Yellow Card Biobank

Information for Healthcare Professionals

What is the Yellow Card Biobank?

The Medicines and Healthcare products Regulatory Agency in collaboration with Genomics England are conducting a two-year pilot study, known as the Yellow Card Biobank (YCBB).

Using pharmacogenomic testing, the aim is to improve understanding of how a patient's genetic makeup may increase their risk of harm from adverse drug reactions (ADRs).

The pilot study is recruiting patients until December 2024, who have experienced one of the following ADRs:

1. Severe bleeding associated with **direct oral anti-coagulants**
2. Severe cutaneous adverse reactions (SCARs) associated with **allopurinol**, including:
   - Stevens Johnson Syndrome (SJS) / Toxic Epidermal Necrolysis (TEN)
   - Drug rash with eosinophilia and systemic symptoms (DRESS)

What is Pharmacogenomics (PGx)?

PGx is the use of genetic information to tailor treatment to an individual based on their likely response to specific medications.

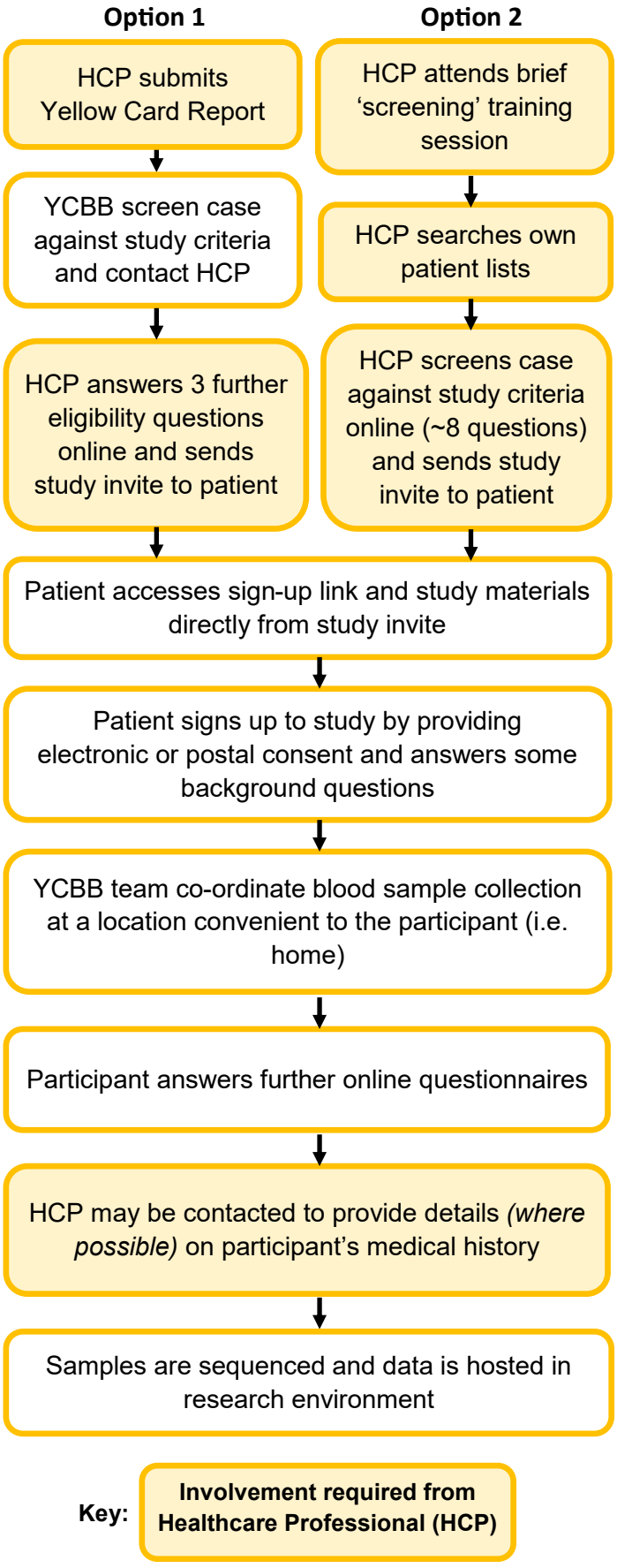
Although the concept is relatively well known, there are currently few drug-gene pairs in which panel testing occurs on a routine basis.

Using whole genome sequencing techniques, the biobank aims to identify novel gene-drug pairs which could lead to changes in prescribing behaviour and increased patient safety in the future.

Can I access the findings?

Overall findings will be shared. Data generated by the pilot (which will be stored in Genomics England's Research Environment) can also be accessed by approved researchers. For details on how to apply to access the data, please contact the YCBB team.

Steps of the Pilot Study



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Study Eligibility Criteria

Inclusion criteria

Individual

Aged 18 or over	UK-based
Alive	With capacity to provide informed consent

Timings

Allopurinol & SCARs	Max. 25 years
DOACs and Severe Bleeding	Max. 5 years

Phenotype for DOAC-induced severe bleeding

⇒ Temporal association with DOAC (rivaroxaban, dabigatran, apixaban, and edoxaban) use

⇒ Hospitalisation

⇒ Bleeding in a critical area/organ (intracranial, intraspinal, intraocular, retroperitoneal, intra-articular, pericardial, gastrointestinal, genito-urinary or intramuscular)

Phenotype for allopurinol-induced SJS/TEN

⇒ Appropriate temporal association with com-mencement of allopurinol use or dose change (typically 4-28 days prior to onset of symptoms)

⇒ Detachment of skin

⇒ Involvement of at least one mucous membrane such as the eyes, nose, oral cavity, GI tract, respiratory tract and/or genitals

Phenotype for allopurinol-induced DRESS

⇒ Appropriate temporal association with commencement of allopurinol use or dose change (typically 2-12 weeks).

⇒ Acute exanthema

⇒ Major organ (usually skin) affected

⇒ Internal organ involvement (e.g., liver or kidney)

⇒ Lymphadenopathy

⇒ White blood cell tests indicating **one** of the following: eosinophilia (>10%), atypical lymphocytes, lymphopenia (<4000), lymphocytosis or thrombocytopenia

Ways to Support Patient Recruitment

1. Yellow Card Scheme

HCPs are asked to submit Yellow Cards on the pilot study topics, providing as much information as possible about the ADR.
For cases that meet the study criteria, the HCP will be contacted to answer some further questions about the case and asked to send a study invite to the patient using materials provided by the MHRA.

2. Searching Patient Lists

HCPs or specialist centres are asked to proactively search their patient lists and screen against the study criteria to identify eligible participants. They are then asked to send study invites to patients which will be provided by the MHRA.
For this option, attendance at a brief training session is required which provides information on how to screen cases against the phenotype.

3. Clinical Practice Research Datalink (CPRD)

HCPs based in GP practices which are signed up to contribute to CPRD may receive an email asking them to sign up and review a patient on behalf of the study.

Webinars

The MHRA are running lunchtime webinars for HCPs wanting to get involved:

- If you submit Yellow Card reports, or can proactively search your patient lists, please contact the YCBB team for dates
- If you are a GP working with CPRD, please contact gpnetwork@mhra.gov.uk for dates

Contact the Yellow Card Biobank team:

yellowcardbiobank@mhra.gov.uk

0203 080 6600
(Mon-Fri, 9am-12pm except bank holidays)

Medicines & Healthcare products Regulatory Agency

Genomics England