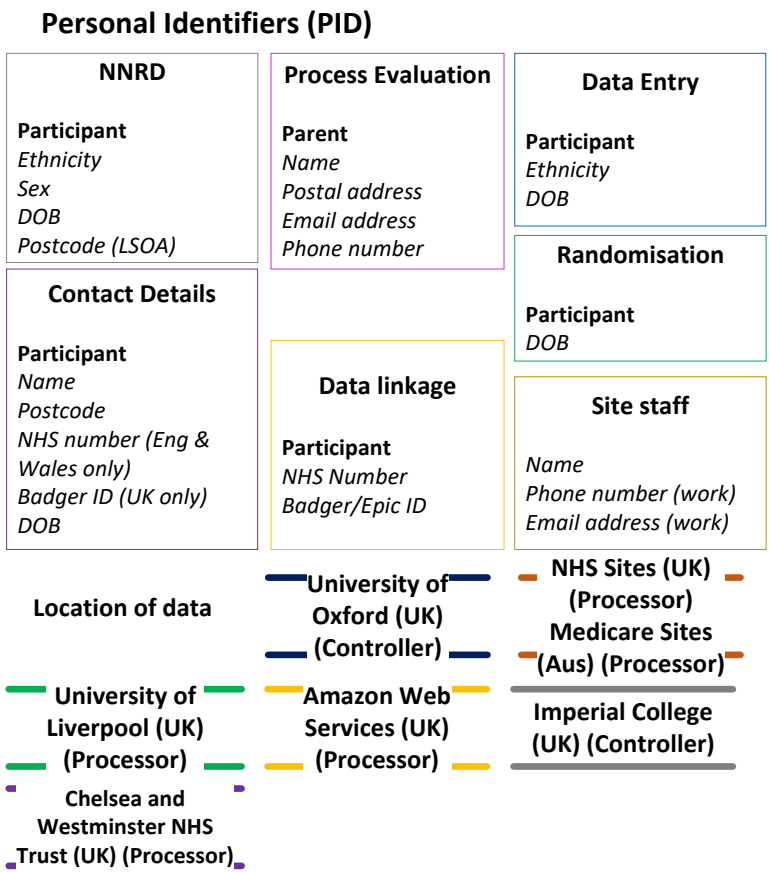
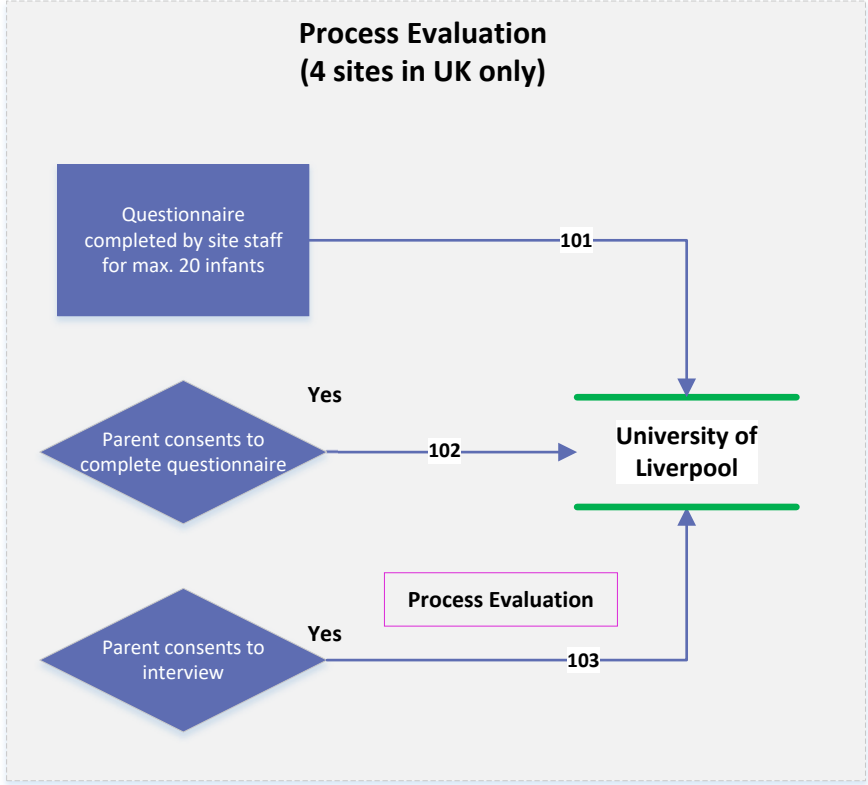


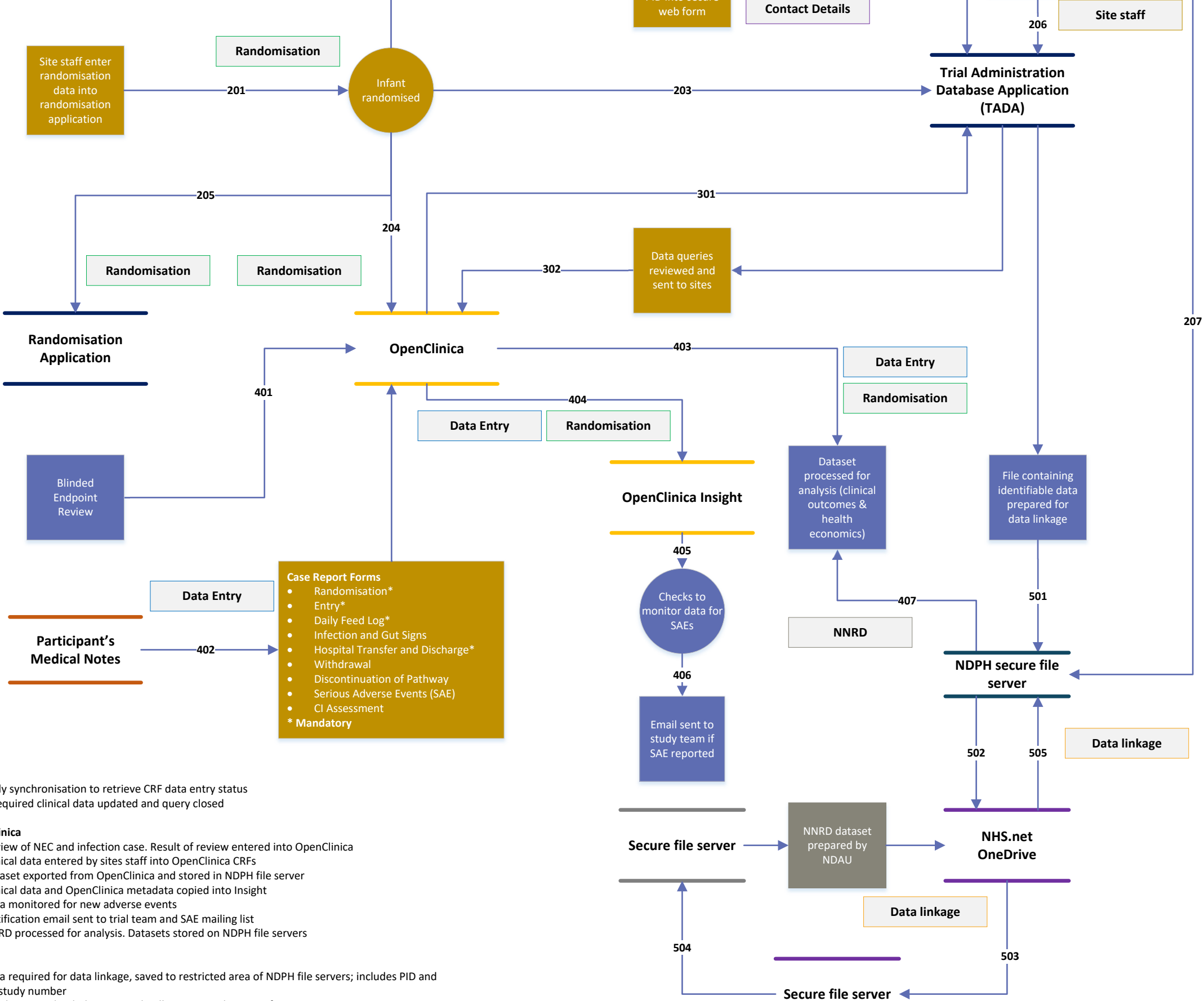


Process Evaluation
101 Paper questionnaire completed by site staff and sent back to UoL
102 Paper questionnaire completed by parent and posted back to UoL
103 Interview with parent completed by UoL

Randomisation
201 Site staff enrol participant using study randomisation application
202 PID transferred using HTTPS protocol and saved into TADA
203 Details of new randomisation POST to TADA
204 Record created in OpenClinica. Randomisation data imported into Randomisation and Entry CRFs
205 Data saved in randomisation MySQL database
206 Details of site staff delegated study duties are entered into TADA
207 Site delegation logs and training records stored sent to NPEU and saved on NDPH file server

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neoGASTRIC Data Flow



TADA
301 Daily synchronisation to retrieve CRF data entry status
302 If required clinical data updated and query closed

OpenClinica
401 Review of NEC and infection case. Result of review entered into OpenClinica
402 Clinical data entered by sites staff into OpenClinica CRFs
403 Dataset exported from OpenClinica and stored in NDPH file server
404 Clinical data and OpenClinica metadata copied into Insight
405 Data monitored for new adverse events
406 Notification email sent to trial team and SAE mailing list
407 NNRD processed for analysis. Datasets stored on NDPH file servers

NNRD
501 Data required for data linkage, saved to restricted area of NDPH file servers; includes PID and unique study number
502 PID dataset uploaded to Imperial College secure data transfer service
503 Data copied from NHS.net OneDrive to ChelWest server and linkage performed
504 Data copied from ChelWest to Imperial College
505 Linked NNRD dataset downloaded from NHS.net OneDrive and saved to secure area on NDPH file server

Abbreviations

NDAU – Neonatal Data Analysis Unit
NNRD – National Neonatal Research Database
NDPH – Nuffield Department of Population Health