



The UK Adult ITP Registry

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October 2018



Background

- Based in The Royal London Hospital
- Active since 2007
- Under the leadership of Dr Drew Provan
- Dr Daniel Hart
- Current CI is Dr Vickie McDonald (July 2018)



Current Team



Aims of the registry

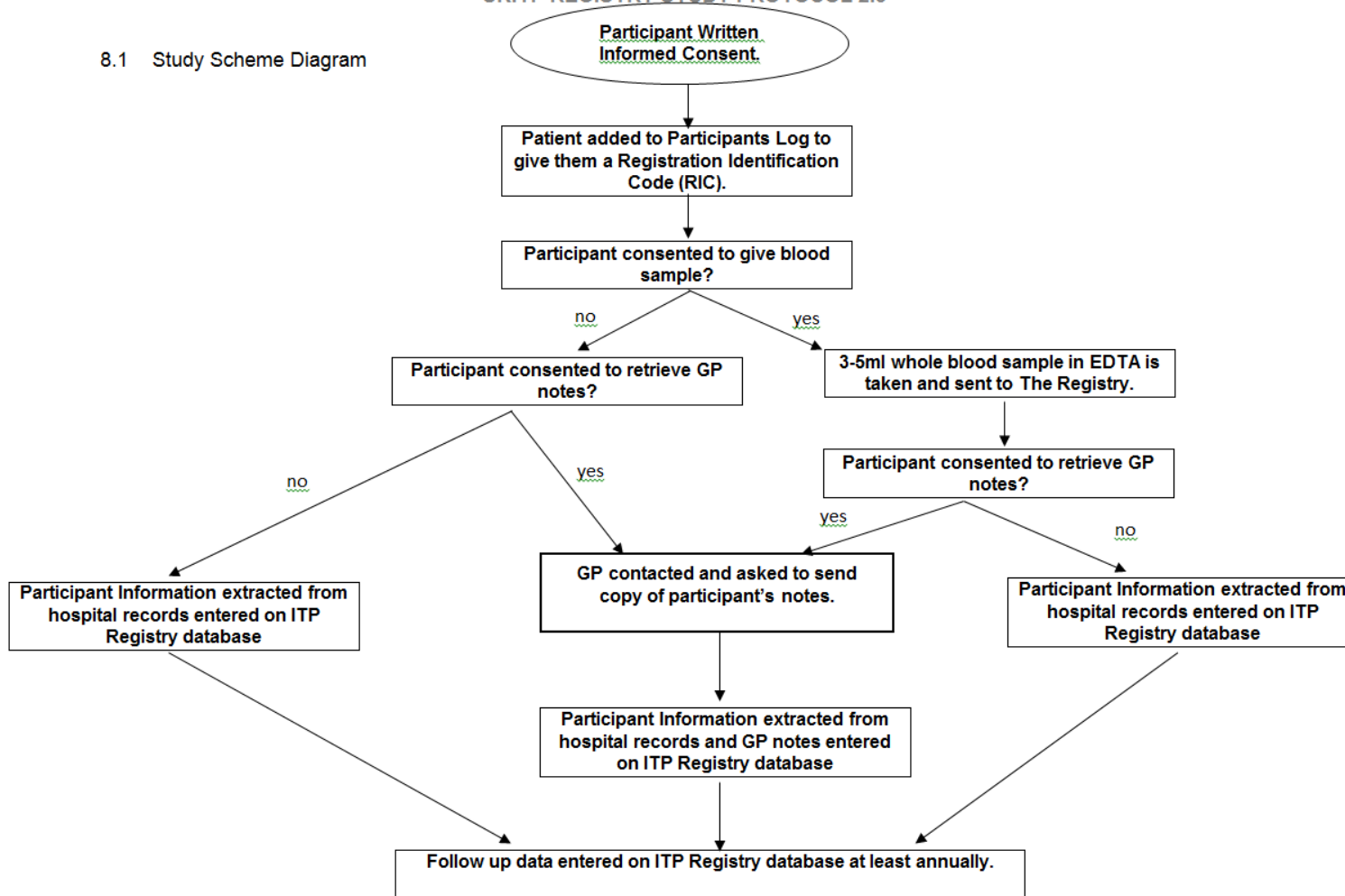
- Understand ITP in the UK, how it is treated, outcomes after treatments and clues to causes throughout all stages of adult life.
- Focusing on patients with **Primary ITP**.
- Collecting clinical information and DNA (if patients give consent).
- Are there possible genetic associations with primary ITP and response to treatments?
- As of September 2018 – a sub-study to investigate primary ITP in Pregnancy added.



Methodology

UKITP REGISTRY STUDY PROTOCOL 2.3

8.1 Study Scheme Diagram



Registry Database

- Moved to a new database – REDCap (2017)
- Secure online database that is encrypted
- Data entry can take place from any participating site
- REDCap is used by over 3000 institutions in 128 countries
- Simplified data entry and easier to use





Log In



Welcome to the REDCap service provided by Queen Mary University of London

Published research should cite REDCap as follows:

Study data were collected and managed using REDCap electronic data capture tools hosted at Queen Mary University of London [1]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

[1]Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

Please log in with your user name and password. If you are having trouble logging in, please contact [Research IT Support](#).

Username:	<input type="text"/>
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Password:	<input type="password"/>
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Log In

[Forgot your password?](#)



Logged in as hmiah | Log out

- My Projects
- Project Home
- Project Setup

Project status: **Production**

Data Collection

- Record Status Dashboard
- Add / Edit Records

Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- E-signature and Locking Mgmt
- Data Quality

Reports

[Edit reports](#)

- Participant Details
- Follow Up Dates
- Clinician Information
- Anthropometric and Lifestyle Data-Adult
- Bleeding Events
- Splenectomy
- ITP Treatments
- Supportive Therapies
- Comorbidities
- Family History
- Biochemical Tests
- Haematological Tests
- Immunological Tests
- Coagulation Fields
- Full Blood Counts
- Bone Marrow and Dat
- Comments
- Test
- Ivlg/Rituximab and plateletts
- Ivlg/Ritux = yes
- RIC and weights

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature

The UK ITP Registry

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: **3,204**

Choose an existing Registry Identification Code (RIC)

Arm 1: UK ITP Registry

-- select record --

Enter a new or existing Registry Identification Code (RIC)

Arm 1: UK ITP Registry

Data Search

Choose a field to search

(excludes multiple choice fields)

All fields

Search query

Begin typing to search the project data, then click an item in the list to navigate to that record.

Data Collection

- Record Status Dashboard
- Add / Edit Records

Registry Identification Code (RIC)
XTS10316

[Select other record](#)

Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
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Reports

[Edit reports](#)

- 1) Participant Details
- 2) Follow Up Dates
- 3) Clinician Information
- 4) Anthropometric and Lifestyle Data-Adult
- 5) Bleeding Events
- 6) Splenectomy
- 7) ITP Treatments
- 8) Supportive Therapies
- 9) Comorbidities
- 10) Family History
- 11) Biochemical Tests
- 12) Haematological Tests
- 13) Immunological Tests
- 14) Coagulation Fields
- 15) Full Blood Counts
- 16) Bone Marrow and Dat
- 17) Comments
- 18) Test

The UK ITP Registry

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Choose action for record

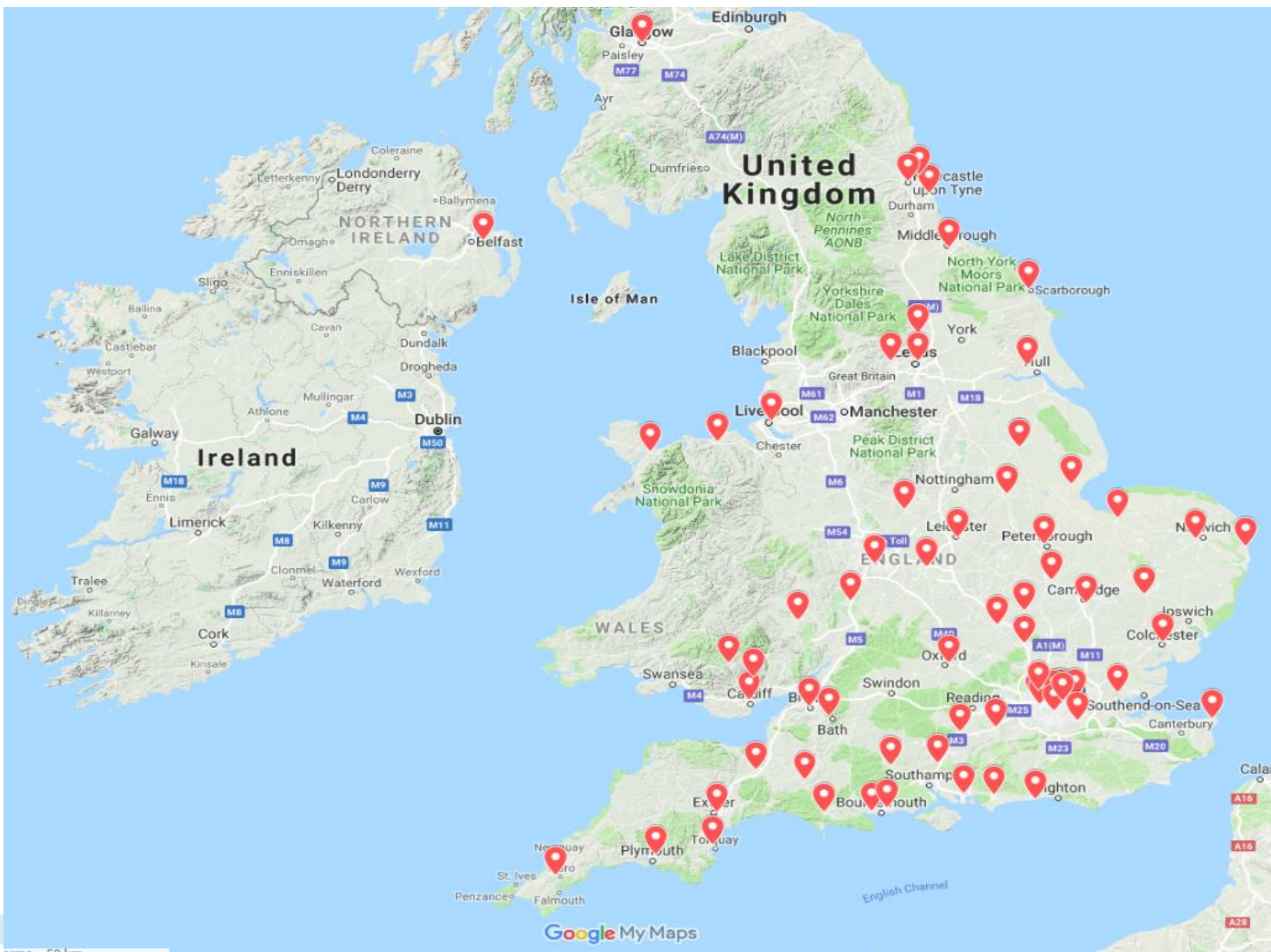
Registry Identification Code (RIC) **XTS10316**

Arm 1: UK ITP Registry — Royal London Hospital

Data Collection Instrument	UK ITP Registry
Participant Details	
Date of Follow Ups	
Clinician Information	
Anthropometric and Lifestyle Data	
Bleeding events	+
Splenectomy	
ITP Treatments	+
Supportive Therapies	
Comorbidities	
Family History	
Biochemical Tests At Diagnosis	
Haematological Fields At Diagnosis	
Immunological Fields At Itp Diagnosis	
Coagulation Fields At Itp Diagnosis	
Full Blood Counts (Hbs, Neutrophils, Plts)	+
Platelet Counts File Upload Function	
Bone Marrow Biopsy, DAT, Indium Scanning	
Comments	+

Legend for status icons:

- Incomplete
- Incomplete (no data saved) ?
- Unverified
- Complete
- Many statuses (all same)
- Many statuses (mixed)



United Kingdom

NORTHERN IRELAND

Ireland

Isle of Man

WALES

ENGLAND

Recruitment

- 3252 patients recruited to date.
- Top 10 recruiting sites by patient numbers:

	Hospital	Number consented
1	THE ROYAL LONDON HOSPITAL	281
2	UNIVERSITY COLLEGE HOSPITAL	150
3	SUNDERLAND ROYAL HOSPITAL	123
4	THE ROYAL VICTORIA INFIRMARY, NEWCASTLE	120
5	HAMMERSMITH HOSPITAL, IMPERIAL	119
6	CASTLE HILL HOSPITAL	110
7	KENT & CANTERBURY HOSPITAL	98
8	NORTHWICK PARK HOSPITAL	94
9	QUEEN ALEXANDRA HOSPITAL	77
10	GLASGOW ROYAL INFIRMARY	71



Importance of the Registry

- ITP is rare and ability to collect data on as many cases as possible means we can understand it better.
- Provide evidence based answers on when treatment is needed and what is the best treatment for a particular patient.
- Information on responses to available treatments
- Susceptibility to co-morbid disease.
- Better to have standard information when trying to perform research



Presentations



Barts Health
NHS Trust

- Talks and Poster presentations of our work at meetings:
 - National:
 - British Society for Haematology meetings: 2017, 2018
 - International
 - European Haematology Association: 2017, 2018
 - American Society for Haematology: 2017
- Topics
 - Rituximab treatment; effectiveness of low dose vs high dose
 - Thrombosis rates
 - Outcomes using treatments such as romiplostim (Nplate) and eltrombopag (Revolade)



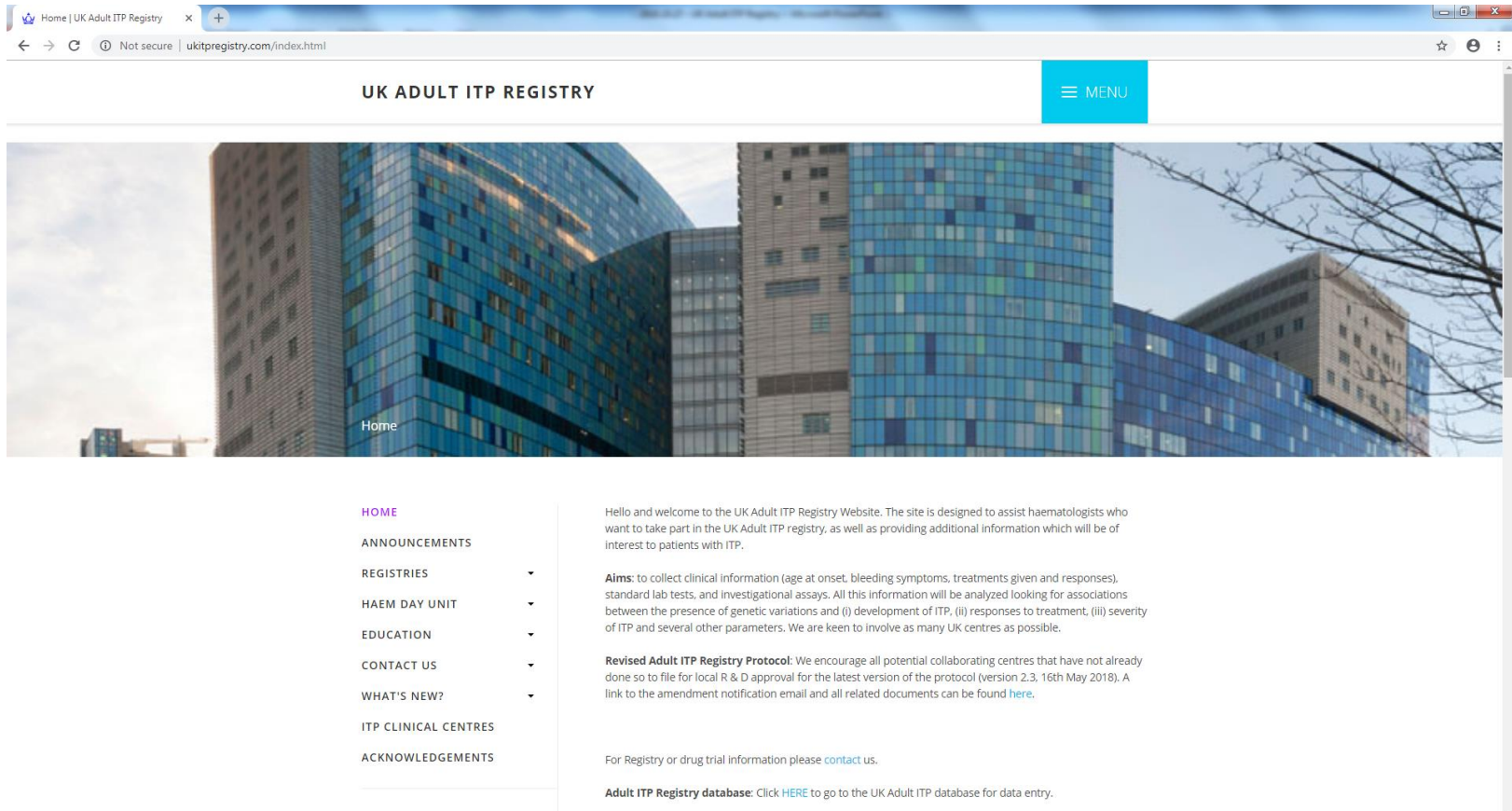
Publications

- **Thromboembolism in adults with primary immune thrombocytopenia: a systematic literature review and meta-analysis.** Doobaree IU, Nandigam R, Bennett D, Newland A, Provan D. Eur J Haematol. 2016 Oct;97(4):321-30
- **Fostamatinib in persistent/chronic adult immune thrombocytopenia.** Newland A, Lee EJ, McDonald V, Bussel JB. Immunotherapy. 2018 Jan;10(1):9-25
- **Safety and efficacy of romiplostim in splenectomized and nonsplenectomized patients with primary immune thrombocytopenia.** Cines DB, Wasser J, Rodeghiero F, Chong BH, Steurer M, Provan D, Lyons R, Garcia-Chavez J, Carpenter N, Wang X, Eisen M. Haematologica. 2017 Aug;102(8):1342-1351
- **Case report of eltrombopag in a pregnant patient with ITP.** KLM White, L Bowles, D Provan, L Taylor, A Newland, BSH, 2017
- **Comparison of the effects of the TPO receptor agonist, Romiplostim, in patients with ITP < 1yr versus > 1yr.** DJ Kuter, AC Newland, BH Chong, F Rodegheiro, MT Romero, I Pabinger, Y Chen, B Metha, M Eisen ASH 2017; BLOOD 2017, 130, 1055



Our website

<http://ukitregistry.com>



Thanks to Drew Provan, our technology guru!



Welcome!

Hello and welcome to the latest issue of the UK Adult ITP Registry newsletter! Thank you to everyone for their ongoing support and working with the registry.

Study Updates

Pregnancy arm of UK ITP Registry

The latest version of the study protocol will now include consenting participants with primary ITP in pregnancy (previously this was an exclusion). Pregnant women diagnosed with primary ITP prior to or during their **current pregnancy** will be consented for the sub-study. It is important to note that this is not a separate study to the main ITP registry and will not require separate R&D approval. Patients who meet the inclusion criteria for the pregnancy arm of the study will have to complete 2 consent forms; one for the main adult ITP registry and the other for the pregnancy registry.

Registry Database

The Registry REDCap database has been successfully updated and is live!

You should have received an email giving you access to the project on REDCap. If you have not received this email or you cannot access the database, please get in touch.

One of the major changes was to incorporate the pregnancy arm of the study, as mentioned above. Please ensure to update your **participant logs** to include a new column titled 'Pregnancy Registry Consent Date'. This is only for participants that consent for the pregnancy arm of the study.

We have updated the user guides and proformas to reflect the latest version of the database—these can be found in the 'File Repository' on REDCap.

For any further information or clarifications, please do not hesitate to contact us.



The UK Adult ITP Registry Team

Reminders

Local approvals for latest substantial protocol amendment:

The HRA notification email was sent to all sites on 06/08/2018 detailing the REC and HRA approvals for the latest substantial protocol amendment along with the document pack.

The new version of the protocol, **version 2.3 dated 16/05/2018**, can now be implemented (as of 10/09/2018). If you haven't done so already, please send through confirmation of your local R&D approvals.

Please send through the localised versions of your patient information sheets and informed consent forms to the registry team.

This is also a great opportunity to send through updated delegation logs and CVs (2 page versions, signed and dated) and GCP certificates.



Funding

- Fantastic support from the patient support association:
THANK YOU!
- Additional Grants from (2010 – 2018)
 - Barts Charity
 - Novartis
 - Amgen
 - Rigel



THANK YOU TO ALL THE PATIENTS
WE COULDN'T DO THIS WITHOUT YOU

