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## Site set up

### What are the steps in the set up process?

* Initial site conversations and nomination of site PI
* DART sends Local Info Pack, including Organisational Information Document (OID) & delegation log, using IRAS templates
* Site R&D Department discuss with networking and PACS teams, IF, finance, TLHC, CT provider, radiology department(s) and pathology labs of follow on hospitals
* Site R&D Department review and sign OID
* Site R&D confirms Capacity & Capability, DPIA (local requirements), ISF, delegation log
* R&D give own green light and request green light from DART
* DART gives green light on behalf of Sponsor
* IT network set up
* Data transfer commences

### What R&D docs and processes are required?

* Send completed version to DART
  + Delegation log
  + Confirmation of Capacity and Capability
  + OID
* Follow local practices
  + DPIA
  + ISF

### What budget is available for site teams?

DART does not want to put a burden on site teams, so is prepared to cover all staff costs at overtime rates, as well as any direct costs such as postage for the slides. The budget is agreed as part of the OID process. We can be flexible when we see how long processes actually take.

### Our infrastructure engineer is concerned by the IG sign off. Who gives IG sign off from the site side?

The R&D Department in liaison with the Principal Investigator is responsible for getting IG sign off before agreeing and signing the OID.

### What about GCP?

The DART central team need to confirm that they have had annual GCP training and the site PI is likely to have had GCP training, but others on the site teams do not require it. We are all GCP compliant within the Oxford University Hospital lab and everybody's GCP approved, which is updated every two years.

### Who else needs to be included?

The Trust Finance Office will need to invoice DART quarterly in arrears. To accompany the invoice there should be a breakdown of costs for each of the following categories, with supporting evidence, in accordance with UKRI guidance.

|  |  |
| --- | --- |
| Staff costs | Name of Staff member, FTE, period of dates worked, total per person |
| Consumables | Item and total amount, with accompanying invoice |
| Other costs | Item and total amount, with accompanying invoice |
| Equipment | Date of purchase / supplier / type of equipment / total amount |

### What is the time frame for the project?

Current UKRI and CRUK funding goes to 31st March 2024. In order of the scientists to develop their algorithms within this time scale, we are looking to receive data as soon as possible.

## Data handling

### How do you anonymise textual report data sent either as a DICOM series, PDF document or plain text?

The approach we take is one of pulling data from those reports rather than pushing those reports to the researchers. So we'd use Natural Language Processing which would look for specific features in the text and pull that data through to a feature store for that information. But we wouldn't actually pass the text on to the researcher.

In terms of the DICOM images, we take a similar approach in that we don't pass all of the DICOM images through. We select only the information from those DICOM images that we want to pass on to the researchers.

The software developers can we can build feature extractors to ensure only coded data is passed along to researchers.

### How do I get a pseudonymised number for the histology slides?

Each site can allocate its own pseudonymisation code (Trial ID) to the slides. This is entered on a spreadsheet along with the MRN and NHS number of the patient, which is emailed to [ouh-tr.dart@nhs.net](mailto:ouh-tr.dart@nhs.net). The trial ID is written on an opaque label, which is attached to the slide, obscuring the patient identifiable data on the slide. The [Digital Pathology Manual](https://dartlunghealth.co.uk/wp-content/uploads/2022/12/2022-07-22-DART_DigPathManual_V1.1_SCM_MY-3_SH-clean-1.docx) explains this process in detail and contains a flow chart of the whole process. A flow chart detailing the processes at the site can be found [here](https://dartlunghealth.co.uk/wp-content/uploads/2022/12/Pathology-flow-chart-for-sites.docx).

### How often do we need to send data?

Our aim is to minimise work for the sites, so data can be transferred quarterly or monthly or even six-monthly, whatever suits the site.

### Are you interested in every TLHC patient or only the ones which have gone on to have a CT?

We would like data for every patient, as members of the DART team are working on the QRisk algorithm and also on Health Economics. An aim of the programme is to help NHSE see if the right patients are being selected for screening.

The projections are that it'll be cost effective and we're going to look to see if it can be made even better and more cost effective for NHS England.

### Our site uses outsourced delivery partners who use the NHS number but not necessarily the MRN. Do you need both?

We can work from one or the other, but having both gives a cross-check for data linkage.

### Do you have a process in place for accidental breaches of PHI (Protected/Personal Health Information) to researchers?

Oxford University and OUH NHSFT are very, very cautious about making sure that we don't send any identifiable information out to academics who shouldn't see it. So we have approvals in place and we are audited annually to make sure that we fulfil them and if any data breach is identified, we have to report it and it gets investigated.

### What about data governance?

We've got all the approvals in place to have the lung health check spreadsheets and CT sent through with their NHS numbers and details on. When they arrive in Oxford, they get anonymised when they put on the Hermes server. From the Hermes server, they can then go off to the academics and we know that there is no link then between the patients and where they come from. We have CAG approval for this (22/CAG/0010) and have taken PPIE advice and had university sing off on this as well.

## Networking

### What will the DART overall structure be?

It will be a hub and spoke structure, with DART (in OUH) as the hub, and each site as a spoke. DART VPN details can be found [here](https://dartlunghealth.co.uk/wp-content/uploads/2022/12/OUH-Dart-Project-VPN-Details-v1.1.docx).

### Will the data be encrypted?

Yes, it will be encrypted and sent to an HSCN VPN, which is AES 256.

### When do you need the VPN up and running?

As soon as possible. The set up can be done concurrently with the governance discussions, **provided no data is transferred.**

## Shared learning

### Is there is a forum on the website (or Slack) for sharing problem-solving?

This is an excellent idea. Our website is on a very basic platform but we will investigate the option of a forum or finding a way to upload these FAQs so they are readily to hand

### How can we ask questions or hear more about DART?

There was a suggestion of an email newsletter to give updates on progress, which we will introduce in 2023. The Chief Investigator and/or Project Manager are always willing to set up 1:1 or teams calls as requested and respond to emails as promptly as possible.

### Could you provide an easy-to-understand guide to the technical requirements?

“[Data transfer information sheet.docx](https://dartlunghealth.co.uk/wp-content/uploads/2022/12/Data-transfer-information-sheet.docx)” covers this and we’d welcome feedback on how to simplify it.

### Will you be sharing the slides from the shared learning meeting on 6th December??

The slides are available [here](https://dartlunghealth.co.uk/wp-content/uploads/2022/12/2022-12-06-DART-shared-learning.pptx)

## Who is who

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