

IMMUNE GLOBULIN QUALITY IMPROVEMENT PROJECT

DATA ENTRY USER GUIDE

ORBCoN Ministry of Health IG Request Form Database

VERSION 6 DATE: MARCH 2025



Inspiring and facilitating best
transfusion practices in Ontario.



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1.0 PROJECT INFORMATION

Your hospital site has volunteered to participate in this Immune Globulin (IG) Quality Improvement Project (QIP) and this document is provided to instruct hospital users on entering their IG data into the Research Electronic Data Capture (REDCap) platform. This QIP was developed in response to recommendation #3 from the Office of Auditor General of Ontario, [Value-for-Money Audit of Blood Management and Safety](#).

Hospitals will enter required data variables for this QIP using the data found on the existing Ministry of Health (MOH) IG request forms ([Neurology](#), [non-Neurology](#) and [SCIG](#)). These IG requests could be submitted to the laboratory as paper forms, through your Laboratory Information System (LIS) via a Computerized Physician Order Entry (CPOE), or a combination of both as applicable. Data extraction from the paper forms/LIS should be straightforward - enter what you see/read, exactly as it is written or typed, into the corresponding fields in REDCap. Hospital sites that can electronically extract the IG product request from their LIS should contact ORBCoN to facilitate electronic transfer of IG information directly into REDCap.

NOTE: Your hospital site may have modified the data variables collected for IG requests if using LIS/CPOE/E-Forms. You may need to review the Ontario MOH IG paper request forms and compare them in advance to map the information collected.

2.0 REDCap BASICS

REDCap is a secure web-based platform that will be used to collect, analyze, and export hospital IG data. Ontario hospitals received a survey link to notify ORBCoN of their intent to participate in the IG QIP. Hospital site/institution information was collected to determine identify the users and how the data would be entered into REDCap. Based on information provided in the survey, user specific usernames and passwords were generated and sent to IG data entry users. The following steps provide basic information on how to get started in REDCap for participating hospital sites entering IG data using paper request forms. Sites with the ability to electronically extract IG data for LIS, ORBCoN will supply site specific information to upload data into REDCap.

Each hospital site will have a Data Access Group (DAG) assigned and users within this DAG will be able to access only records created by users within that group. Users will not have access to other DAGs unless the user has been granted access to another affiliated DAG. Users with more than one DAG will be required to use the DAG switcher, to ensure that they are entering IG information into the correct DAG. When assigned to multiple DAGs, the user will see a blue banner at the top of every project page, which will present the option to switch to another DAG.

2.1 Login: <https://mctr.mcmaster.ca/>.



Log In

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

Username:

Password:

[Forgot your password?](#)

Welcome to REDCap!

2.2 Enter your user credentials: username, and password.

- If you already have access to REDCap for another ORBCoN/TTISS project, you will use the same username and password you have already been given to access the IG QIP
- If you are a new user to REDCap, your username and password will be supplied by ORBCoN staff after the hospital site agreement to participate in the IG QIP is complete.

2.3 After login, you should be taken to the REDCap homepage or *My Projects* page.

Welcome to REDCap!

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

Learn more about REDCap by watching a [brief summary video \(4 min\)](#). If you would like to view other quick video tutorials of REDCap in action and an overview of its features, please see the [Training Resources](#) page.

NOTICE: If you are collecting data for the purposes of human subjects research, review and approval of the project is required by your Institutional Review Board.

If you require assistance or have any questions about REDCap, please contact [Melanie St John](#).

REDCap Features

- Build online surveys and databases quickly and securely in your browser** - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.
- Fast and flexible** - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.
- Advanced instrument design features** - Auto-validation, calculated fields, file uploading, branching/skip logic, and survey stop actions.
- e-Consent** - Perform informed consent electronically for participants via survey.
- Diverse and flexible survey distribution options** - Use a list of email addresses or phone numbers for your survey respondents and automatically contact them with personalized messages, and track who has responded. Or

2.4 Click on **My Projects** to be directed to the page displaying all the projects your username has been assigned to in REDCap.

2.5 Click on the project titled **ORBCoN Ministry of Health IG Request Form Database**. This will take you to the data collection home page.

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#)

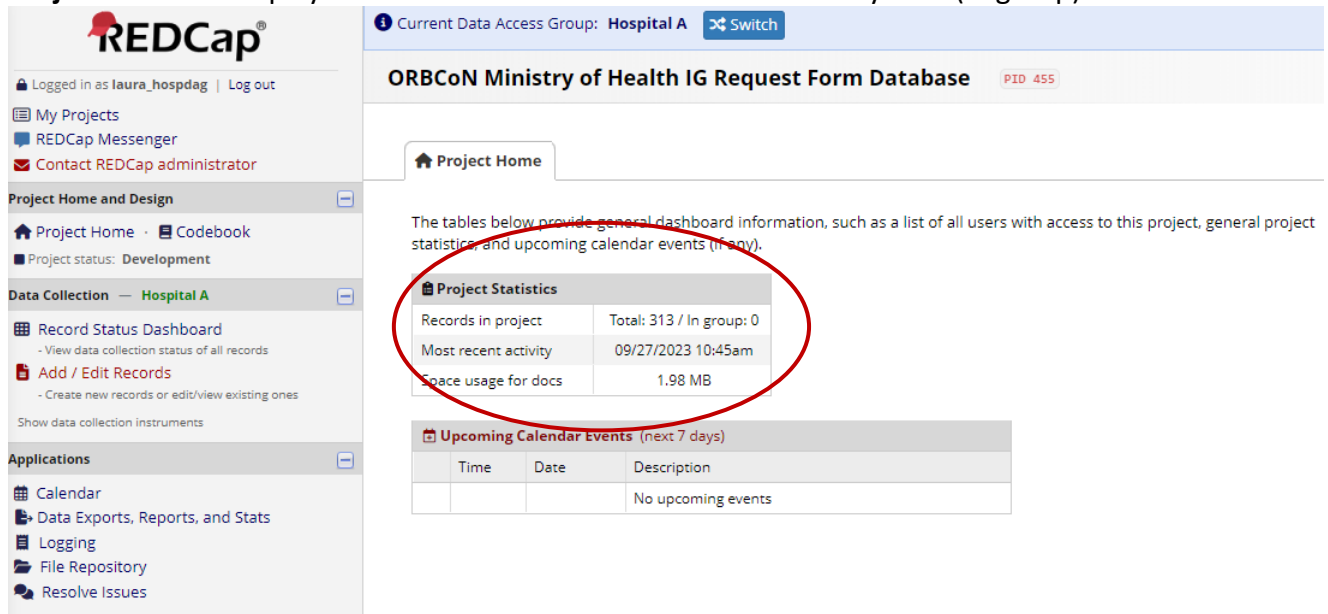
Project Title	Records	Fields	Instruments	Type	Status
ORBCoN Ministry of Health IG Request Form Database	313	89	1 form		



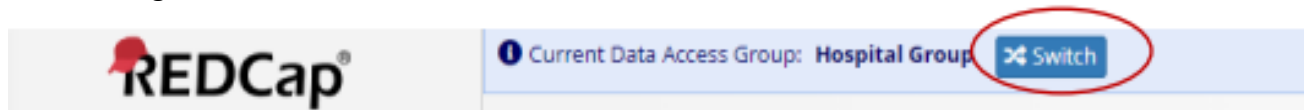
- 2.6 On the left side of your screen, you should see various links to areas within the project, including:
- **My Projects** – brings you back to the overview of all REDCap projects you can access.
 - **REDCap Messenger** – a built-in messaging service between REDCap users.
 - **Project Home** – brings you to the home page of the project you're in.
 - **Record Status Dashboard** - shows an overview of every IG recipient entered by you (by Record ID) and the status of the form (complete/incomplete/unverified).
 - **Add/Edit Records** – add a new IG recipient record or search for an existing record.

Your view should be like the following:

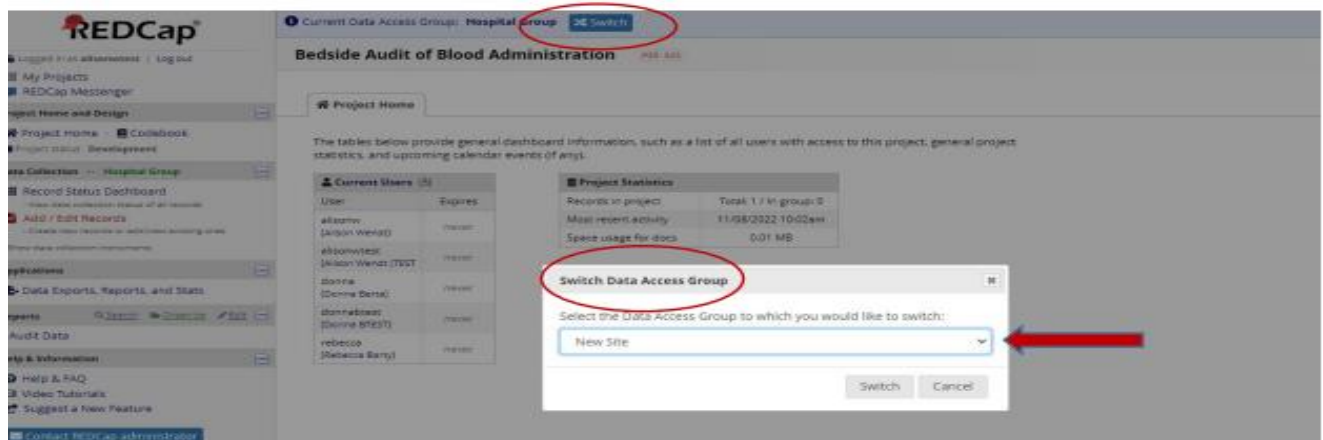
Project statistics display the number of records both in total and by DAG (in group).



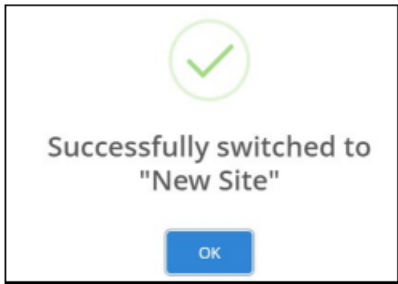
- 2.7 If the user is assigned to multiple DAGs, an additional blue banner will be visible on the top of the page to allow the user to switch back and forth between the different DAGs in which they will be entering data.



- 2.8 Click on **Switch**, for a pop-up box with drop down option of all assigned DAGs to appear. Choose the correct DAG from the list and click **Switch**.

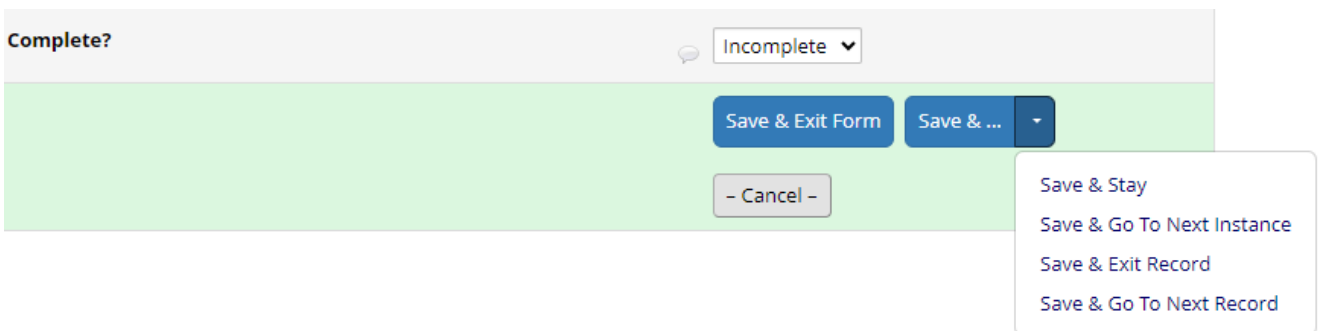
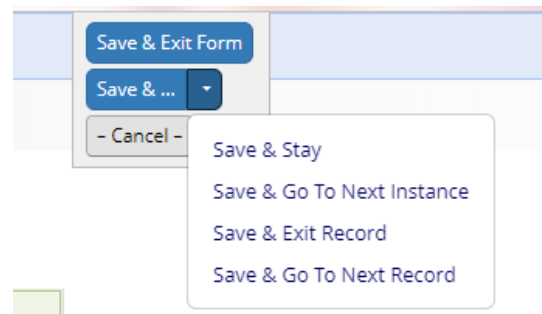


2.9 Once the selection has been made, the following pop-up will be displayed to confirm that user is in the appropriate DAG.



2.10 Once a record has been created, the information entered can be saved via several options so as not to lose data entered. These save options are located at the top right of the page and continually scrolls down along with the entry of data, as well as there is a separate section the very bottom of the form.

- **Save & Stay**- saves work stays in current record.
- **Save & Go to Next Instance** – saves work and opens a new Instance for the patient.
- **Save & Exit Record** – saves work and exits form.
- **Save & Go to Next Record** – saves work and opens a new patient record.



3.0 TRACKING LOGS

3.1 PATIENT LOG

For this QIP, patient identification is **not** collected in REDCap, but hospital sites will need to ensure a patient with multiple/repeated IG requests is not duplicated. To avoid duplication, a patient tracking log has been developed ([Appendix 1](#)). For patient privacy reasons, this log will be maintained at the hospital site and **will not** be shared with ORBCoN or anyone outside of the hospital organization for this QIP. This log should be stored securely at your hospital site when not in use. The log is provided in both paper and excel ([electronic](#)) formats.

Using the REDCap generated *Record ID* for unique patient identification: Each IG recipient entered in REDCap will be automatically assigned a record number that should be kept unique to that patient.



This record number is generated based on your DAG (e.g., Mock Hospital DAG= 3285) and the assigned subsequent next sequential number. As there may be multiple MOH IG request forms for the same IG recipient, the recipient record number should be tracked, so that additional request forms can be added to that recipient record (multiple request forms for an IG recipient will be known in REDCap as *Instances*).

IG Recipient Patient Tracking Log

REDCap Record ID	Instance Number	Request Date (YYYY/MM/DD)	For Hospital Use ONLY		
			Last Name	First Name	Hospital Medical Record Number (MRN)

3.2 PHYSICIAN / PRESCRIBER LOG

Hospital sites have the option of coding their IG ordering physician/prescriber information and not entering it into REDCap. A physician/prescriber tracking log has been developed ([Appendix 2](#)) to assign a unique identifier to the ordering physician/prescriber. The identification code used can be any alphanumeric combination but should be different from patient identification code. The log is provided in both paper and excel (electronic) formats. Sites that choose to enter physician/prescriber information do not need to use the physician/prescriber tracking log.

Physician / Prescriber Contact Information Log

Physician / Prescriber Specialty	Physician / Prescriber Identification Code	For Hospital Use ONLY		
		Physician / Prescriber Last Name	Physician / Prescriber First Name	Email Address / Phone #

4.0 IG REQUEST DATA ENTRY INTO REDCap

Using the MOH IG request form or information obtained from LIS, enter the IG recipient data into REDCap. This may be a [New Record](#) for a recipient, or a [New Instance](#) for a recipient already entered but has had a new request form submitted (e.g. IG recipients on maintenance / long term use).

4.1 CREATING A NEW IG RECIPIENT RECORD

A new record is created when IG is initially ordered for a patient. As per QIP protocol, sites can decide to enter retrospective data from 2018-present date. The record ID will be created for the very first request for IG.

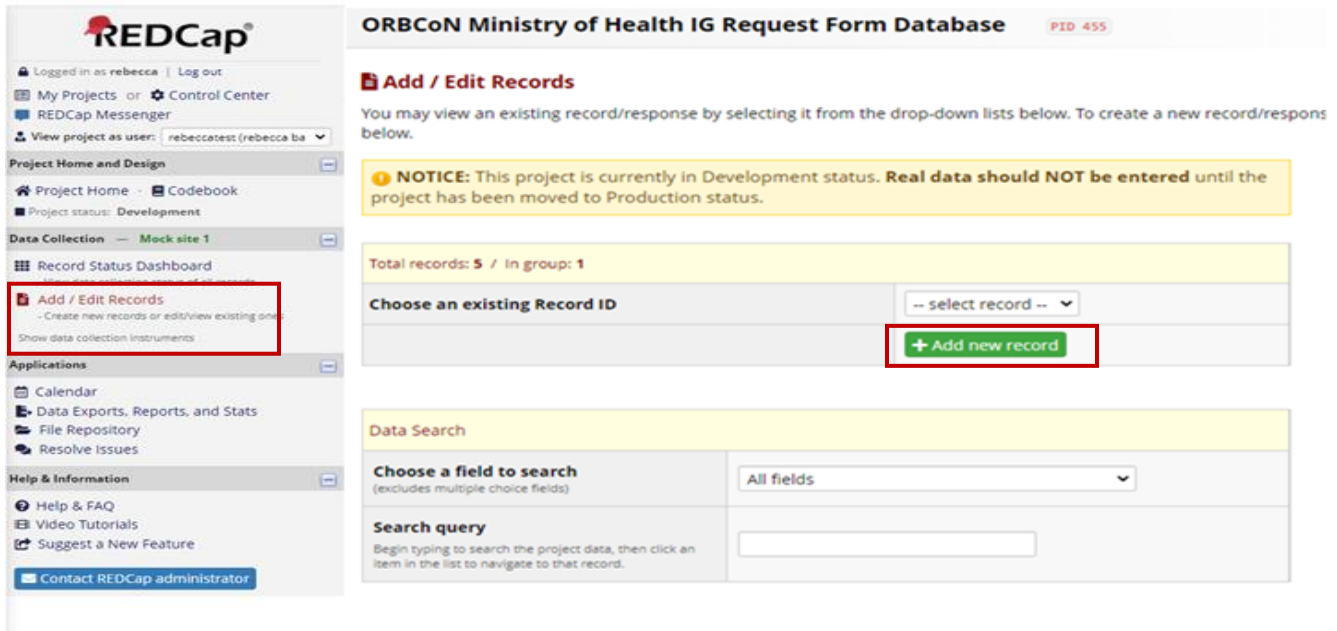
Note: Users entering IG data with multiple DAGs **must ensure they are in the correct DAG** before they create a new record for the patient IG data they are entering or use the DAG switcher to switch to the correct DAG.



There are 3 options for entering a new IG recipient into REDCap:

4.1.1. Option One: Using Add/Edit Records

- a. Click on **Add/Edit Records** on the left menu bar.
- b. Then on the right of the webpage, select the green toggle button **+Add new record**.



4.1.2. Option Two: Using Record Status Dashboard

- a. Click on **Record Status Dashboard** on the left menu bar.
- b. Then on the right of the webpage, select the green toggle button **+Add new record**.



4.1.3. Option Three: After Entering a Previous Record

- a. If you are in an existing record or finishing entering a record, you can **Save & Go To Next Record**.
- b. Once the page opens, select **Add new record**.



The screenshot shows a form with a 'Save & ...' dropdown menu. A tooltip explains that clicking the down arrow shows more save options. The dropdown menu includes options like 'Save & Stay', 'Save & Go To Next Instance', and 'Save & Go To Next Record'. To the right, a summary bar shows 'Total records: 6 / In group: 2' and lists 'Incomplete Records (2)' and 'Complete Records (0)'. An 'Add new record' button is highlighted with a red box.

4.1.4. Once the new record has been created, a *Record ID* will automatically be generated for that IG recipient. The first four digits reflect your DAG group ID followed by the next sequential record number. Document this number on your Patient Tracking Log ([Appendix 1](#)) and complete the *Hospital Use Only* section with the remainder of patient information.

IG Online Data Collection Form

The screenshot shows the 'IG Online Data Collection Form' interface. A green header bar indicates 'Adding new Record ID 3285-1. (Instance #1)'. Below this, the 'Record ID' field contains the value '3285-1'. The text 'ORBCoN Ministry of Health IG Request Form Database' is visible at the bottom of the form area.

4.1.5. Continue to [Entering Form Demographics](#) to enter required information for QIP.

4.2 CREATING A NEW INSTANCE

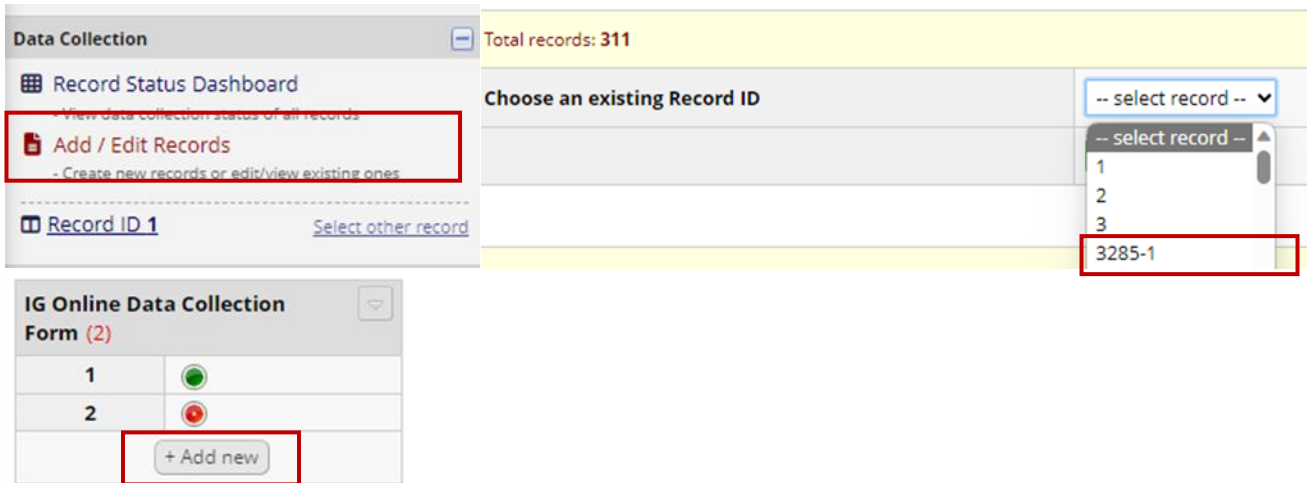
A new instance will occur when an IG recipient has had multiple MOH IG request forms submitted. This scenario is likely when a patient is on maintenance/long term IG therapy. You will have to refer to your patient log to determine if you have entered information for your IG recipient previously or not, to determine if it's a new record or a new instance. For example, if you have 3 forms for one patient you will have 3 instances entered in REDCap for one *Record ID*. Therefore, each additional order/form will be an instance for that IG recipient in the data capture system.

There are 3 options for entering a new instance for an IG recipient into REDCap:

4.2.1. Option One: Using Add / Edit Record

- a. If an existing record has already been created and you would like to enter another form, select the **Add /Edit Records**.
- b. Choose your existing IG recipient *Record ID* from the drop-down menu.
- c. Once record home page displays, select **+ Add new**.





4.2.2. Option Two: Multiple Orders for Same Record ID

- If you are entering multiple MOH IG request forms for the same patient continuously from the first form/instance, choose **Save & Go To Next Instance** at the top right side or at end of the data entry form (e.g., this option can be chosen if back entering multiple forms/requests since the project allows for patient records back to the year 2018).



4.2.3. Option Three: Record Status Dashboard

- Click on **Record Status Dashboard**.
- Find existing IG recipient *Record ID* number.
- Click on + symbol to enter a new instance for existing patient.



4.1.6. Once new instance is created, continue to enter request [Form Demographics](#).

4.3 ENTERING IG DATA INTO REDCap FORM

IG request data is entered for both new records and new instances. If at any time the wrong information was selected, you can choose the opposite radio button or select the reset option at the far-right side of the form. All demographics with an asterisk * indicate that the variable/field is mandatory on the form and must have data entered to successfully move forward.

4.3.1. Form Demographics

- a. **Hospital site (where form is received):** Select your hospital site by one of the following methods:
 - Using the drop-down arrow select your hospital name; or
 - Start to type the hospital name until your site name appears to be selected; or
 - Enter the 'first letter' of the hospital name repeatedly until your site name appears to be selected.



b. **Form type:** Select either the form type by clicking on the appropriate radio button:

- Neurology
- Non-Neurology

Note: Choosing the appropriate form type will determine the IG indications available further down in the form demographics. If your site uses a modified / adapted form for LIS, you may need to determine if the indication/diagnosis of the patient fits under Neurology or Non-Neurology form type.

c. **Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG):** Select the product that is being requested by the physician for the IG recipient:

- IVIG
- SCIG

The screenshot shows a form section with the following elements:

- Hospital site (where form is received):** A dropdown menu with a downward arrow.
- Form type:** Two radio buttons: Neurology and Non-Neurology.
- Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG):** Two radio buttons: IVIG and SCIG.
- Two "reset" buttons are located on the right side of the form.

4.3.2. Patient Demographic Information

a. **Age Category:** Will need to be extrapolated from DOB information provided in top right corner of MOH IG request form or pulled from LIS. In REDCap, categorize patient into the following:

- Adult (defined as greater or equal to 18 years old)
- Pediatric (defined as less than (<) 18 years old)
- Neonate (defined as less than (<) 4 months old)

b. **Sex:** MOH IG request forms use the term 'Gender', however the intent of the form when written was to collect *biological sex* of the recipient. Please note dose calculator is based on *biological sex*.

- Male
- Female

c. **Patient Location:** Categorize your institution location (e.g., 4W Reception Area) into one of the following categories:

- Inpatient
- Outpatient (clinic)
- Outpatient (home infusion)
- Outpatient (not specified)
- Emergency Department



Patient Demographic Information

<i>See Appendix 1 IG Recipient Patient Tracking Log</i> <i>Please ensure that the patient is coded with the Record ID to be used for multiple order forms</i>	
Age Category: <input type="radio"/> Adult <input type="radio"/> Pediatric < 18 yrs <input type="radio"/> Neonate < 4 months	reset
Sex: <input type="radio"/> Male <input type="radio"/> Female	reset
<i>Please note the form uses the term Gender; however, the intent is to collect the sex of the patient</i>	
Patient Location: <input type="radio"/> Inpatient <input type="radio"/> Outpatient (Clinic) <input type="radio"/> Outpatient (Home Infusion) <input type="radio"/> Outpatient (not specified) <input type="radio"/> Emergency Department	reset

4.3.3. Section A: Physician/Prescriber and Hospital Information

- a. **Date Requested:** Format (YYYY/MM/DD) – Enter as supplied on MOH IG request form. If the date is not supplied on form, or LIS request submitted, use the date that the request was received in the Transfusion Medicine Laboratory.
- b. **Date Required:** Format (YYYY/MM/DD) – Enter as supplied on MOH IG request form or LIS submitted request.
- c. **Physician/Prescriber Contact Information Code:** To be used if hospital site is choosing to code physician/prescriber information. Code entered should match the code used on the Physician/Prescriber Contact Information Log ([Appendix 2](#)). Each physician/prescriber should only have one code associated with them on the physician/prescriber log and used for all IG recipient entries.

If your hospital site is providing physician/prescriber contact information, the following information would be entered into REDCap:

- Name of ordering/treating physician/prescriber
 - Physician/prescriber phone number
 - Physician/prescriber email address
- d. **Physician/Prescriber Specialty:** Using the down arrow, select the appropriate specialty for the ordering/treating physician/prescriber. The following specialties are listed:
 - Neurology
 - Immunology
 - Hematology
 - Dermatology
 - Infectious Disease
 - Transplant
 - Rheumatology
 - Emergency Medicine
 - Internal Medicine
 - Other (if selected, an additional data collection field will appear to enter other specialty)
 - No Information
 - Unknown



- e. **Is the Patient being seen by Neurologist/Neuromuscular Specialist:** Radio buttons only appear when *Neurology* is selected under physician/prescriber specialty data collection field and neurology form type. If radio buttons available, choose either:
 - Yes
 - No

- f. **Hospital where the patient will receive IG:** This might be referred to as where the product is being picked up; some multi-site hospital laboratories may have a centralized location for IG requests to be receive, but product is issued for infusion at another site. Select your hospital site by any of the following methods:
 - Using the drop-down arrow select your hospital name; or
 - Start to type the hospital name until your site name appears to be selected; or
 - Enter the 'first letter' of the hospital name repeatedly until your site name appears to be selected.

Depending on the product type (IVIG or SCIG) selected either of the two questions will be shown:

- g. If IVIG is selected, **Will this IVIG be infused at another hospital?**
 - Yes
 - No

- h. If SCIG is selected, **Will this SCIG be picked up at another hospital?**
 - Yes
 - No



SECTION A: Physician/Prescriber & Hospital Information

* Date Requested (YYYY/MM/DD)	<input type="text"/>
Date Required (YYYY/MM/DD)	<input type="text"/>
<i>See Appendix 2 Physician/Prescriber Contact Information Log</i>	
Physician/Prescriber contact information code:	<input type="text"/>
If you are providing contact information for the Physician/Prescriber please enter the information below:	
Name of Ordering/Treating Physician/Prescriber	<input type="text"/>
Physician/Prescriber's Contact Phone Number:	<input type="text"/>
Physician/Prescriber's Email:	<input type="text"/>
* Physician/Prescriber Specialty:	<input type="text"/> <input type="button" value="H"/> <input type="button" value="M"/>
Other Specialty if applicable:	
Is the patient being seen by a Neurologist/Neuromuscular Specialist	
Hospital where patient will receive IG	<input type="text"/> <input type="button" value="H"/> <input type="button" value="M"/>
Will this IVIG be infused at another hospital?	
Will this SCIG be picked up at another hospital?	

4.3.4. Section B: Request Type

- a. **Initial Request or Renewal Request:** Select radio button Yes for the appropriate request type (only 1 request type per instance to be chosen):
- Initial request
 - Renewal request

SECTION B: Request Type

NOTE: Only select Initial request or Renewal request not both

<input type="radio"/> Yes reset Initial request: Maximum 6 month approval	<input type="radio"/> Yes reset Renewal request: A reassessment should be done to confirm IG treatment continues to be effective and that minimum effective dose is being applied. Maximum 12 month approval
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4.3.5. Section C: Clinical Indication

- a. **Indication:** Use the down arrow, type the indication or type the first letter of indication repeatedly, selecting the appropriate indication as documented on MOH IG request form or LIS request. The indications available for selection are:
- Acquired hemophilia
 - Acquired red cell aplasia
 - Acquired von Willebrand's disease (AvWD)
 - Active antibody mediated rejection (ABMR) prevention/management in solid organ transplant
 - Acute disseminated encephalomyelitis (ADEM)
 - Allogeneic bone marrow or stem cell transplantation - Cytomegalovirus (CMV) induced pneumonitis
 - Antiphospholipid syndrome catastrophic
 - Autoimmune Blistering Diseases / Pemphigus Vulgaris (PV) and Variants
 - Autoimmune encephalitis mediated by antibodies (AMAE) / N-methyl-D-aspartate (NMDA) encephalitis
 - Autoimmune hemolytic anemia (AIHA)
 - Autoimmune neutropenia
 - Autoimmune Retinopathy (AIR)
 - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
 - Community acquired respiratory virus- upper respiratory track infection in high risk patients
 - Demyelinating neuropathy associated with IgM paraproteinemia, without anti-MAG antibodies
 - Desensitization in Solid Organ transplant prevention/treatment of rejection
 - Eosinophilic Granulomatosis with Polyangiitis (EPGA) / Churg-Strauss disease
 - Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)
 - Gestational Alloimmune Liver Disease (GALD) / alloimmune neonatal hemochromatosis
 - Guillain-Barré Syndrome (GBS) including Miller Fisher Syndrome and other variants
 - Hematopoietic Stem Cell Transplant in primary immunodeficiencies
 - Hemolytic Disease of the Fetus and Newborn (HDFN)
 - Hemolytic transfusion reaction (HTR)
 - Hemolytic transfusion reaction in sickle cell disease (HTRSCD)
 - Heparin Induced Thrombocytopenia (HIT)
 - Idiopathic Inflammatory Myopathy (IIM) Includes Dermatomyositis and Polymyositis
 - Immune Thrombocytopenia (ITP) Adult
 - Immune Thrombocytopenia (ITP) Pediatric
 - Juvenile Idiopathic Inflammatory Myopathy (J-IIM) (previously Juvenile Dermatomyositis)
 - Kawasaki Disease (KD)
 - Kidney transplant from living donor to whom the patient is sensitized
 - Lambert-Eaton Myasthenic Syndrome (LEMS)
 - Macrophage Activation syndrome (MAS)
 - Measles Post exposure Prophylaxis (PEP)
 - Multifocal Motor Neuropathy (MMN)
 - Multiple Sclerosis - relapsing remitting, short term therapy
 - Multisystem inflammatory syndrome in Children (MIS-C) associated with SARS CoV-2/COVID-19
 - Myasthenia Gravis (MG)






- Myelin Oligodendrocyte Glycoprotein antibody associated disorders (MOGAD)
- Opsoclonus - Myoclonus Ataxia (OMA)
- Parvovirus B19 in solid organ transplant recipients
- Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)
- Peri-transplant (heart, lung, kidney, pancreas)
- Post-transfusion Purpura
- Post-transplant (Solid Organ Transplant)
- Pre-transplant (Heart)
- Primary Immune Deficiency (PID)
- Pyoderma Gangrenosum
- Rasmussen's encephalitis
- Scleromyxedema
- Secondary Immune Deficiency (SID) / Hypogammaglobulinemia
- Sjogren Syndrome associated neuropathy
- Stiff Person's syndrome (Moersch-Woltman syndrome)
- Sydenham Chorea
- Systemic Capillary leak syndrome (SCLS)
- Toxic epidermal necrolysis (TEN)/Stevens-Johnson Syndrome (SJS)
- Toxic Shock Syndrome (TSS) - Invasive Group A streptococcal fasciitis
- Toxic Shock Syndrome (TSS) - Staphylococcal Toxic Shock
- Varicella-Zoster Virus Prophylaxis
- Vasculitic Neuropathy associated with systemic disorder
- Virus associated hemophagocytic syndrome (VAHS)
- Other
- Missing Data Codes:
 - No Information (NI)
 - Unknown (UNK)

If “Other” is selected from the indication list, an appropriate data collection field will appear to enter other indication.

SECTION C: Clinical Indication

Clinical indication for use Refer to Ontario IG Management Utilization Guidelines for additional indication where IG may be appropriate.

Indication (please select from the drop down)	<input type="text" value="Other"/> <div style="text-align: right;">    </div>
If applicable request is for another indication please specify	<input type="text"/>



If “Secondary Immune Deficiency (SID)” is selected, an additional drop-down list will appear to enter the primary reason for SID if it is available. The list will include the following primary reasons for SID

- Multiple myeloma pre-transplant
- Multiple myeloma post-autologous stem cell transplant
- Multiple myeloma post CAR-T cell infusion
- Multiple myeloma post BiTE therapy
- Lymphoma pre-transplant
- Lymphoma post-autologous stem cell transplant
- Lymphoma post CAR-T cell infusion
- Lymphoma post BiTE therapy
- Leukemia post CAR-T cell infusion
- Leukemia post BiTE therapy
- Other diagnoses post BiTE or CAR-T therapy
- Chronic lymphocytic leukemia
- All diagnoses after allogeneic stem cell transplant
- Other malignant conditions not listed above
- Non-malignant conditions with drug induced hypogammaglobulinemia (e.g., post-Rituximab)
- Other
- Missing Data Codes:
 - No Information (NI)
 - Unknown (UNK)

If “Other” is selected from the indication list, an appropriate data collection field will appear to enter other indication.

SECTION C: Clinical Indication

Clinical indication for use Refer to Ontario IG Management Utilization Guidelines for additional indication where IG may be appropriate.

Indication (please select from the drop down)	Secondary Immune Deficiency(SID) ⓘ 🗨 Ⓜ
If applicable request is for another indication please specify	
If Secondary Immune Deficiency, please select patient primary diagnosis	Lymphoma post CAR-T cell infusion ▼
Please specify "other" primary diagnosis if secondary immune deficiency	

4.3.6. Other Treatment Information

- a. **Has the patient used other therapies to treat this condition:** If this information is provided on the MOH IG request for or is known, please indicate the number of lines of treatment used previously to treat this condition. By selecting the appropriate numbered radio button corresponding to the number of treatments previously used, appropriate number data table will become available to enter the following information:

- Treatment (name/description)
- Dose (if applicable)
- Duration of treatment
- What was the outcome? Select the appropriate outcome:
 - No Response
 - Contraindications
 - Intolerance

b. **Other Comments:** includes notes regarding response to IG therapy or any other pertinent comments.

Other Treatment Information

Has the patient used other therapies to treat this condition.

Please indicate the number of lines of treatments: 1 2 3 4 5 reset

If Yes, specify other treatments below

Treatment	Dose (if applicable)	Duration of treatment	What was the outcome?
<input type="text"/> Expand	<input type="text"/> Expand	<input type="text"/> Expand	<input type="radio"/> No Response <input type="radio"/> Contraindications <input type="radio"/> Intolerance reset
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

Other Comments (include notes regarding response to IG therapy)

Expand

4.3.7. Section D: Dosage Information

If MOH IG request form includes more than one dose type, another instance will need to be entered for the second dosing information (e.g., Initial induction dose and maintenance dose indicated on one form received).

- a. **Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG):** The response entered at the beginning of the form will display. This serves as a review to make sure the right



product was selected. If you need to correct it, you will need to go to the beginning and review the information previously entered.

Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) IVIG SCIG Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) IVIG SCIG

OR

Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) IVIG SCIG Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) SCIG IVIG

- b. **Patient Weight (Kg):** Enter the patient weight in the unit kilogram (Kg).
- c. **Patient Height (cm):** Enter the patient height in the unit centimeter(cm).
- d. **BMI (calculated field by REDCap):** The patient’s weight and height will be used to automatically calculate the *Body Mass Index (BMI)*.
- e. **Dose:** Indicate the dose type from the options:
 - Single (one time) dose
 - Induction dose
 - Maintenance dose

Patient Weight	<input type="text"/>	(Kg)
Patient Height	<input type="text"/>	(cm)
BMI (pre calculated field)	<input type="text"/>	View equation Dose must be adjusted for BMI greater than or equal to 30

- f. If you select **Single (one time Dose)** or **Induction Dose** for IVIG use, the following fields will be active:
 - Dose in g/Kg (please enter number to one decimal place)
 - Total dose (g)
 - Divided over ‘ x ’ days.
 - Options include 1-7
 - Missing Data Codes:
 - No Information (NI)
 - Unknown (UNK)

Dose: <input checked="" type="radio"/> Single (one time) Dose <input type="radio"/> Induction Dose <input type="radio"/> Maintenance Dose reset
Dose in g/Kg (please enter number to one decimal place) <input type="text"/>
Total dose (g): <input type="text"/>
Divided over <input type="text"/> H M
days
Frequency Every <input type="text"/> weeks
For a duration of <input type="text"/>

- g. If **Maintenance Dose** is selected, the following will be active:
 - Dose in g/Kg (please enter number to one decimal place)



- Total dose (g)
- Divided over ' ___x___ ' days.
 - Options include 1-7
 - Missing Data Codes:
 - No information
 - Unknown
- Frequency Every ' ___x___ ' weeks.
 - Options include 1-6
 - Missing Data Codes:
 - No information
 - Unknown
- For a duration of (e.g., number of treatments or number of months) Note: Displays for any dose selected.
 - Options include 1, 2, 3, 6, 12
 - Missing Data Codes:
 - No information
 - Unknown

Dose: <input type="radio"/> Single (one time) Dose <input type="radio"/> Induction Dose <input checked="" type="radio"/> Maintenance Dose reset	
Dose in g/Kg (please enter number to one decimal place) <input style="width: 80%;" type="text"/>	
Total dose (g): <input style="width: 80%;" type="text"/>	
Divided over	
<input style="width: 80%;" type="text"/>	<input type="button" value="H"/> <input type="button" value="M"/>
days	
Frequency Every	
<input style="width: 80%;" type="text"/>	<input type="button" value="H"/> <input type="button" value="M"/>
weeks	
For a duration of	
<input style="width: 80%;" type="text"/>	<input type="button" value="H"/> <input type="button" value="M"/>

- h. **Was the dose calculator used?** Select one of the options:
- Yes
 - No
 - Unknown
- i. **If no, why was it not used:** If you select *No* or *unknown* the comment box will open for you to enter any information on why the dose calculator was not used.



Was the dose calculator used?

Yes
 No
 Unknown

[reset](#)

If No, why was it not used

[Expand](#)

4.3.8. Laboratory Testing Results

- a. If laboratory testing results are provided on the MOH IG request for or are readily available in LIS, the following testing results are available for entering:
- IgG level
 - Platelet count
 - Other, specify the test name and result.

Date of associated test can be entered using the format YYYY-MM-DD.

Laboratory Testing Results (as documented on form)

If applicable, enter the appropriate test results

Test Result	Date (YYYY-MM-DD)
IgG level <input type="text"/>	<input type="text"/>
Platelet count <input type="text"/>	<input type="text"/>
Other, specify the test name and result <input type="text"/> <input type="text"/>	<input type="text"/>

4.3.9. Dose Calculator

Based on the pre-set variables entered in the form from the MOH IG request form/LIS request, the dose calculator will show the calculations to determine the dose. An example of the blank dose calculator and what it might look like once your form information has been enter is shown below:






Adjusted Dose (BMI >30) [linked to dose calculator]			Dosing Calculation steps	If Male	If Female
Dosing Calculation steps	If Male	If Female	3.78		View equation
Ideal Body Weight (male) = 50.0 kg + 2.3 kg (each inch > 5 feet) Ideal Body Weight (female) = 45.5 kg + 2.3 kg (each inch > 5			Ideal Body Weight (male) = 50.0 kg + 2.3 kg (each inch > 5 feet) Ideal Body Weight (female) = 45.5 kg + 2.3 kg (each inch > 5		54.2 View equation
Adjusted Dosing Weight (kg) Used when patients body weight is greater than the ideal body weight			Adjusted Dosing Weight (kg) Used when patients body weight is greater than the ideal body weight		66.9 View equation
Dosing Weight To be used in the dose calculator			Dosing Weight To be used in the dose calculator		66.9 View equation
Dose (gram/kg)			Dose (gram/kg)		
IVIG Dose Calculator			IVIG Dose Calculator		
IVIG Dose Round to Nearest 5g (to be validated)			IVIG Dose Round to Nearest 5g (to be validated)		
If an Adult < 152.4 cm			If an Adult < 152.4 cm		

4.3.10. Section E: Transfusion Medicine Only

- a. **Dose Verified:** Select *Yes* if dose was verified by technologist.
- b. **Dose adjusted to:** Enter the adjusted dose.
- c. **Adjusted by:** Enter the appropriate information; your site may code this information, or you could enter the role of the person making this decision (MLT, TM Physician).
- d. **Confirmed with ordering physician:** Select *Yes* if dose was confirmed with ordering physician/prescriber.
- e. **Date confirmed (YYYY-MM-DD):** Enter the date the dose was confirmed with ordering physician/prescriber.
- f. **Transfusion Medicine Medical Director/Designate Approval (request status):** Select using the down arrow:
 - Approved as ordered
 - Denied
 - Adjusted dose approved
 - No information
 - Unknown
- g. **Signature of approving Physician/Prescriber (please type name if allowed by your institution):** This information can be coded as per the Physician/Prescriber Tracking Log ([Appendix 2](#)).



SECTION E: For Transfusion Medicine Use Only


Dose Verified <input type="radio"/> Yes	reset
Dose adjusted to: <input type="text"/>	
Adjusted by: <input type="text"/>	
Confirmed with ording physician/prescriber <input type="radio"/> Yes	reset
Date confirmed (YYYY-MM-DD) <input type="text"/>	
Transfusion Medicine Medical Director/Designate Approval (request status)	  
<input type="text"/>	
Date Approved/Denied (YYYY-MM-DD) <input type="text"/>	
Signature of approving Physician/Prescriber (please type name if allowed by your institution)	
<input type="text"/>	


4.3.11. Additional Notes/Information

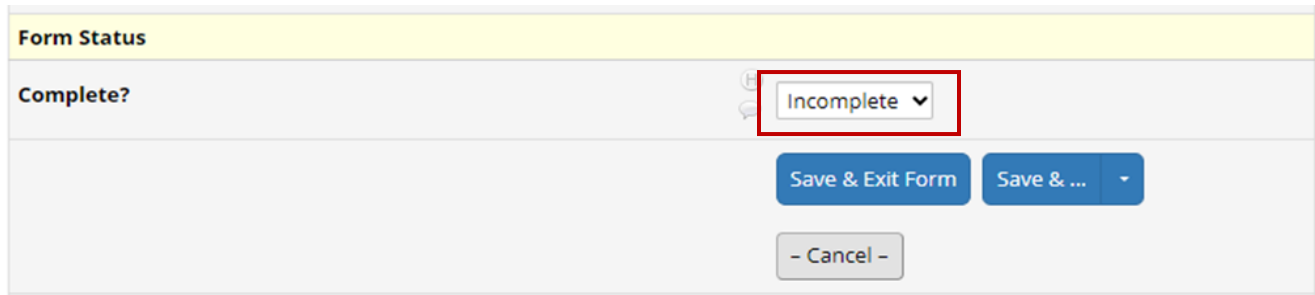
If there are additional explanatory notes on the form outside of the standard questions on the MOH IG request form (e.g., in the margins), please enter those notes here.

If there are additional notes on the form outside the boundary of the question (ex. in the margins), please enter those notes here.	<input type="text"/>
	Expand

4.4 FORM STATUS

To save the data information entered in the form and come back to it at another time to finish entering the data, the **Save & Exit** option can be used to create the record. The *Form Status* in this situation can be left as **Incomplete**. On the *Record Status Dashboard*, the coloured radio button will stay **Red**. 

The *Form Status* must be changed to **Complete** by using the down arrow, once all the data has been entered to change the coloured radio button on the *Record Status Dashboard* to **Green**.  Changing the record to complete does not affect the option to add additional instances in the future.



4.5 OTHER IMPORTANT INFORMATION

IMPORTANT: For privacy purposes, do **NOT** enter any of the following data into REDCap (there should not be any fields in REDCap to enter this data into) – patient name, date of birth, or OHIP number.

- If information from the MOH paper form is missing in any text field in REDCap, please type/enter *NI* into the REDCap field to indicate that the paper form was blank. If information from the MOH form is missing in a drop-down field in REDCap, please choose the option **Missing Code – No Information**. If information from the MOH form is provided, but it cannot be deciphered or interpreted, please choose the option **Missing Code – Unknown**.
- For Treating/Ordering Physician and Physician Phone fields, do not pull this information from the hospital derived patient information sticker. The Most Responsible Physician (MRP) and Family Physician (FP) from the sticker may not be the same as the treating/ordering physician for the IG request and shouldn't infer that they're the same. Enter the information that is typed/written into the corresponding fields on the paper form. If the fields are blank, enter them as null.
- Ensure you are recording any additional notes from the paper forms at the bottom of the REDCap forms in the **Additional Notes / Information** section.

4.6 CHANGES FROM PREVIOUS VERSIONS

The table below outlines the significant changes across the previously published versions of the Immune Globulin Quality Improvement Project Data Entry User Guide.

Version / Date	Change
V4 – Sept 2023	Newly published document.
V5 – June 2024	<ul style="list-style-type: none"> • 4.3.5. Section C: Clinical Indication – Primary reason for SID option list added
V6 – March 2025	<ul style="list-style-type: none"> • 1.0 Project information – Included data found on SCIG form with link • 4.3.5. Section C: Clinical Indication – 2025 V5.0 of IG Utilization Management new 'Can use' indications added to option list. Previous indications with updated names in table below.



	Previously Named	Updated Name
	Pemphigus Vulgaris (PV) and Variants	Autoimmune Blistering Diseases / Pemphigus Vulgaris (PV) and Variants
	N-methyl-D-aspartate (NMDA) encephalitis	Autoimmune encephalitis mediated by antibodies (AMAE) / N-methyl-D-aspartate (NMDA) encephalitis
	Invasive Group A streptococcal fasciitis with associated toxic shock	Toxic Shock Syndrome (TSS) - Invasive Group A streptococcal fasciitis
	Staphylococcal Toxic Shock	Toxic Shock Syndrome (TSS) - Staphylococcal Toxic Shock
	Secondary Immune Deficiency (SID)	Secondary Immune Deficiency (SID) / Hypogammaglobulinemia
	Pre-transplant (Heart) Peri-transplant (heart, lung, kidney, pancreas) Post-transplant (Solid Organ Transplant)	Active antibody mediated rejection (ABMR) prevention/management in solid organ transplant Desensitization in Solid Organ transplant prevention/treatment of rejection
	<ul style="list-style-type: none"> 4.6 Changes from Previous Versions – Change control section to reflect changes in current version. 	

5.0 Acknowledgements

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6.0 Appendices

[Appendix 1](#): Patient Tracking Log. ([electronic version](#))

[Appendix 2](#): Physician / Prescriber Information Log. ([electronic version](#))



