

British Society for Rheumatology

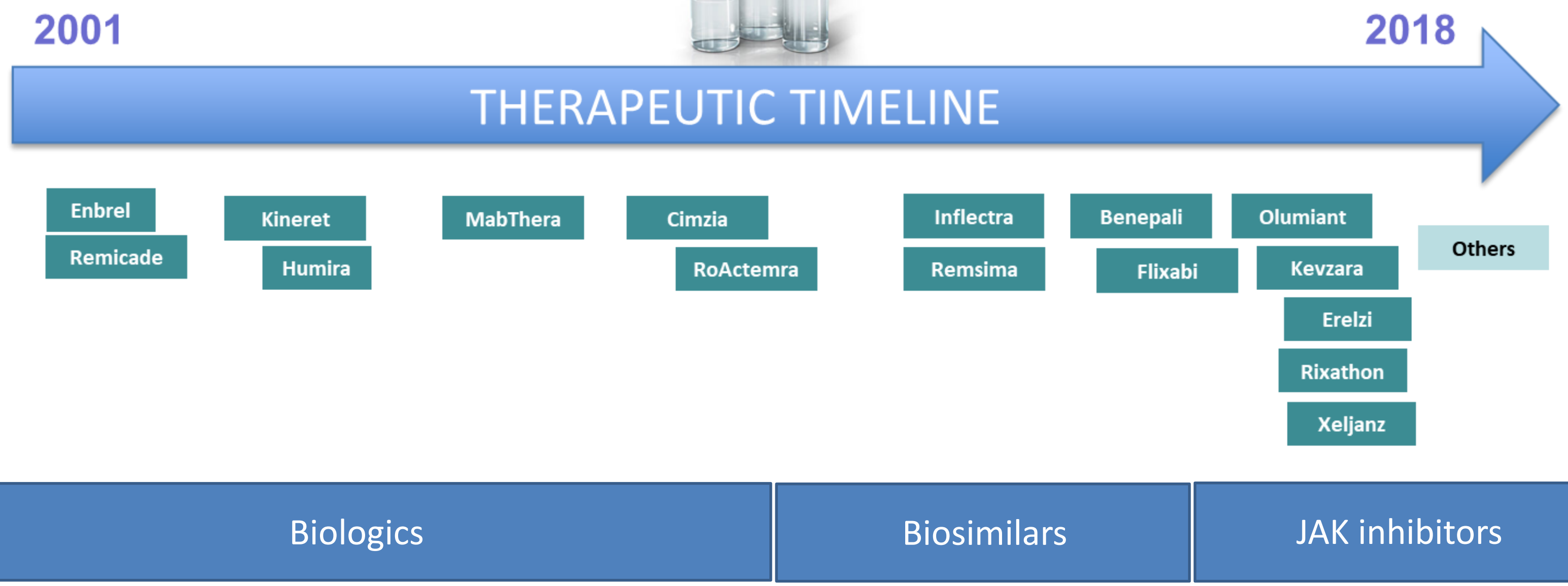
Biologics Register for Rheumatoid Arthritis



UKCRN ID: 7302

Primary Aim

To monitor the long-term safety of biologic, biosimilar, and other new targeted therapies in the UK



2023
JAKi (Jyseleca, Rinvoq) adalimumab biosimilars (Amgevita, Hymiroz, Idacio, Imraldi), rituximab biosimilars (Ruxience, Truxima), Remsima SC...

Where are the data used?

Pharmacovigilance

Used for post-marketing surveillance for pharmaceutical companies for the drug regulators (EMA, FDA)

Independent Study

c. 100 scientific academic study papers have been published using BSRBR-RA data

View related publications: <https://bit.ly/2jWtOle>

Open Data Access

External parties are encouraged to access and analyse the rich BSRBR-RA data set

Visit the BSR Website to find out more

<https://www.rheumatology.org.uk/practice-quality/registers>

Clinical Research Network and Accruals

BSRBR-RA is part of the NIHR Clinical Research Network Portfolio. This means that the study is eligible for consideration for support from the Clinical Research Network in England.

The coordinating centre at The University of Manchester are responsible for uploading recruitment figures to the Central Portfolio Management system (CPMS) on a monthly basis.

Further information on this, including a guide on accessing study support can be found on our website, at the following link:

<https://www.bsrbr.org/hospitals/research-development/clinical-research-network/>

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Recruitment Eligibility

	Aged 16 Years or over	Started eligible biologic treatment	
	Diagnosis of Rheumatoid Arthritis	Registration within 6 months of the therapy start date*	

***Patients already registered, and starting a new eligible therapy: cohort switch request needs to be made within 24 months of therapy start**

Drugs we recruit for

ANTI-TNF originators

adalimumab originator*
Humira

etanercept originator*
Enbrel

infliximab originator*
Remicade

*patients must be biologic, biosimilar &
targeted therapy naive to be eligible

BIOSIMILARS

adalimumab
biosimilars
Amgevita
Hulio
Hyrimoz
Idacio
Imraldi
Yuflyma

infliximab
biosimilars
Flixabi
Inflectra
Remsima IV
Remsima SC

etanercept
biosimilars
Benepali
Erelzi

rituximab
biosimilars
Rixathon
Ruxience

tocilizumab
biosimilars
Tyenne

OTHER TARGETED THERAPIES

baricitinib
Olumiant

certolizumab
Cimzia

tofacitinib
Xeljanz

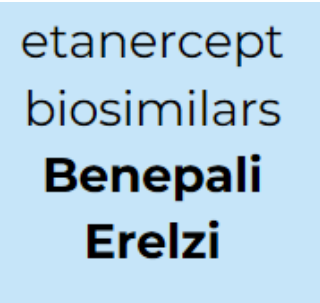
filgotinib
Jyseleca

tocilizumab
RoActemra

sarilumab
Kevzara

upadacitinib
Rinvoq

Information *required* to register patients

- ✓ Patient Details - Including NHS number (CHI number for Scotland) and HRN
- ✓ DAS28 Assessment / disease activity (originator to biosimilar only) - at the time patient started drug
- ✓ Tradename of biologic / biosimilar/targeted therapy → 
- ✓ Start date of biologic (within 6 months of registration)
- ✓ **Completed and initialled/ticked current version Consent Form***

Registration documents available to download here:

<https://www.bsrbr.org/hospitals/data-collection/registration/>

*For further information on the BSRBR-RA consent process visit:

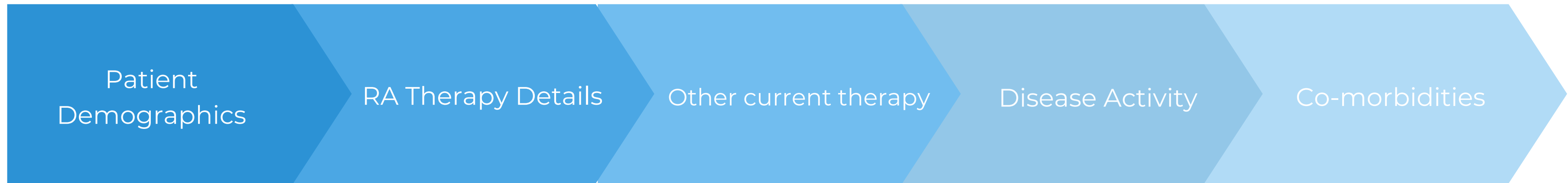
<https://www.bsrbr.org/hospitals/eligibility/consent-process/>



Baseline Data Capture

Completed upon registration of patients

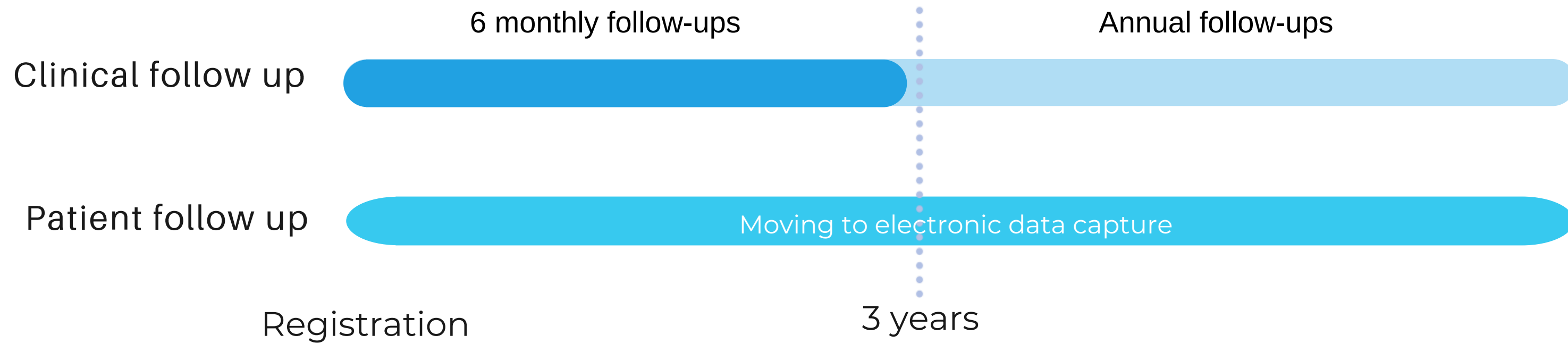
Clinic



Patient



Follow-up Timeline



Clinical follow-up data is collected every 6 months for 3 years (FUPs 1-6), then annually thereafter (FUP7+ onwards)

Patient follow-up data is collected every 6 months. We are in the process of setting up an ePROMs system to capture this data directly from patients – watch this space!

Follow-up Data Capture

1) Biologic therapy

Includes any changes to the patient's biologic/biosimilar/JAKi therapy (start & stop dates, dose, route, and reasons for discontinuation; even if temporary)

2) Other RA therapy

Includes any changes to the patient's DMARD therapy (start & stop dates and reasons for discontinuation; even if temporary) and any steroids the patient has had during the follow up period. It also includes COVID-19 vaccine information, if available.

3) Adverse Events

Details for any new illnesses or adverse events that have occurred since the last follow up

For more information on how to report adverse events:

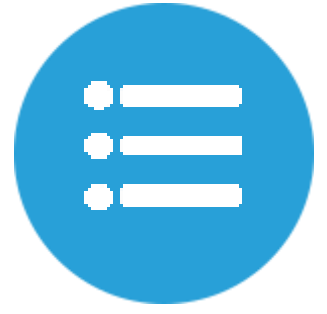
<https://www.bsrbr.org/hospitals/data-collection/adverse-events/>

4) Latest DAS28 score, weight measurement (if available)

The BSRBR-RA is Online!

What's New?

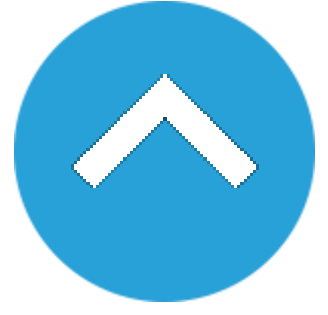
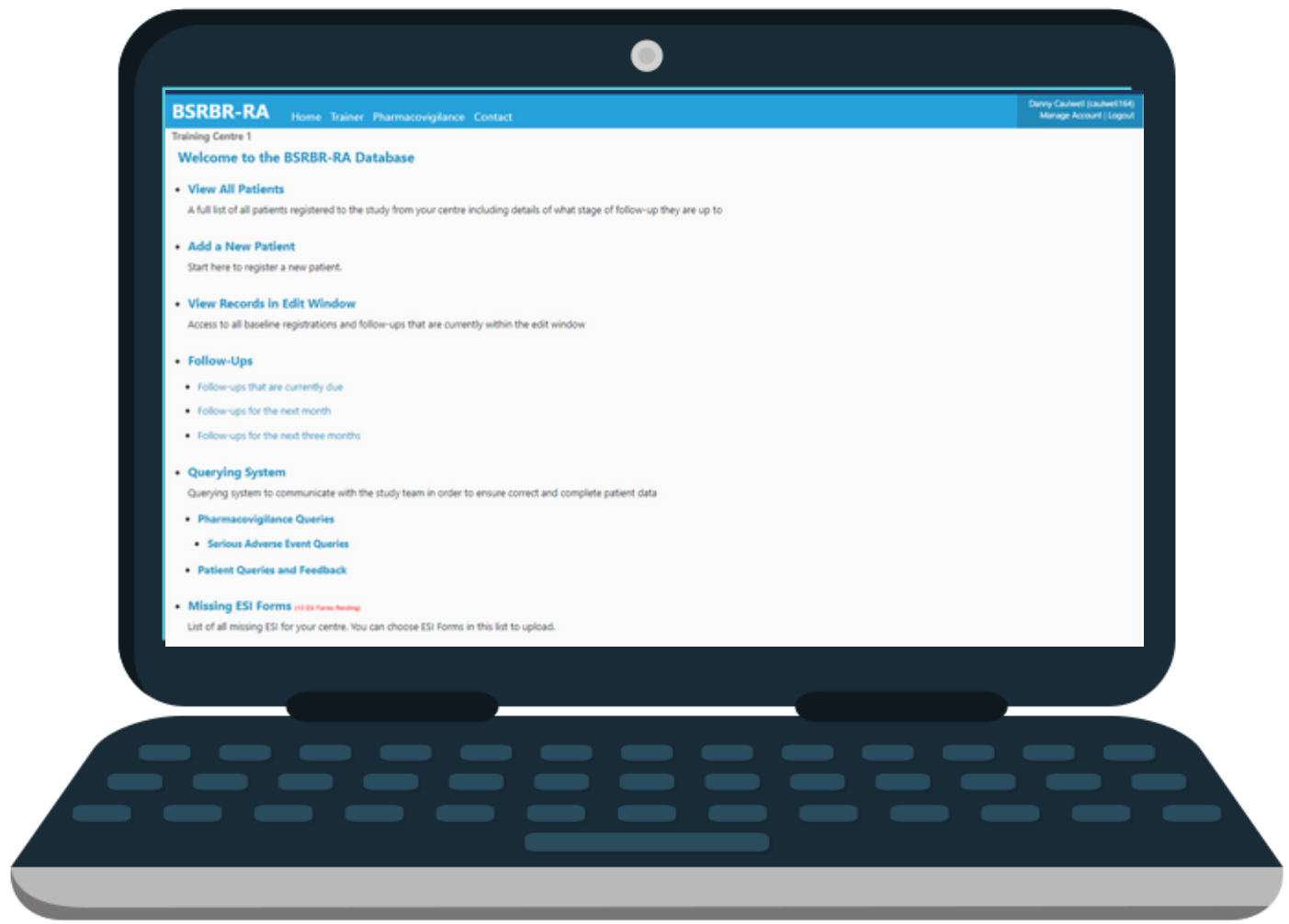
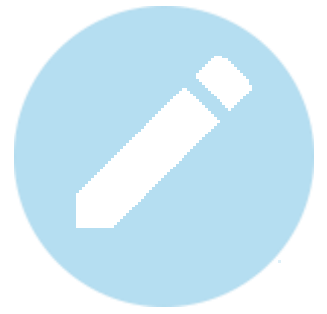
Patient List



Patient Summary



Missing ESI Forms
for serious
infections



View Follow-ups

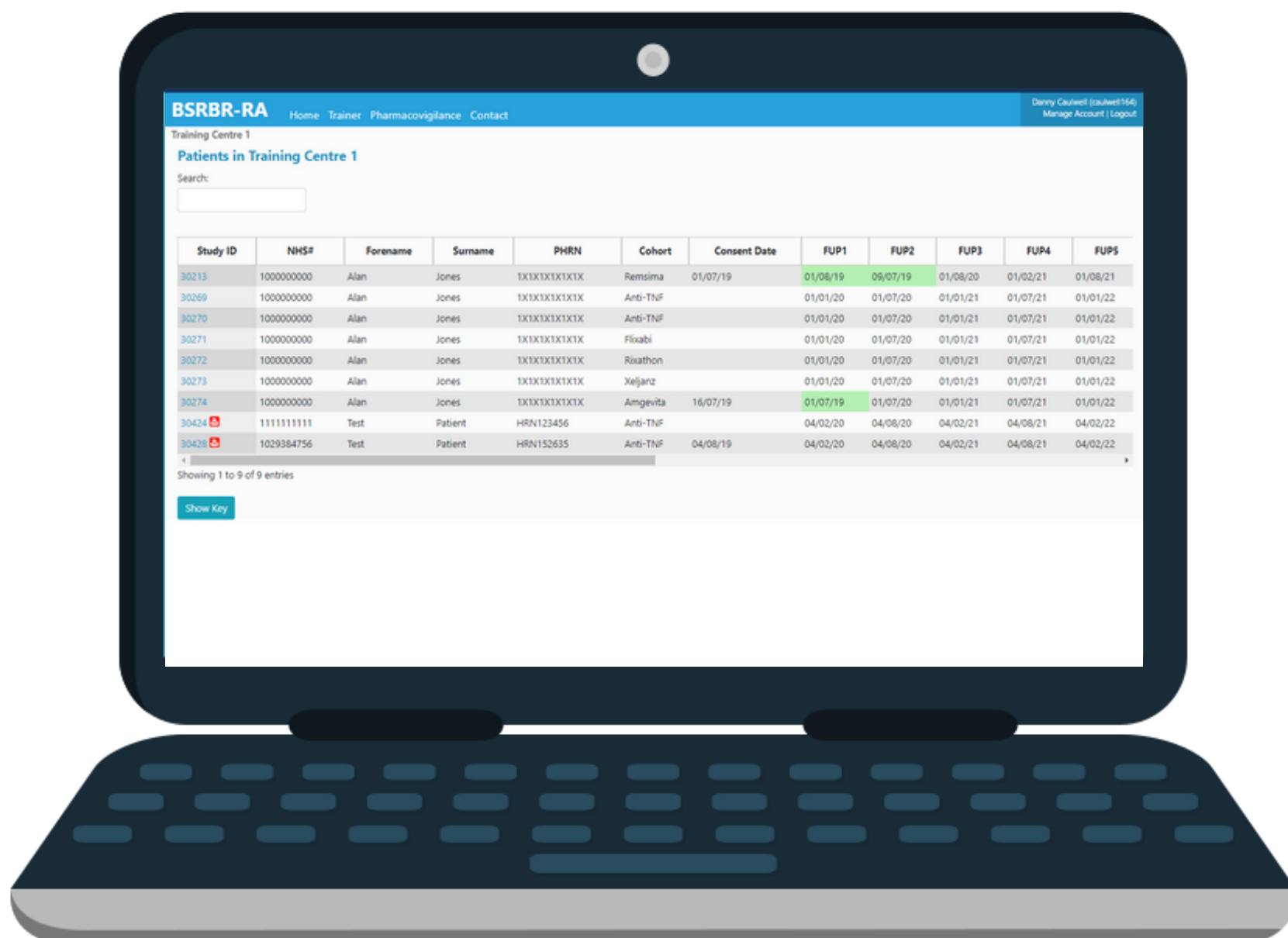


Querying system

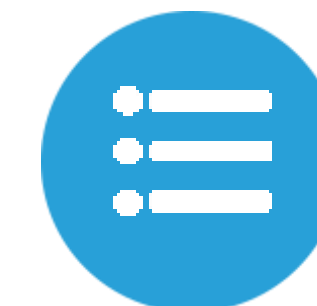


Site File

Welcome to the BSRBR-RA Database!



Patient List



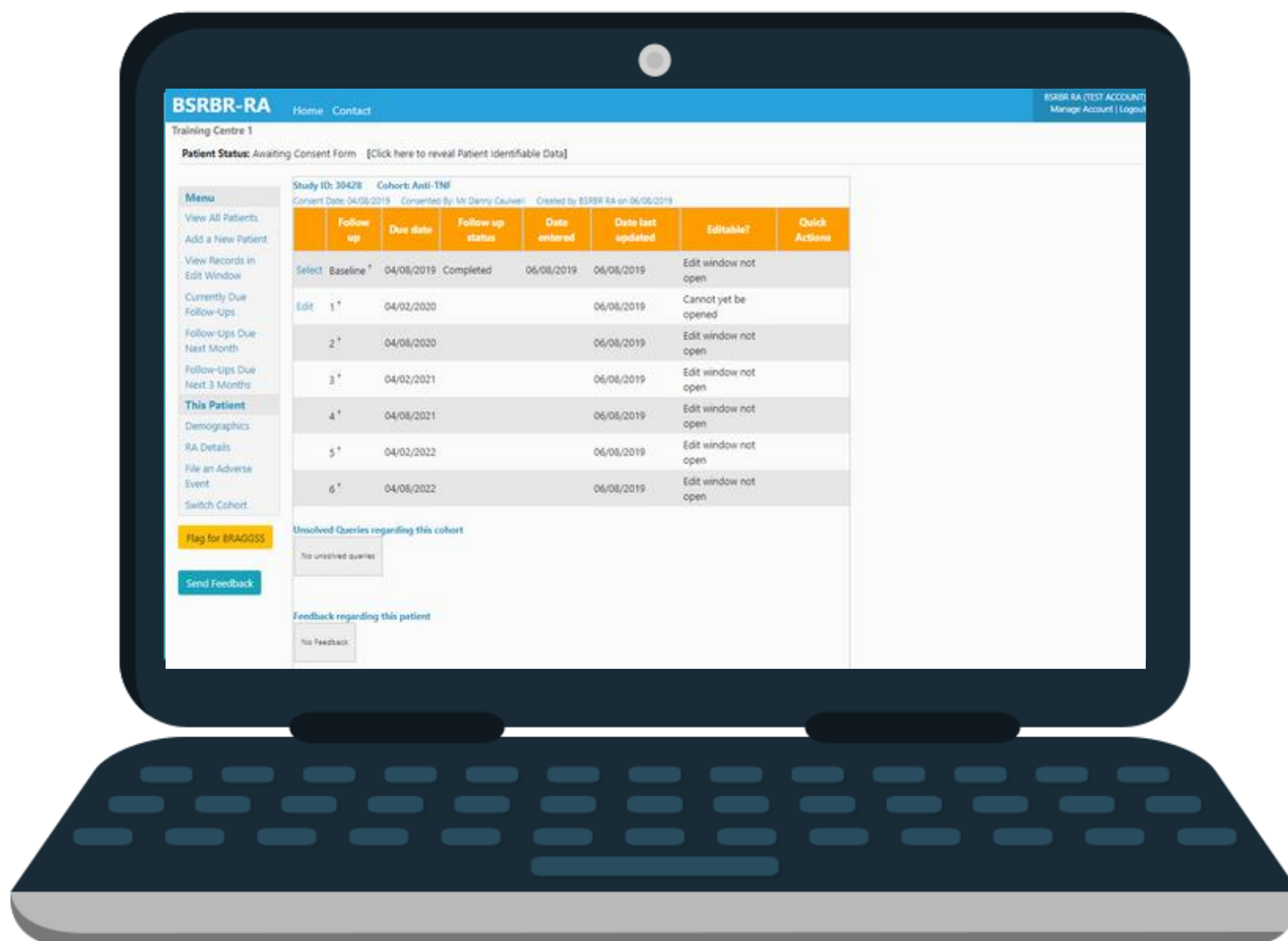
Keep track of your centre's registered participants

Search for individual participants

View follow up timeline & see when their next follow is due

Access the Patient Summary page

Welcome to the BSRBR-RA Database!



Patient Summary



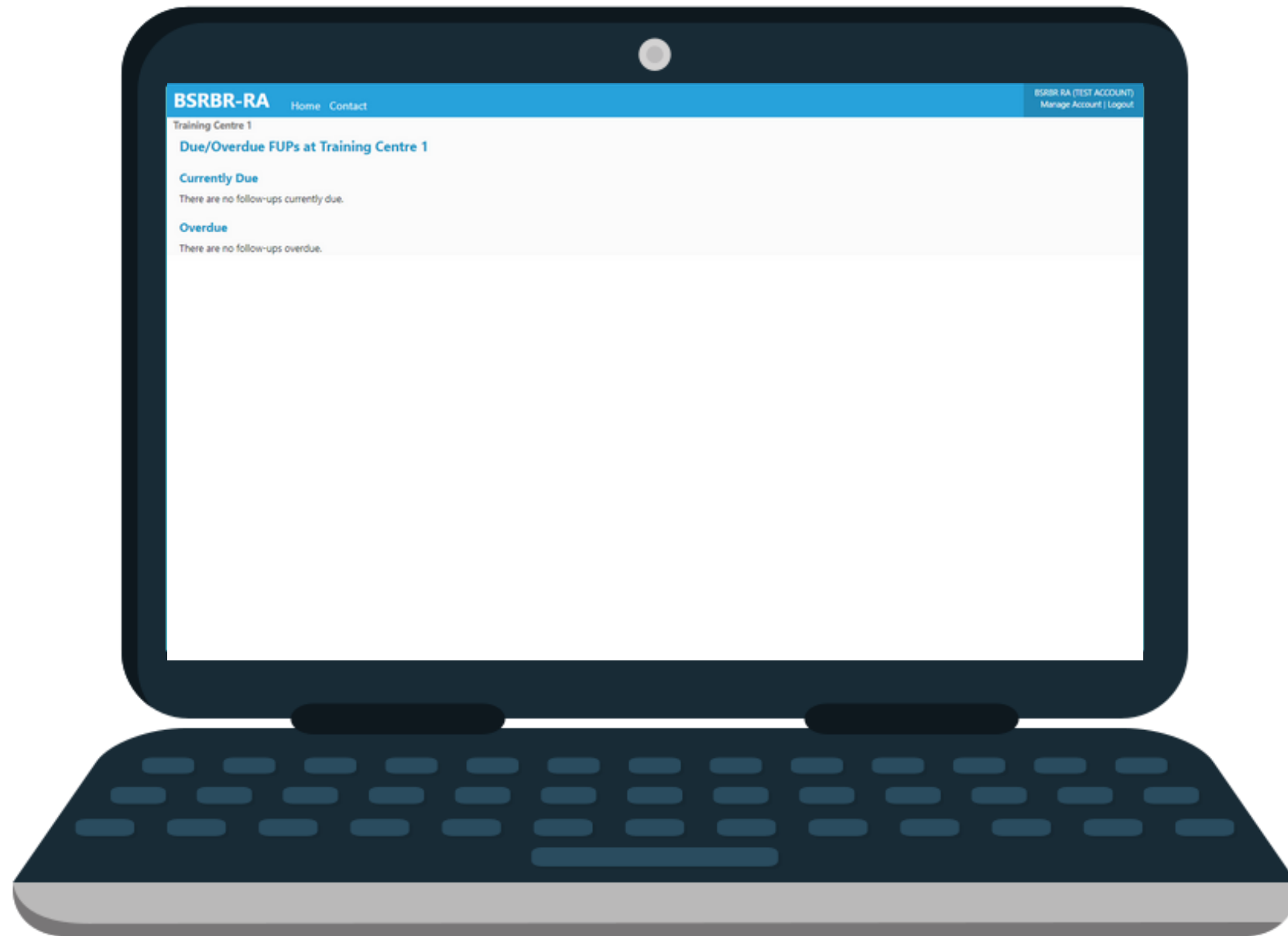
Complete the Patient Baseline & upload consent forms

See follow up timeline & complete any follow ups due

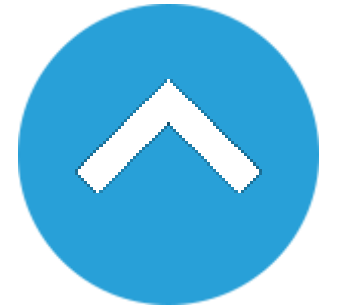
View patient demographics

See any queries for the patient

Welcome to the BSRBR-RA Database!

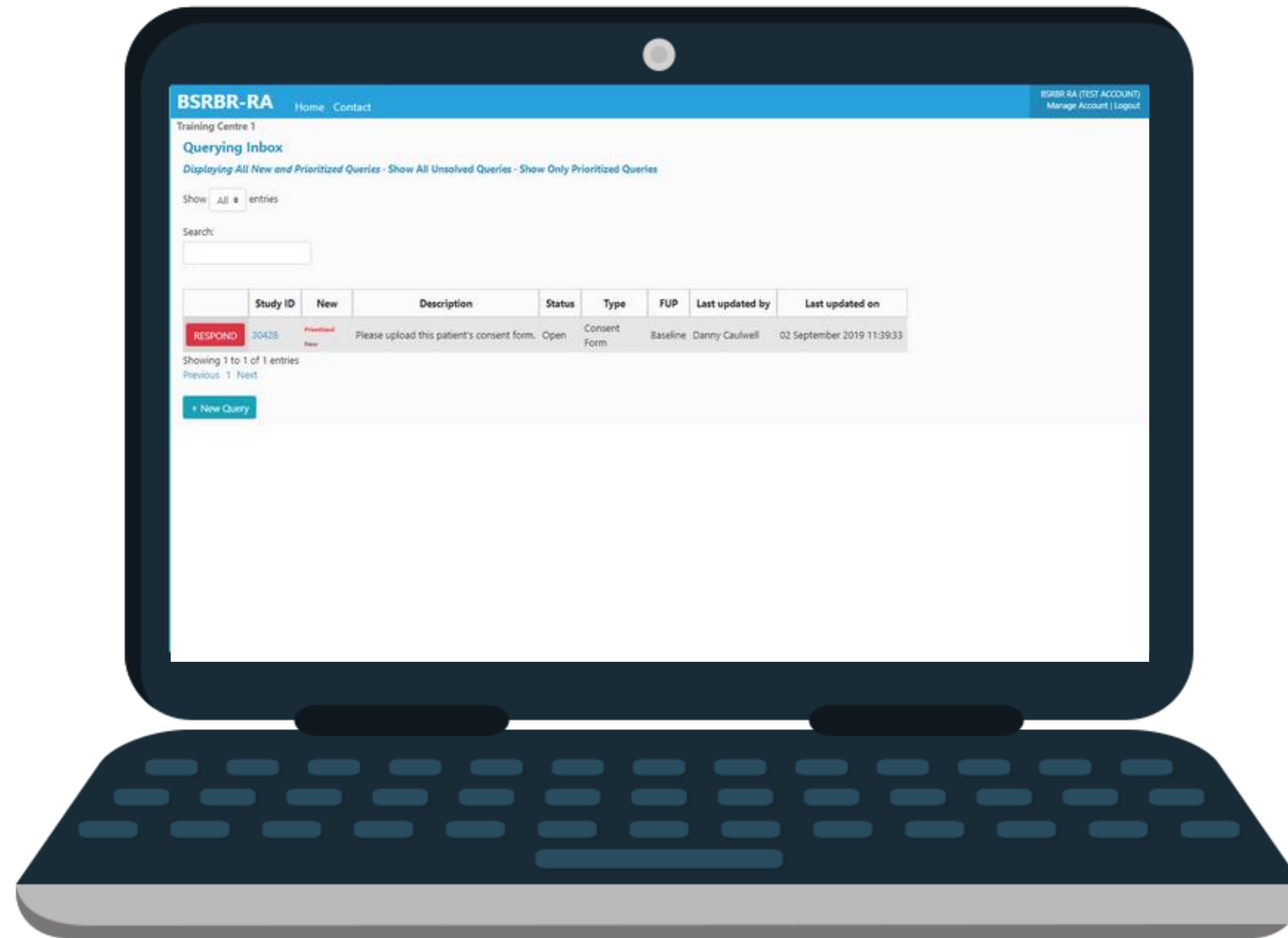


View Follow-ups



- View follow-ups currently due
- View follow-ups for the next month
- View follow-ups for the next 3 months
- Access follow-ups to be entered

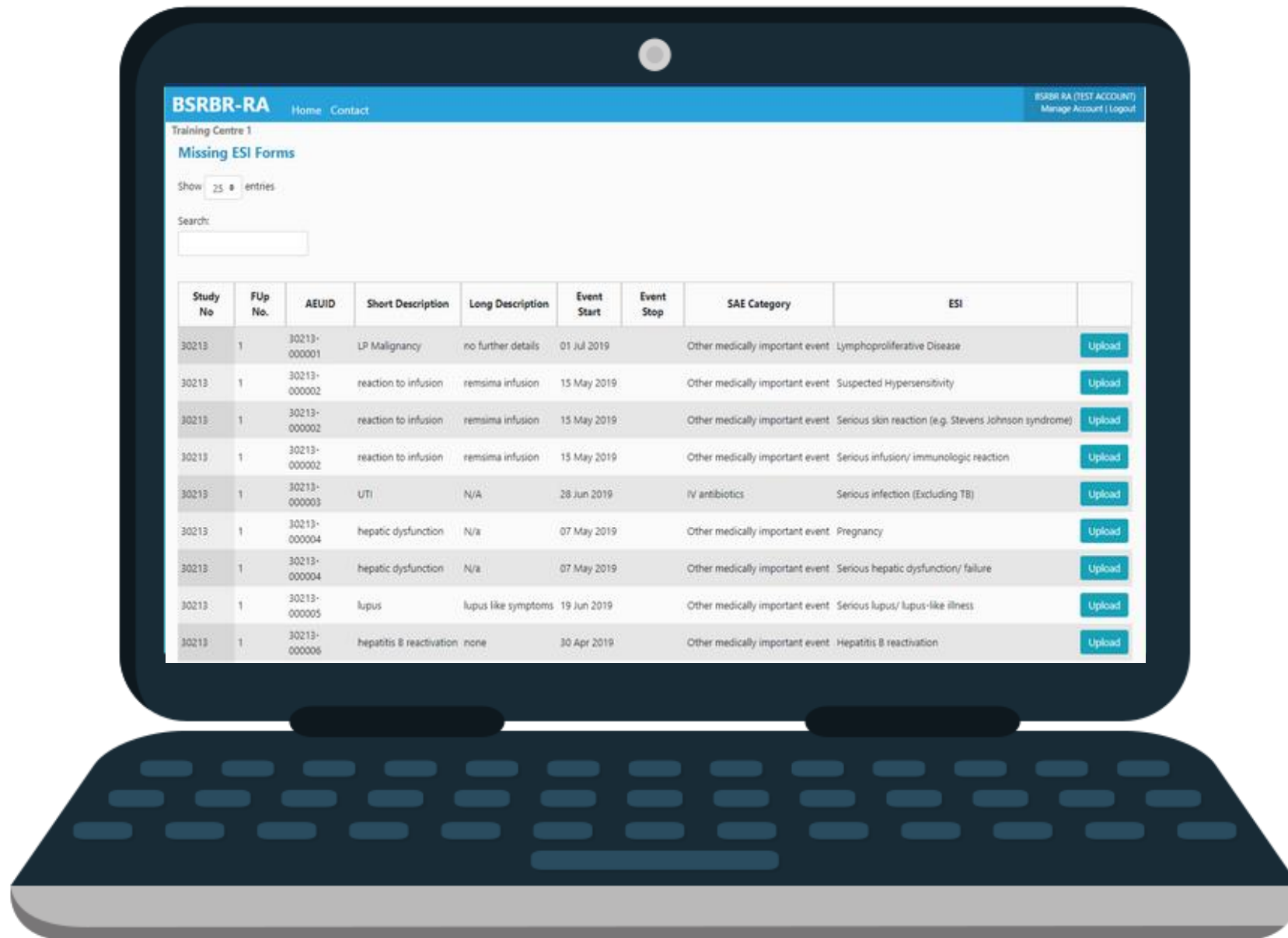
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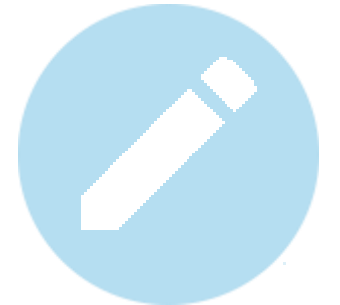
Querying system



- Communicate with the study team to ensure correct and complete data
- Communicate directly via the database, not via email, to protect patient personal data
- Respond to queries
- Pharmacovigilance Queries
- Provide feedback to the BSRBR-RA study team



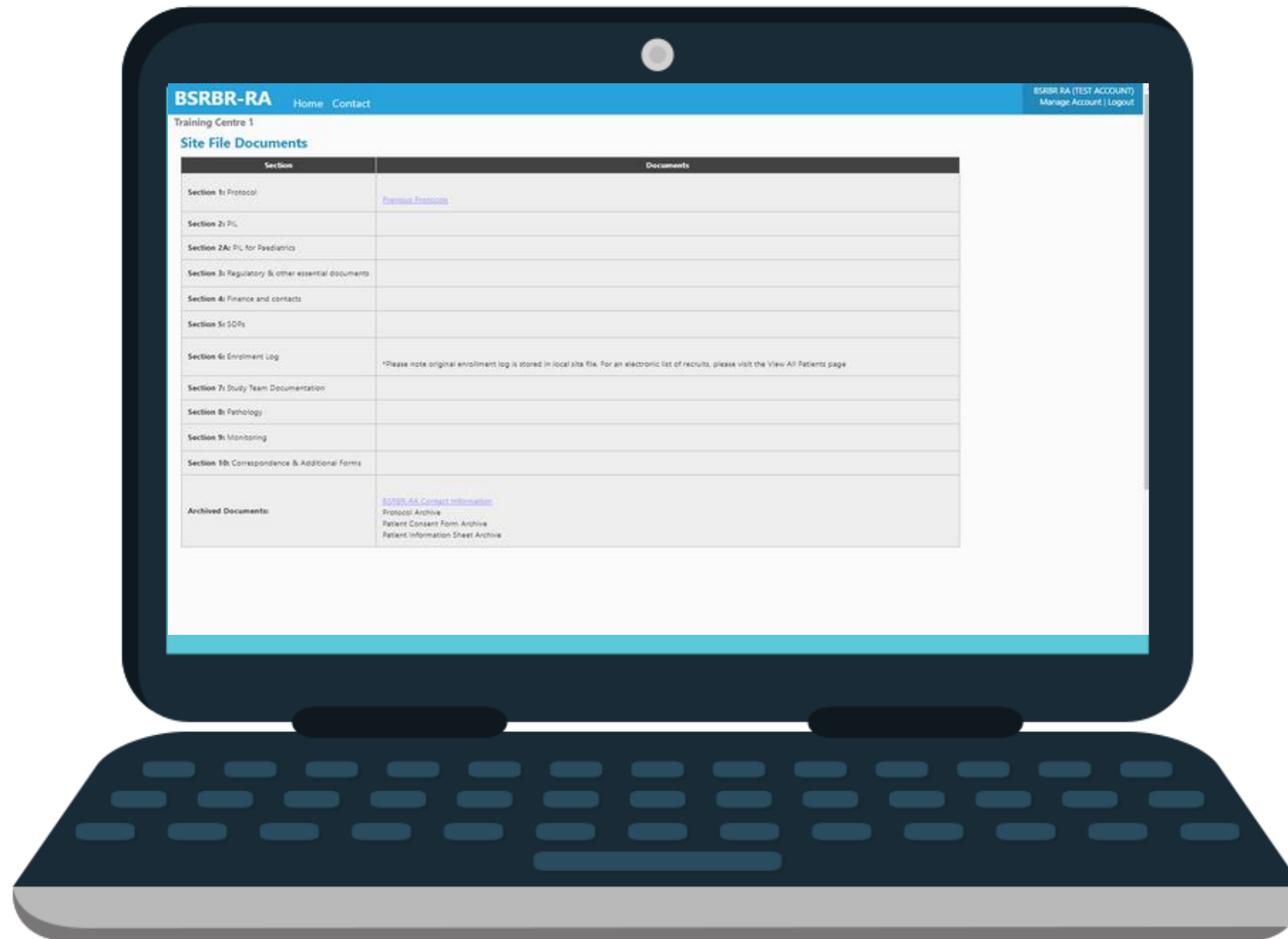
Missing ESI Forms for Serious Infections



List of all missing ESI forms for your centre

Upload and complete any outstanding ESI forms

Welcome to the BSRBR-RA Database!

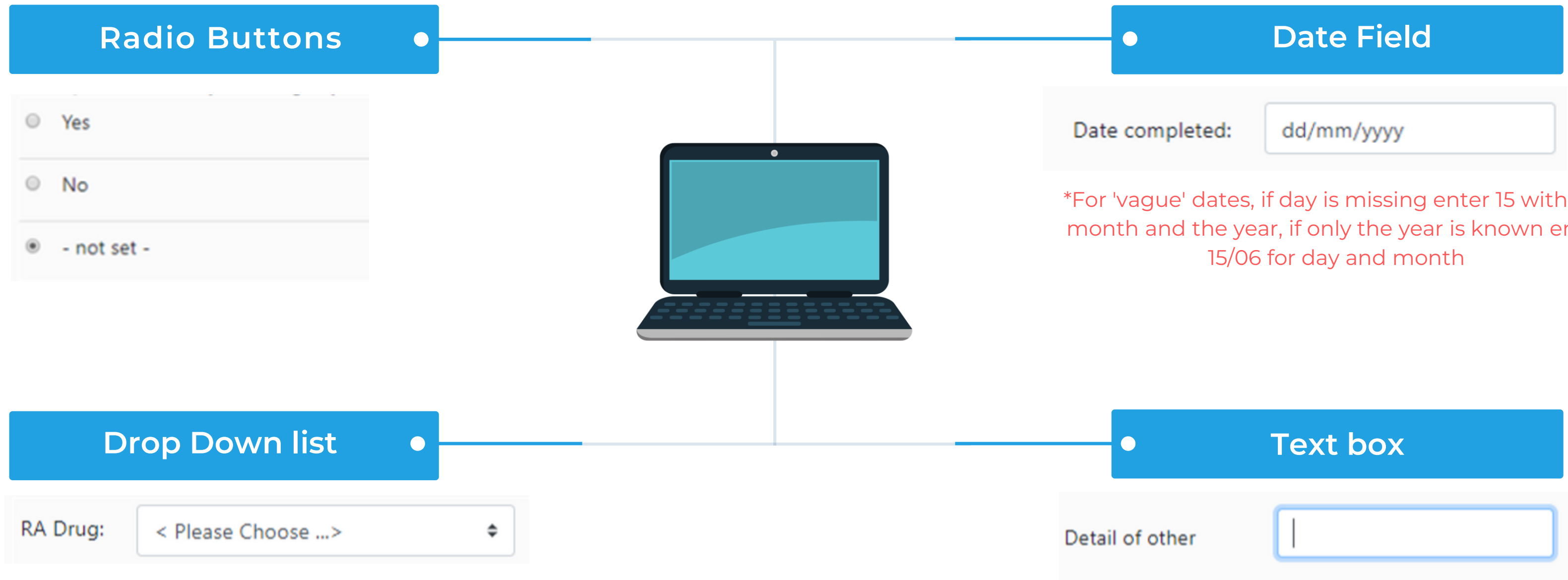


Site File



- Approve user accounts (PI only)
- View Electronic Delegation Log (Database users)
- View site file documents

Data Entry Types



Advantages of online data collection

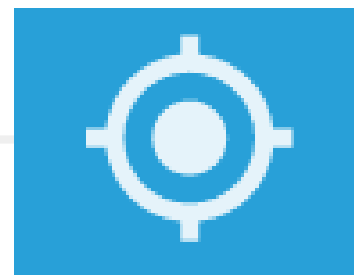
TIME EFFICIENT

Data will be available to us in real time, queries can be dealt with more efficiently



MORE ACCURACY

Less data duplication and better data validation



BETTER COMMUNICATION

All queries and feedback will be communicated to the study team and logged onto the system



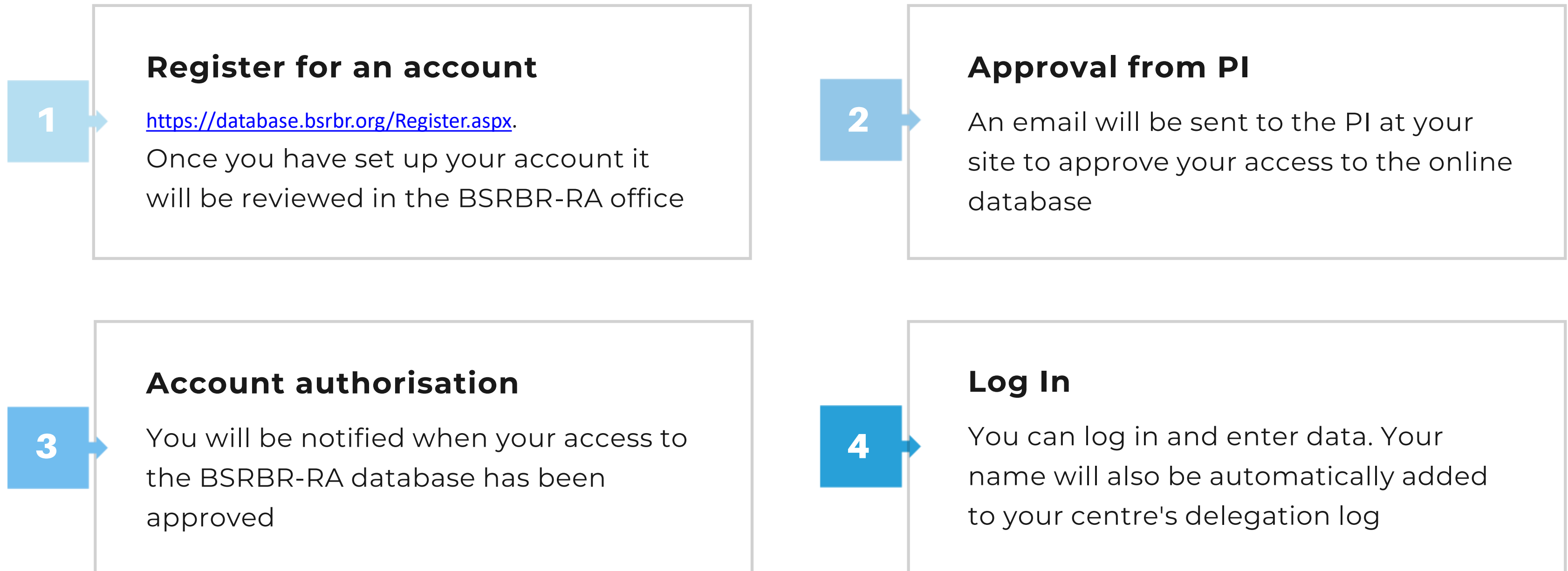
IMPROVED SECURITY

Data entered on the system is encrypted



Registering an Account

Once your signed CV and GCP certificate has been received by us, you can register for an account



Thank you for completing the BSRBR-RA Database training!

Further information on the register can be found here :

<https://www.bsrbr.org/database/training-help/training/>



Getting in touch with us is easy

Please contact the team if you have any questions

BSRBR-RA Team: 0161 275 1652

biologics.register@manchester.ac.uk

