

GCP INSPECTION STATEMENT

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| Inspection Number | INSP GCP 13605/19486-0003 |
| Type and Purpose of Inspection | Statutory GCP Systems Inspection |
| Organisation Inspected | Plymouth Hospitals NHS Trust |
| Organisation Address | ITTC Building, Tamar Science Park Derriford, Plymouth. PL6 8BX |
| Organisation Type | Non-Commercial Sponsor |
| Dates of Inspection | 9 th – 12 th June 2014 |
| Lead Inspector | Gail Francis, Expert Inspector GCP |
| Accompanying Inspector(s) | Emma Whale, GCP Inspector |
| Date of Inspection Statement | 2 nd October 2014 |

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 was **one Critical finding** identified during this inspection relating to Data Integrity.

There was **one Major finding** identified during this inspection relating to Organisation's Oversight of Clinical Trials of IMPs

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

Gail Francis
Expert GCP Inspector, MHRA