

Efficacy of SARS-Cov-2 vaccination in wait-listed and transplant recipients.

- Assess the humoral response to SARS-Cov-2 vaccination
- Blood at one time point (4 weeks after second dose)
- 3000 transplant patients (kidney, liver, cardiothoracic)
- 500 waiting-list patients (any organ)
- 500 healthy controls (spouse / partner of tx patient).



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Inform patients of the study



Patient groups
& Charities

Transplant
Units

Social
Media

★ THE ORIGINAL INTERNET RANDOMISER



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Patient registration.
On-line consent

On-line platform.
Study Details
Contact Information.

Automatic Validation
NHSBT transplant /
Waiting List Registry

Serum samples sent
and stored central
biobank (QUOD).
On-line platform.
Study Details
Contact Information.



RANDOMISATION AND ONLINE DATABASES
FOR CLINICAL TRIALS

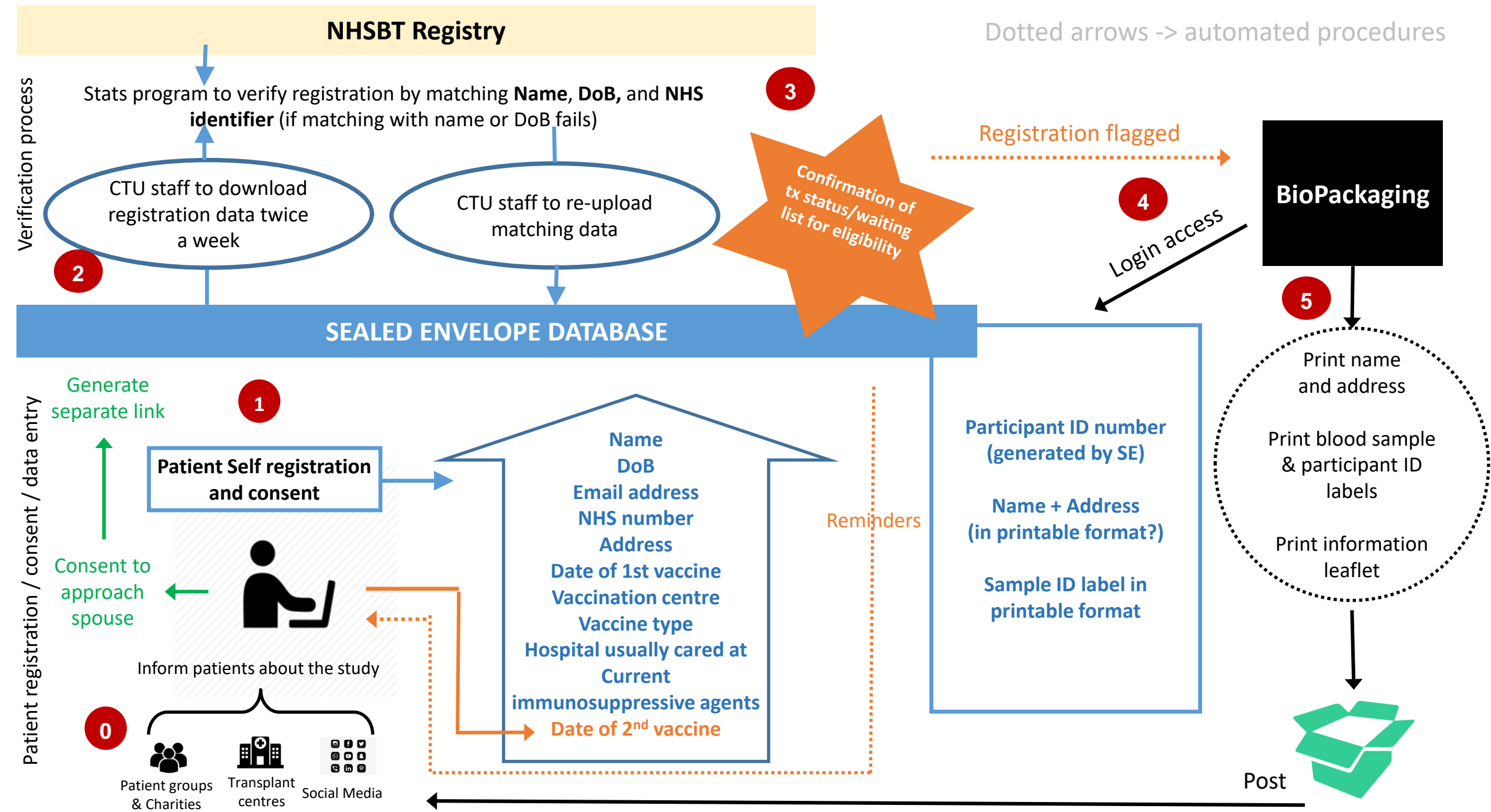
Automatic dispatch
of study blood
bottles to patient.

Bloods taken locally
four weeks after 2nd
vaccination.

Batch analysis of Ab
against spike protein.
Neutralisation assay

Sealed Envelope provides high quality and easy to use online software applications for randomising patients into clinical trials and recording their case report form data (EDC and ePRO).

<https://www.sealedenvelope.com/>



What stage are we at?



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- Web-platform being designed. Working version by 2 weeks.
- Anticipate fast-track HRA and REC approval through CUH.
- Other transplant centres nominated as 'PIC' sites.
- Dependent on funding application – (referred to NCS panel)

Badge as NIHR high priority research

NIHR | National Institute
for Health Research

High priority COVID-19 Urgent Public
Health Research Prioritisation
application

For discussion?



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- Best way of notifying patients of study?
- How to include ethnic minority groups?
- Is the one blood test sufficient?
- PPAG meeting next Tuesday 1pm.
- Volunteers to act as contacts for the PIC sites.

