Barts and The London
School of Medicine and Dentistry

Full Title:	United Kingdom Adult Immune ThrombocytoPenia ~~Idiopathic Thrombocytopenic Purpura~~ (ITP) Registry: An Investigation of Disease Progression, Treatment Effectiveness, and Co-morbid Conditions
Short Title/Acronym:	UK Adult ITP Registry / UKITPR
Sponsor:	Barts Health NHS Trust Joint Research Management Office Research Services Dept. W 69-89 Mile End Rd London E1 4UJ Email: research.governance@qmul.ac.uk
Sponsor contact:	Dr Mays Jawad, Research Governance Operations Manager
REC Reference:	07/H0718/57
Sponsor reference or ReDA:	005148
IRAS Project ID:	92703
Chief Investigator:	Dr Vickie McDonald

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2 Glossary

CRN	Clinical Research Network
EDC	Electronic Data Capture

GP	General Practitioner
HSCIC	Health and Social Care Information Centre
ITP	Immune Thrombocytopenia
JRMO	Joint Research Manage Office for Barts Health Trust and Queen Mary University of London
MREC	London Research Ethics Committee
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
REDCap	Research Electronic Data Capture
RLH	Royal London Hospital (is part of Barts Health Trust)
RIC	Registry Identification Code
SNP	Single Nucleotide Polymorphism
UK	United Kingdom

3 SIGNATURE PAGE

Chief Investigator Agreement

The clinical study as detailed within this research protocol or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social

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Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Chief Investigator Name: Dr. Vickie McDonald

Chief Investigator Site: Barts Health NHS Trust

Signature and Date:

Sub-Investigator (responsible for the Pregnancy Registry) Name: Dr. Suesan Robinson

Sub-Investigator Site: Guy's and St Thomas' NHS Foundation Trust

Signature and Date:

Sub-Investigator (responsible for the Secondary ITP Registry) Name: Dr. Quentin Hill

Sub-Investigator Site: St James' Institute of Oncology, Leeds Teaching Hospitals University Hospital, Leeds

Signature and Date:

4 Summary of Study

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This study seeks to uncover information regarding the aetiology, epidemiology, natural progression[1], treatment effectiveness, and co-morbidities of adult ITP in the United Kingdom via a multi-centre disease registry.

Short Title	United Kingdom Adult ITP registry
Methodology	A UK-wide registry of patients with ITP
Research Sites	Barts Health NHS Trust and Queen Mary, University of London with other NHS Trusts as data collection centres
Objectives/Aims	To better understand the causes, treatment responses and outcomes in patients with ITP
Number of Participants/Patients	No restriction – open to all patients in the UK with ITP who fit the eligibility criteria
Main Inclusion Criteria	Adults (age >18 years) with ITP or pregnancy-associated ITP
Main Exclusion Criteria	Patients <18years of age, patients unwilling or unable to consent
Statistical Methodology and Analysis (if applicable)	N/A
Proposed Start Date	Commenced 2007 (REC 07/H0718/57) Previous Substantial Amendment (7~~6~~ – 21/09/2021~~18/05/2018~~) Current amendment start date: May 2023~~July 2021~~
Proposed End Date	31st ~~0th~~ December 2025~~June 2024~~

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5 Introduction

[1] Natural progression shall be defined as platelet count, bleeding events, and mortality over time.

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Primary Immune Thrombocytopenia (ITP) is a rare bleeding diathesis, characterised by a platelet count <100x 10^9/L with an (auto)immune aetiology.

It is a complex heterogeneous disease, the clinical features, severity and current treatment practices vary considerably[1, 2, and 3]. In order to identify subgroups or clusters of patients with shared attributes or outcomes a large study cohort is required. This will also allow the generation of statistically meaningful as well as valid and reliable research findings.

The UK ITP Registry aims to collect data in order to understand the epidemiology, aetiology, prognosis, treatment and outcomes of people with ITP. The present extension of the Registry sets out to occupy a central position in ITP research and fill the gaps in existing literature by assessing the development of ITP throughout all stages of adult life.

In 2018 an update to the protocol was made to include ITP in pregnancy to further our understanding of the epidemiology of ITP in pregnancy, pregnancy outcome and provide a prospective tool to guide evidence based consistent practice.

In 2021, we ~~are~~ added~~ing~~ secondary ITP to the registry protocol in order to further develop understanding of the epidemiology, aetiology, prognosis, treatment and outcomes of people with ITP, and the influence of treatment for the ITP trigger on ITP outcomes. As a response to the wider public health issue, this includes COVID19 and vaccinations.

6 Study Objectives

6.1 Primary Objectives:

To collect clinical information and biological samples from participants with ITP in order to investigate its epidemiology, aetiology, prognosis, treatments and outcomes throughout all stages of adult life (including pregnancy).

6.2 Secondary Objectives:

To investigate factors influencing need for treatment and response to treatment in patients with ITP.

To investigate the molecular basis of ITP including omics studies such as genomics, metabolomics and proteomics and correlate this with epidemiology, aetiology, prognosis, treatment effectiveness and outcomes

7 Methodology

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7.1 Inclusion Criteria (non pregnancy)

- **Primary ITP**: Patients with platelet count of <100 x10^9/L and no evidence of other known thrombocytopenic inducing drugs or disease*.
- **Secondary ITP:** Patients with platelet count of <100 x10^9/L, thought to be due to immune aetiology but with a specific trigger or cause such as (but not limited to) auto-immune disease, malignancy, drugs, vaccinations, viral infections*.
- Patients aged 18 and over living in the UK
- Patients able to give informed consent

*Patients who have previously been diagnosed with ITP which has resolved can still be included if retrospective data from the period of active ITP disease can be collected. If retrospective baseline data from the time of ITP diagnosis is not available, patients would not be eligible.

7.2 Exclusion Criteria (non pregnancy)

1. Patients not meeting the inclusion criteria
2. Patients unwilling or unable to give consent

For inclusion / exclusion criteria for ITP in pregnancy please see section 9.7

8 Study Design

This study is a registry. As with previous versions of the protocol, the study will entail investigation of prospective and past study participants. Any patients who were diagnosed with ITP at any time will continue to be enrolled onto the registry, providing data from the period of active ITP can be obtained (please see Study Scheme Diagram below).

The UK ITP Registry is designed to collect longitudinal epidemiological data as well as collect blood sample for genetic analysis. Patients who are eligible for the study are identified by the local Principle Investigator's delegated team and consented locally. If the participant consents to donating a blood sample, (4-8ml EDTA), this will be taken by the local team and sent to the ITP Registry. The local teams are responsible for extracting participant data from both hospital and GP medical notes and adding this information to the Registry database. Follow up information on the participant should be obtained at least annually and added to the database.

Pregnancy data will be collected alongside non-pregnancy ITP-related data in two separate databases.

The UK ITP Registry will use the data collected to analyse patterns in the UK ITP population. Blood samples are used for immunology and platelet studies and to extract DNA for genomic studies including whole genome sequencing and ribonucleic acid (RNA) sequencing. Analyses will be run at different time points throughout the lifespan of the Registry. Data quality checks will be run regularly and the site will be expected to help with data queries.

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8.1 Study Scheme Diagram

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9 STUDY PROCEDURES

9.1 Informed Consent Procedure

Adult patients presenting at haematology clinics or within collaborating centres with a low platelet count (e.g. < 100 × 10^9 /L) and a diagnosis of ITP following a standard ITP workup will be invited to take part in the study.

Identified eligible adult patients should be given the Participant Information Sheet (PIS) (v 5.1) to familiarise themselves with the study and given sufficient time to review and ask questions before entering the study. Consent should be taken using 'UKITPR Study Informed Consent Agreement v.6.1' (for the study procedure relating to potential patients entering the pregnancy sub-study, please refer to sections '9.7 ITP during Pregnancy').

9.2 Remote consenting

Ideally, we would like for research sites to consent potential participants face to face. However, there may be situations in which ~~the~~ participants will not be able to attend the hospital/clinic to sign the consent form in person.

To accommodate for sites to consent participants in such scenarios, research staff should:

1. Contact the potential participant over the phone to make them aware of the study.
2. If the participant would like to be part of the registry study, send out a copy of the PIS, along with 2 blank copies of the consent form and a pre-paid envelope to return the consent forms.
3. The participant will then be able to read the PIS and have time to ask questions about the study.
4. If the participant is happy to take part in the study, they should to sign the consent forms and send all copies back in the pre-paid envelope
5. When the site research staff have received the signed consent forms, they should call the participant, letting them know that they have received their consent forms and verbally confirm consent over the phone, before countersigning and dating the consent forms. A copy of the fully signed consent form by the researcher, should then be sent to the participant to keep for their records.
6. A note of the verbal consent process should be made in the participant's medical notes and the consent forms stored as you would for face to face consent.

9.3 Anonymisation of patient

Following consent, the participant will be added to the site's Participants' Log. This will assign them a UK ITP Registry Identification Code (RIC) which is used to add the clinical details to the database anonymously.

Following entry of each new participant, a copy of the consent form and the updated Participants Log should be sent securely to the registry data manager via the registry nhs.net email account. This is stored securely and separately from participant clinical data to ensure anonymisation of clinical data.

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9.4 Funding for recruitment

This study is registered with the UK CRN portfolio. Sites are allocated NIHR funding proportional to the number of new participants they have recruited that year. The registry requires a copy of the consent form and updated Participants Log for each new recruit in order to include them in the site NIHR funding returns. It is the responsibility of the research team to upload all recruitment activity on their Local Portfolio Management System; the activity then gets transferred to the NIHR Central Portfolio Management System and the CI or delegated research staff member confirms the recruitment activity for each site every month.

9.5 Blood Collection for Genetic Analysis, Blood Cell Analysis and Immune Profiling

9.5.1 Samples for genetic analysis

Following registration, a blood sample will be drawn. The sample does not have to be taken at the time of consent but as close to this time as possible. The sample should be clearly labeled with the patient RIC as well as the date of venepuncture. The sample should then be sent to:

Mr. Sean Platton
The UK ITP Registry C/O Haematology Laboratory
4th Floor
Pathology and Pharmacy Building
Royal London Hospital
80 Newark Street
E1 2ES

Blood Samples will be used to isolate genetic materials which will be used to analyse for factors related to ITP, including disease severity and progression. Genetic contents will be isolated and stored for state of the art genomic technologies including whole genome sequencing, exome sequencing, RNA sequencing and gene-arrays. The genomic testing and analysis can take place at any of our (future) partnering institutions including, but not limited to, Genomics England or the NIHR Bbio~~r~~Resource. Samples for genomic testing are stored and analysed anonymously.

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9.5.2 Sub-study- Platelet and Immunological Investigation

A subset of participants will be invited to take part in a sub-study looking at platelet functionality and immunological profiling. These will need to be patients for whom samples can be rapidly transferred to the laboratory at Queen Mary University London and therefore will be restricted to recruiting sites in London.

These participants will be invited to contribute up to of 50mls (10 teaspoons) over a six month period. Existing registry patients or those who have expressed an interest in participating will be given the patient information leaflet with a verbal explanation of the sub-study. Donations will be obtained at a subsequent routine visit when the participants have had chance to consider their involvement in the study.

The samples could be used for metabolomic and proteomic analysis including the study of antiplatelet antibodies, leucocyte surface markers, leucocyte (in particular B and T cell)

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functional assays, autoantibody analysis and of protein expression. Any new relevant assays for ITP or autoimmune disease will also be used.

In addition to participants with ITP, a group of gender and age matched volunteers will be recruited for data comparison. The inclusion criteria for this non-ITP control group will be:

- Adult (≥ 18 years) patients without a diagnosis of ITP
- No thrombocytopenia or autoimmune disease

Note: Guidance on sample collection, storage and transfer, including dispatch addresses, are described in appendix 1.

9.6 Data Collection

Once a new participant has consented to be part of the registry, the site should use their medical notes and local electronic systems to extract ITP-related information and enter the data on the online EDC system, REDCap. A new record must be created for each new participant on the ITP Registry Database using their unique RIC. We advise that Initial data entry is done within six weeks of consent.

The REDCap database consists of the following forms:

- Participant Details
- Date of Follow Ups
- Clinician Information
- Anthropometric and Lifestyle Data
- Bleeding events
- Splenectomy
- ITP Treatments
- Supportive Therapies
- Comorbidities and events of Specialist Interest
- Family History
- Vaccination 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)
- Bone Marrow Biopsy, DAT, Indium Scanning
- Comments

For initial data entry, all the forms will have to be completed but for follow-up, the forms relating to diagnosis will not need to be completed (unless missing data needs to be entered or there is an update). Follow-up of participants should be done at least annually. Participants are not required to come in for follow-up data collection.

For secondary ITP participants, datasets pertaining to the trigger for the ITP will also need to be completed on a separate third arm on the REDCap database.

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Please note that the secondary ITP arm of the registry will be led jointly by Dr Quentin Hill, Consultant Haematologist & Honorary Clinical Associate Professor at Leeds Teaching Hospital, and the Chief Investigator the Registry study. Dr Quentin Hill will handle any clinical enquiries which are relevant for this part of the Registry.

Appendix 2 should be used when entering ITP treatment to ensure doses are given in the correct units.

Appendix 3 specifies time periods in which platelet counts are required relative to treatments. This should be used to collect participant's platelet counts.

The Registry team will be responsible for reviewing the quality and completeness of the data regularly. Any unusual or missing values will be sent back to the centre to be checked against local medical records.

9.6.1 General Practitioner (GP) Notes

Although we expect that most information that we require will be available from the medical records at the referral hospital (i.e. collaborating centre), some may not be available. To overcome these gaps in data, GP notes should be requested. The 'UKITPR General Practitioner Letter template UK version 1.2' and 'UKITPR GP Proforma version 1.2' along with a copy of the participant's consent form should be sent to the participant's GP. Once the medical notes are received back, the site team should extract the relevant ITP-related information and add this to the registry Database. Please note that GP practices should send participant notes to the site team instead of via the Registry as was the case in previous versions.

9.7 ITP during Pregnancy

Extension of the ITP Registry to include ongoing, prospective data collection regarding the management and outcome of pregnancy in patients with ITP will further our understanding of the epidemiology of ITP in pregnancy, pregnancy outcome and provide a prospective tool to guide evidence based consistent practice.

Pregnant women who meet the following criteria will be invited to take part in the pregnancy sub-study:

- Primary immune thrombocytopenia diagnosed prior to pregnancy.
- Primary immune thrombocytopenia diagnosed in pregnancy where:

  the platelet count falls to <50 x10^9/L

  OR

  treatment for ITP is required during pregnancy or up to 3 months post-partum.

Participants should be consented for the pregnancy registry **in addition** to the main registry (i.e. separate consents). Identified eligible participants should be given the UK ITP Pregnancy Registry Patient Information Sheet v 2.1. If they agree to participate, they should sign the ITP Pregnancy Study informed consent agreement v 1.0.

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Participants may be looked after by a different team or hospital during their pregnancy. The medical notes and maternity note for these patients should be requested for data extraction.

Please note that this part of the Registry will be led jointly by Dr Sue Robinson, Consultant Haematologist of Guy's and St Thomas' NHS Foundation Trust, and the Chief Investigator the Registry team. Dr Sue Robinson has a specific interest in obstetric haematology and will handle any clinical enquiries which are relevant for this part of the Registry. All contact details are provided on the Registry website and at the end of this protocol.

9.8 Data capture for pregnancy registry

Data for the pregnancy registry will be captured using the online REDCap database. However, the data for the pregnancy registry is collected in a separate arm or sub-registry, which is linked to the main adult ITP registry via the participant's unique RIC.

9.9 Subject Withdrawal

Patients are free to withdraw from the Registry at any time. Their site team should inform the ITP Registry team so that their data can be removed.

If a cause of participant's thrombocytopenia is found, so that ITP is no longer the lead diagnosis, the registry team must be contacted so that the participant's data can be removed.

9.10 End of Study Definition

The study recruitment has been extended to 31st December 2024~~30th June 2023~~ and the new study end date will be 31st December 2025~~30th June 2024~~.

9.11 Statistical Consideration

Standard Statistical methods will be used to analyse data with the assistance of standard statistical software.

10 ETHICS

The Principal Investigator is responsible for ensuring that the study will be carried out in accordance with the ethical principles in the Research Governance Framework for Health and Social Care, Second Edition, 2005 and its subsequent amendments as applicable to legal and regulatory requirements.

10.1 Safety Considerations

As a data collection centre, participants' safety is not at risk by being in the study. The usual phlebotomy risks apply to taking a blood sample.

10.2 Past Study Participants

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Owing to the non-sensitive nature of the proposed revisions, the London MREC (03/07/2007 - 07/H0718/57) determined that it would not be necessary to re-consent past study participants. The same information will be extracted from the medical records of past participants as from those of prospectively enrolled participants.

10.3 Data Handling and Record Keeping

Information relating to participants will be kept confidential and managed in accordance with the GDPR, the Data Protection Act, NHS Caldecott Principles, the Research Governance Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval.

All electronic data is kept securely within restricted access shared drives at Barts Health NHS Trust. Data from the Registry is kept separately from information with patient identifiers. Patient Identifiable information such as Participants Logs are kept encrypted and in their own restricted access drive. The registry keeps this information to monitor patients and avoid duplication as patients may move between sites and to ensure accurate NIHR returns. Only the Chief Investigator's team and the site team can view data from any site.

According to the Research Governance Framework and Trust Policy, records will be kept for 20 years from study closure. For studies involving Bart's Health Trust patients, undertaken by Trust staff, or sponsored by BH or QMUL, the approved repository for long-term storage of local records is the Trust Modern Records Centre. External centres are expected for follow the same records retention time frame.

10.4 Laboratories

Blood samples will be initially received at Bart's Health NHS Trust or Queen Mary, University of London campus. Samples will be processed as soon as possible and DNA stored in a secure location. All samples received by the Registry should be anonymised and only have the RIC on the label. Received samples will be logged on our central database and on the UK ITP Registry itself. Samples waiting for DNA extraction will be stored in a -20ºC freezer until a batch has been collected to undergo DNA extraction. Extracted DNA will be stored in a -20ºC/-80ºC freezer until they need to be used for analysis.

10.5 Indemnity

The Registry is sponsored by Barts Health. The Joint Research Management Office (JRMO) for Bart's Health and QMUL also oversee the research activities within Barts Health Trust. All confidential materials, including all data received from NHS Digital (or HSCIC) and ONS, which are related to the Registry, will remain within Barts Health NHS Trust's secure premises and network. These data will also be processed within Barts Health NHS Trust. Only anonymised data received by the Registry will be analysed, if required, using QMUL facilities.

While we do not expect the participants to suffer any harm as a result of their participation in the study, Barts Health has agreed that if they are harmed as a result of their participation in the study, they will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of their participation in the study. These special compensation arrangements apply where an injury is caused to the participants that would not have occurred if they were not in the study. These arrangements do not affect your right to pursue a claim through legal action.

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10.6 Finance and Funding

To date, the UK ITP Registry has received funding from:

- Barts Health Charity
- NIHR
- ITP patient support association
- Grifols: unrestricted educational grants
- Novartis (formerly GSK): unrestricted educational grants
- Amgen: unrestricted educational grants

10.7 Dissemination of Research Findings

Analyses of registry data will be carried in stages throughout the life span of the registry; results from these investigations will be presented at haematology meetings and published in peer-review journals, in our study newsletter, and, where appropriate, in *The Platelet*, the official newsletter of the ITP Support Organisation.

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12 APPENDICES

12.1 Appendix 1 – guidance on sample collection, storage and transfer.

Sample collection, transfer and storage for the ITP Registry Sample

Before collecting any biological sample, please check that the participant has agreed and consented to donate a sample for use in research

When to take blood and what precaution should be used during registration?

The blood sample should be taken at the time that the participant agrees to be part of the Registry. If it is not possible to take a sample on this occasion, this can be done on the next outpatient or hospital visit as arranged between the staff and the participants. If participating sites are unsure whether the samples have been sent, this can be checked by contacting the registry team.

Please follow the following steps and procedures

Please observe standard (universal) precaution when taking and handling biological samples

Using standard venipuncture techniques, take a 4-8 ml blood sample with a standard EDTA (purple top) tube.

Label sample collected with the date of sample collection and the Registry Identification Code (RIC). This should be obtained from the Participants Log for your centre. Identifying information should not be put on the sample.

How long to store the blood if sample is stored before transfer, what temperature is the sample required being stored?

If dispatching is possible within 24 hours, it can be kept at room temperature.
If shipping will happen in 1 to 3 days, please keep the sample in a medical fridge (about 5 ^{0}C)

PLEASE DO NOT FREEZE (i.e. DO NOT STORE AT 0 ^{0}C OR BELOW)

Do not consider sending blood sample on Friday or a day before a bank holiday.

What are the minimum requirements for sample transfer and package?

General packaging and transfer requirement for biological substances is Category B

Packing for exempt patient specimens must be packaged and marked according to the biological substance, category B, UN 3373~~34~~

The sample should be packaged in the following (please find a link to the full sample packaging guide in the references section above)

Wrap the sample tube in absorbent material.
The wrapped sample tube should be placed into the plastic leak-proof packaging bag.

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Tightly close the top of the plastic leak-proof packaging container.

An outer packaging of adequate strength for its capacity, mass and intended use (fibreboard, wood, or rigid plastic), and with at least one surface having minimum dimensions of 100 mm × 100 mm.

You could use Safe box™ from Royal Mail for secure package or any similar services using mailboxes for biological sample which comply with the triple packing safety requirement is needed as described above.

The address for sending blood samples for genetic analysis (i.e. 4 to 8 ml purple top container):

UKITP Registry
4th Floor Haematology Laboratory
Pathology & Pharmacy Building
The Royal London Hospital
80 Newark Street
London
E1 2ES

If you have any queries please contact:

Study Coordinator & Data Manager
Email: uk-itp.registryteam@nhs.net
T: 0203 246 0473

For participants involved in platelet or immunology sub study:

For participants involved in the sub-study, up to 50ml of blood will be taken and sent to The Registry within 24-36hrs of collection. This may include one citrate, one serum and two EDTA blood samples.

Please do not send the samples to the wrong addresses as this may render the samples becoming unusable because of the time lapse it will take to redirect the samples internally to the right person.

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12.2 Appendix 2 – units of treatment doses

Treatment	Units of Dose	Course length	Notes
Anti-D	µg	days	
Azathioprine	mg/day	days	
Cyclophosphamide	mg/day	days	
Cyclosporine	mg/week	days	
Danazol	mg/day	days	
Dapsone	mg	days	
Dexamethasone	mg/day	days	
Eltrombopag	mg/day		
IVIg	g/day	days	
Methylprednisolone	mg/day	days	
Mycophenolate	mg/day	days	
Prednisolone	mg/ day	days	Please only enter the initial dose given. We don't need tapering doses. Course length should be total duration of therapy including tapering doses.
Rituximab	$mg/m^2/week$	days	
Romiplostin	µg/kg/week	days	
Vinca Alkaloids	mg/week	days	

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12.3 Appendix 3 – recommended minimum timing of platelet count results during ITP follow up

*+/- 14 days

Treatment	0-1 weeks	1-2 weeks	2-3 weeks	3-4 weeks	2 months*	4 months*	6 months*	1 year*	6 monthly*
Anti-D	daily counts*	✓	✓	✓	✓	✓	✓	✓	
Azathioprine	✓	✓	✓	✓	✓	✓	✓	✓	
Cyclophosphamide	✓	✓	✓	✓	✓	✓	✓	✓	
Cyclosporine	✓	✓	✓	✓	✓	✓	✓	✓	
Danazol	✓	✓	✓	✓	✓	✓	✓	✓	
Dapsone	✓	✓	✓	✓	✓	✓	✓	✓	
Dexamethasone	daily counts*	✓	✓	✓	✓	✓	✓	✓	
Eltrombopag	✓	✓	✓	✓	✓	✓	✓	✓	
IVIg	daily counts*	✓	✓	✓	✓	✓	✓	✓	
Methylprednisolone	daily counts*	✓	✓	✓	✓	✓	✓	✓	
Mycophenolate	✓	✓	✓	✓	✓	✓	✓	✓	
Prednisolone	daily counts*	✓	✓	✓	✓	✓	✓	✓	
Rituximab	✓	✓	✓	✓	✓	✓	✓	✓	
Romiplostin	✓	✓	✓	✓	✓	✓	✓	✓	
Vinca Alkaloids	✓	✓	✓	✓	✓	✓	✓	✓	

*****Please give as many counts as are available in this time period

Please use this table to guide which platelet counts need to be entered on the database. The time frames start from the day that treatment is initiated. No specific clinic visits are required; the time which is closest to the defined period should be entered.

6- 12 monthly update of information is recommended where possible, if a patient has a repeat treatment episode, the above table should be used to guide data entry

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