR) sample processing, extraction and analysis was not retained in the TMF for the [redacted] rial. While it was noted that sample receipt documentation had been filed, section 08.01.03 of the GSK TMF model (laboratory results documentation) was missing from the TMF index and had not been used for the trial. In addition, there was no signpost/locator within the TMF to indicate that the PCR assay data was retained outside the TMF and was available via access to other GSK computerised systems:

- [redacted](for sample traceability).
- [redacted] (for sample processing and extraction).
- Real time PCR instrument software (for sample analysis data).

This was graded as a Major finding as the [redacted] trial was not the only trial impacted by this issue. This approach had been routinely used for maintenance of laboratory data and supporting documentation relating to clinical trial sample analysis conducted by GSK laboratories at the sites in [redacted]

It was confirmed during the inspection the laboratory data could be provided on request and had been appropriately maintained and archived. However, the TMF was deemed to be incomplete and did not meet the requirements of UK Statutory Instrument 2004/1031 (as amended), Regulation 31A as detailed above.

Inspected Organisation's Response - 01

[redacted]

[redacted]

Corrective Actions (s)	Due Date (DDMMMYYY)
[redacted]	

Preventative Action(s)	Due Date (DDMMMYYY)
[redacted]	

MHRA Review – 01

Response Accepted.

9. Other Findings

There were **four Other findings** identified during the inspection relating to Clinical Sample Analysis, Clinical Sample Management, Contract and Agreements and Computer System Validation.

9.1. Clinical Sample Analysis

9.1.1 Finding Detail

Discrepancies were identified in Task IDs recorded in PCR sample analysis documentation provided for review during the inspection (document request [redacted] Examples included:

- The Task ID for run [redacted] was detailed on page 1 of the .pdf extract [redacted] as [redacted]
- The Task ID for run [redacted] was detailed on pages 1 and 3 of the .pdf extract [redacted] as [redacted]
- The Task ID for run [redacted] was detailed on page 1 of the .pdf [redacted] as [redacted]

Inspectors were informed during the inspection that the Task ID was unique to the analysis of each PCR plate.

9.2. Clinical Sample Management

9.2.1 Finding Detail

It was identified post inspection that participant [redacted] (from UK site [redacted] had requested destruction of any remaining biological samples from the [redacted] trial on 10 September 2024 but this request had not been actioned. Section 3 of [redacted] version [redacted] effective 12 January 2024) detailed the mandated response times for processing individual rights requests (such as sample destruction) within the scope of privacy laws in the EEA, UK and Switzerland and indicated that these 'require completion without undue delay or within 1 calendar month'. It was noted that this had been actioned once it was identified and samples were destroyed on 14 October 2025. It was acknowledged that post inspection a deviation had been raised to document the issue and [redacted] had been updated to version [redacted] (effective 14 October 2025) to reinforce identification and escalation of individual rights requests in future.

9.3. Contracts and Agreements

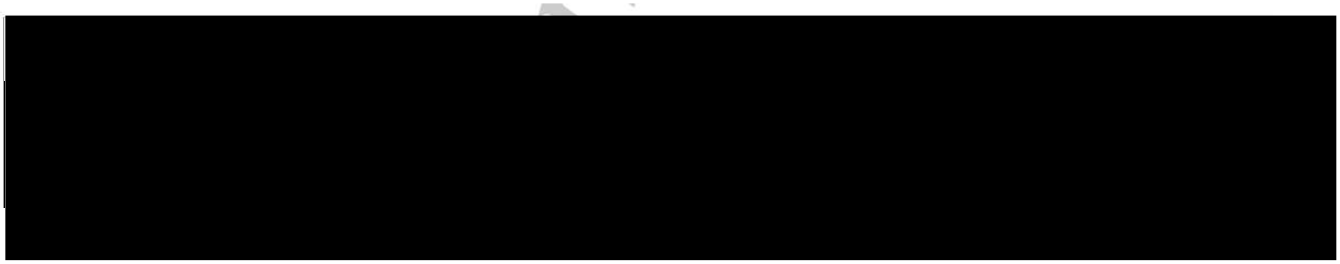
9.3.1 Finding Detail

The global Central Laboratory Worksheet (CLW) representing the written agreement between [redacted] and GSK for sample logistics in the [redacted] trial contained internal inconsistencies. There were examples of sections that were completed as 'N/A' that also contained trial specific instructions and information, for example, page 79 which indicated shipment frequencies for samples.

9.4. Computer System Validation

9.4.1 Finding Detail

Section 3.2 of the validation report for the [redacted] (report reference [redacted] version [redacted] issued 15th November 2023) contained the following error (screenshot) which had not been identified and corrected during report review and issue:



Report Authorship & Review

Report Author:

[redacted]

GCP Inspector, Compliance Team 1, Standards and Compliance, MHRA

Report Reviewer (for Inspected Organisation and Other Inspection Organisation 01):

[redacted]

[redacted] GCP Inspector, Compliance Team 1, Standards and Compliance, MHRA

Report Reviewer (for Other Inspection Organisation 02):

[redacted]

[redacted] Compliance Team 1, Standards and Compliance, MHRA and UK GLPMA

The factual matter contained in the Inspection Report relates only to those things that the inspection team saw and heard during the inspection process. The Inspection Report is not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined during the inspection.

Inspection Closing Statement

GCP INSPECTION STATEMENT

Inspection & Organisation Information	
Inspection Number	INSP GCP 19494/37251014-0002
Purpose of Inspection	Statutory GCP Trial Specific Inspection
Type of Inspection	Hybrid
Organisation Inspected	GSK
Organisation Address	GSK HQ, 79 New Oxford Street, London. WC1A 1DG
Organisation Type	Commercial Sponsor
Dates of Inspection	19-23May2025 with a remote inspection day on the 13May2025
Lead Inspector	[redacted] GCP Inspector[redacted]
Accompanying Inspector(s)	[redacted] GCP Inspector[redacted] [redacted] GCP Inspector[redacted] [redacted] GLP Inspector[redacted]
Date of Inspection Statement	12Feb2026

The organisation has provided corrective and preventative actions in response to the inspection report. These have been reviewed by the GCP Inspectorate and are considered acceptable. This inspection can be considered closed.

In summary:

There were no “Critical” findings identified during this inspection.
There were two “major” findings identified during this inspection relating to:

- Pharmacovigilance
- Monitoring

The factual matter contained in the GCP Inspection Report relates only to those things that the Inspection team saw and heard during the inspection process. The GCP Inspection Report and Inspection Statement are not to be taken as implying a satisfactory state of affairs in documentation, premises, equipment, personnel or procedures not examined on this occasion.

Statement Issued by

[redacted]

GCP Inspector, Compliance Team 1, Standards and Compliance, MHRA

Appendix I Summary of Activities

Inspected Trial

Activity	Assessed			Comment
	Yes	Partial	No	
Analytical Laboratory			✓	
Archiving			✓	
BE/ BA Activities			✓	
Clinical Pathology Laboratory			✓	
Clinical Trial Reporting	✓			
Computerised Systems	✓			
Contracts & Agreements	✓			
Data Management	✓			
eCRF / Diaries / IVRS			✓	
IMP Management	✓			
Medical Affairs			✓	
Monitoring	✓			
Pharmacovigilance	✓			Reviewed in relation to IMP [redacted]
Project Management	✓			
Quality Assurance	✓			
Quality Systems	✓			
R&D Unit (Non-commercial only)			✓	
Regulatory Affairs			✓	
Statistical Analysis	✓			

Technical Facility (i.e. x-ray)			✓	
Training	✓			
Trial Master File/Essential Documents	✓			
Other			✓	

Other Inspected Organisation 01

Activity	Assessed			Comment
	Yes	Partial	No	
Principal Investigator	✓			
Research Nurse	✓			
Sub-Investigator			✓	
Laboratory			✓	
IMP Management / Pharmacy	✓			
Consents	✓			
CRFs, eCRFs, Participant Diary, IVRS	✓			
Source Data	✓			
Site Master File		✓		Reviewed in relation to the [redacted] trial.
Technical Facility (i.e. x-ray)			✓	
Other			✓	

Other Inspected Organisation 02

Activity	Assessed			Comment
	Yes	Partial	No	
Analytical Laboratory	✓			
Archiving			✓	
BE/ BA Activities			✓	
Clinical Pathology Laboratory			✓	
Clinical Trial Reporting		✓		Reviewed laboratory data presentation in the CSR
Computerised Systems		✓		Reviewed computerised systems used to support generation of laboratory data
Contracts & Agreements			✓	
Data Management		✓		Reviewed management of laboratory data
eCRF / Diaries / IVRS			✓	
IMP Management			✓	
Medical Affairs			✓	
Monitoring			✓	
Pharmacovigilance			✓	
Project Management			✓	
Quality Assurance			✓	
Quality Systems			✓	
R&D Unit (Non-commercial only)			✓	
Regulatory Affairs			✓	

Statistical Analysis			✓	
Technical Facility (i.e. x-ray)			✓	
Training	✓			Training for laboratory staff
Trial Master File/Essential Documents	✓			
Other	✓			Reviewed laboratory facilities

Appendix II Definitions of Findings

Critical

a. Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that:

   i. the rights, safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or

   ii. the clinical trial data are unreliable and/or

   iii. there are a number of Major non-compliances (defined in (d) and (e)) across areas of responsibility, indicating a systematic quality assurance failure, and/or

b. Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances (defined in (d) and (e)).

c. Where provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the Regulations

Major

d. A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or

e. Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure.

Other

f. Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.

Appendix III Reference Texts

- UK Medicines Act 1968.
- The Human Medicines Regulations 2012, SI 1916 and the applicable statutory instruments including 2004/1031 (and subsequent amendments).
- ICH E6 ‘Note for Guidance on Good Clinical Practice’.
- Annex 13 to the EU Guide to Good Manufacturing Practice, ‘Manufacture of Investigational Medicinal Products’, July 2010.
- ICH E2A ‘Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting’.
- Communication from the Commission — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (‘CT-1’) (2010/C 82/01).
- Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use (‘CT-3’) (2011/C 172/01).
- Heads of Medicines Agencies, Clinical Trial Facilitation & Coordination Group — Q&A Document: Reference Safety Information, November 2017 (RSI).

Appendix IV Glossary

AE	Adverse Event
ADR	Adverse Drug Reaction
ASR	Annual Safety Report
ATMP	Advanced Therapy Medicinal Product
CA	Competent Authority
CAPA	Corrective Action Preventive Action
CI	Chief Investigator
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organisation
CSR	Clinical Study Report
CSV	Computer Systems Validation
CTA	Clinical Trial Authorisation or Clinical Trial Agreement
CTFG	Clinical Trial Facilitation Group
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	Curriculum Vitae
DE	Dose Escalation
DSMB	Data Safety Monitoring Board
DSUR	Development Safety Update Report
eCRF	Electronic CRF
eCOA	Electronic Clinical Outcome Assessment
ePRO	Electronic Patient Reported Outcome
eTMF	Electronic Trial Master File
FIH	First in Human
FPFV	First Patient First Visit
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HRA	Health Research Authority
IB	Investigator's Brochure
ICF	Informed Consent Form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IDMC	Independent Data Monitoring Committee
IMP	Investigational Medicinal Product
IRT	Interactive Response Technology
ISF	Investigator Site File/Investigator TMF
LPLV	Last Patient Last Visit
MAA	Marketing Authorisation Application
MHRA	Medicines and Healthcare products Regulatory Agency
MVR	Monitoring Visit Report

PI	Principal Investigator
PIS	Patient Information Sheet
PV	Pharmacovigilance
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
QP	Qualified Person
RA	Regulatory Authority
R&D	Research and Development
REC	Research Ethics Committee
RMP	Risk Management Plan
RSI	Reference Safety Information
RWD	Real World Data
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SDR	Source Data Review
SmPC / SPC	Summary of Product Characteristics
SI	Sub-investigator
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TOPS	The Over-volunteering Prevention Scheme
UAT	User Acceptance Testing