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TEXAS
Health and Human
Services

Texas Department of State
Health Services

Monoclonal Antibody Disaster Reporting

Texas Immunization Registry

Agenda

- What is the “Registry”?
- Reporting Requirements: Monoclonal Antibodies
- ImmTrac2 Consent
- How to Add Regeneron-IgG
- How to Add Regeneron-COV
- How to Add Bamlanivimab and Etesevimab
- Resources for Reporting Monoclonal Antibodies
- Questions



What is the “Registry”?



The Texas Immunization Registry (ImmTrac2)

- The registry is secure and confidential, and safely consolidates and stores immunization records from multiple sources in one centralized system.
- Authorized organizations (org's) include health care providers, schools, and public health departments.



**9.1 million Texans' immunization records.
33,000 organizations store them in 1 place.**



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Reporting Requirements: Monoclonal Antibodies



Providers Must Report AIMs

- A health care provider who administers an antiviral, immunization, or other medication (AIM) during a publicly declared disaster shall provide the data to DSHS.
- Title 25, Chapter 100, Rule 100.7
[https://texreg.sos.state.tx.us/public/readtac\\$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=100&rl=7](https://texreg.sos.state.tx.us/public/readtac$ext.TacPage?sl=R&app=9&p_dir=&p_rloc=&p_tloc=&p_ploc=&pg=1&p_tac=&ti=25&pt=1&ch=100&rl=7)
- Report AIMs in a timely manner. Failure to promptly report administration of monoclonal antibody treatments could affect future allocations.



ImmTrac2 Consents



Disaster and Standard Consents

- **Disaster** consents only affect **disaster** AIMs being reported.
- **Standard** minor or adult consents only affect **standard** (ACIP recommended) immunizations being reported.
- A client can have:
 - No consents at all,
 - Only a disaster consent,
 - Only a standard minor or adult consent, or
 - Both a disaster consent and a standard minor or adult consent



Disaster Consents

- **Disaster AIMs must be reported regardless of ImmTrac2 consent status.**
- **BUT**, If the client did sign a “Disaster Information Retention Consent”, then the Registry can keep the disaster AIM longer than 5 years after the end of the disaster.
- Otherwise, the client’s disaster AIM is deleted 5 years after the end of the disaster.
- For more info about disaster consents, see the “Online Disaster Reporting” video on our User Training webpage at <https://www.dshs.texas.gov/immunize/immtrac/User-Training/>



How to Add **REGENERON-IgG**



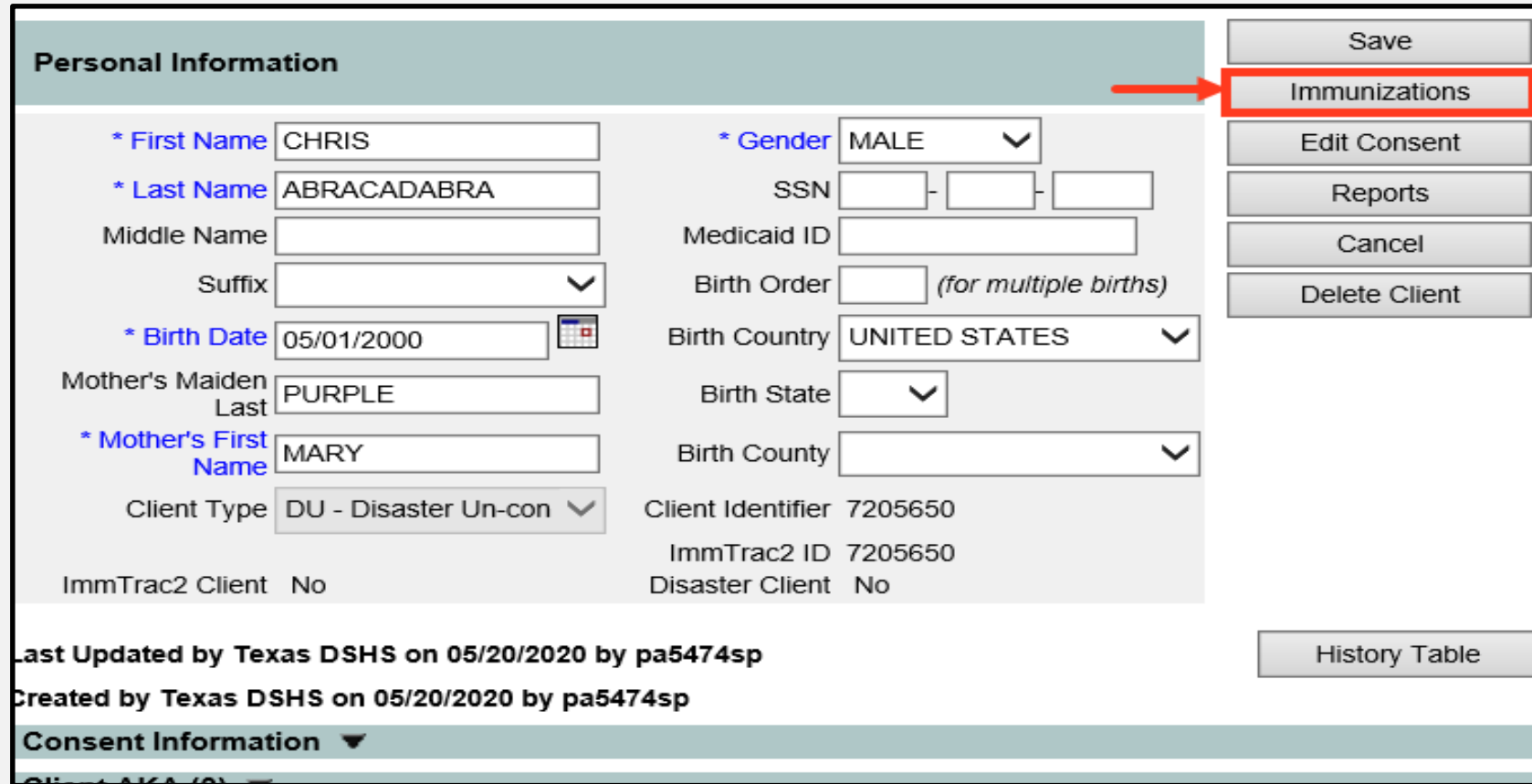
REGENERON-IgG 1 Dosing

Individual CASIRIVIMAB AND IMDEVIMAB solutions must be ADMINISTERED TOGETHER but REPORTED SEPARATELY

Antibody	Concentration	Package Size	NDC Number
Casirivimab REGN10933	1,332 mg/11.1 mL (120 mg/mL)	1 vial per carton	61755-024-01
	300 mg/2.5 mL (120 mg/mL)	1 vial per carton	61755-026-01
Imdevimab REGN10987	1,332 mg/11.1 mL (120 mg/mL)	1 vial per carton	61755-025-01
	300 mg/2.5 mL (120 mg/mL)	1 vial per carton	61755-027-01



In the Client's Record, Click the Immunizations Button



Personal Information

* First Name	CHRIS	* Gender	MALE
* Last Name	ABRACADABRA	SSN	- - -
Middle Name		Medicaid ID	
Suffix		Birth Order	(for multiple births)
* Birth Date	05/01/2000	Birth Country	UNITED STATES
Mother's Maiden Last	PURPLE	Birth State	
* Mother's First Name	MARY	Birth County	
Client Type	DU - Disaster Un-con	Client Identifier	7205650
ImmTrac2 Client	No	ImmTrac2 ID	7205650
		Disaster Client	No

Last Updated by Texas DSHS on 05/20/2020 by pa5474sp
Created by Texas DSHS on 05/20/2020 by pa5474sp

Consent Information

Buttons: Save, Immunizations, Edit Consent, Reports, Cancel, Delete Client, History Table



Add New Imms Button

Client Information ImmTrac2 ID 219214200

Client Name (First - MI - Last)	DOB	Gender	Tracking Schedule	Client ID
CHRIS ABRACADABRA	05/01/2000	M	ACIP	219214200
Address/Phone 1000 BUDDY HOLLY LANE, AUSTIN, TX 78704				
Comments				

Current Age: 20 years, 18 days

Client Notes (0) [view or update notes](#)

Last Immunization Date: None Reported

Immunization Record Tracking Schedule

Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
This client record has no immunizations associated with it.										

Vaccines Recommended by Selected Tracking Schedule

Select	Vaccine Group	Vaccine	Earliest Date	Recommended Date	Past Due Date
Select <input type="checkbox"/>	HPV	HPV, NOS	05/01/2009	05/01/2011	05/01/2013
Select <input type="checkbox"/>	Influenza-seasnl	Flu NOS	05/01/2009	07/01/2019	05/01/2009
Select <input type="checkbox"/>	Meningo	MCV4, NOS	05/01/2016	05/01/2016	05/01/2019
Select <input type="checkbox"/>	Td/Tdap	Tdap	05/01/2007	05/01/2007	05/01/2007



Adding REGENERON-IgG 1

Providers are required to report two records for the administration, one for each product.

Enter New Immunization

* Date Administered 09/17/2021

Prescribed By

Remove	Immunization	* Trade Name	* Lot #	Vaccine Eligibility	Prescribed By
<input type="checkbox"/>	Regeneron-IgG1	Casirivimab, 1332mg/11.1mL	ABC123		
	* Manufacturer	REG-Regeneron Pharmaceuticals	Body Site	Route	Dose Full
<input type="checkbox"/>	Regeneron-IgG1	Imdevimab, 1332mg/11.1mL	DEF456		
	* Manufacturer	REG-Regeneron Pharmaceuticals	Body Site	Route	Dose Full



REGENERON-IgG 1 Override Warning

Click the selection boxes on the right and click "Save Selected".

WARNING!

You are attempting to enter potential duplicate immunization records.

Admin Date	Vaccine Group	Trade Name	Lot #	Date Entered	Hist?	Selected
Incoming: 09/17/2021	Regeneron-IgG1	Casirivimab, 1332mg/11.1mL	ABC123		N	<input checked="" type="checkbox"/>
Incoming: 09/17/2021	Regeneron-IgG1	Imdevimab, 1332mg/11.1mL	DEF456		N	<input checked="" type="checkbox"/>

To make corrections to your entries, click Make Edits.

To OVERRIDE the system and save the DUPLICATE immunizations, check the incoming immunizations you want to save and click Save Selected.

Make Edits



Save Selected



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Casirivimab and Imdevimab Are Added to the Record

Immunization Record Tracking Schedule

Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
Regeneron-IgG1	09/17/2021	21Y 8M		Casirivimab monoclonal antibodies [Casirivimab, 1332mg/11.1mL @]	Full				Yes	
	09/17/2021	21Y 8M		Imdevimab monoclonal antibodies [Imdevimab, 1332mg/11.1mL @]	Full				Yes	



How to Add **REGENERON-COV**



REGENERON-COV Dosing


One vial per carton contains both Casirivimab and Imdevimab with 600mg/600mg per 10mL. One vial is one dose. It is administered intravenously and reported as one full dose.

Antibody	Concentration	Package Size	NDC Number
REGEN-COV (Casirivimab and Imdevimab)	600 mg/600 mg per 10 mL (60 mg/60 mg per mL)	1 vial per carton	61755-039-01



Adding Regeneron Dose Pack

Enter New Immunization

* Date Administered 09/20/2021 

Prescribed By

Remove	Immunization	* Trade Name	* Lot #	Vaccine Eligibility	Prescribed By
<input type="checkbox"/>	Regeneron-DosePk	Regeneron Dose Pack 039	ABC123	<input type="text"/>	<input type="text"/>

* Manufacturer REG-Regeneron Pharmaceuticals


Body Site

Route

Dose Full



Regeneron Dose Pack Added

Immunization Record		Tracking Schedule		ACIP						
Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
Regeneron-DosePk	09/20/2021	21Y 8M		Casirivimab-Imdevimab Dose Packs [Regeneron Dose Pack 039 @]	Full				Yes	



How to Add Bamlanivimab and Etesevimab

Bamlanivimab and Etesevimab Combined Treatment for Post Exposure Prophylaxis: Dosing is 1 vial Bam + 2 vials Ete

Antibody	Concentration	Package Size	NDC
Bamlanivimab	700 mg/20 mL (35 mg/mL)	one vial per carton	0002-7910-01
Etesevimab	700 mg/20 mL (35 mg/mL) X 2 = 1400 mg	one vial per carton (use <u>two</u> vials)	0002-7950-01



Adding Bamlanivimab and Etesevimab if Pulling Etesevimab from ONE Lot Number. Ete Dose = 2.

Enter New Immunization

* Date Administered 09/25/2021

Prescribed By

Remove	Immunization	* Trade Name	* Lot #	Vaccine Eligibility	Prescribed By
<input type="checkbox"/>	Bamlanivimab	Bamlanivimab	MNP1246		
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose Full
<input type="checkbox"/>	Etesevimab	Etesevimab	QRZ9874		
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose 2



NOTE: Dose = 2 Indicates TWO Doses, NOT the second in a sequence.

Enter New Immunization

* Date Administered 09/25/2021

Prescribed By

Remove	Immunization	* Trade Name	* Lot #	Vaccine Eligibility	Prescribed By
<input type="checkbox"/>	Bamlanivimab	Bamlanivimab	MNP1246	<input type="text"/>	<input type="text"/>
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose Full
<input type="checkbox"/>	Etesevimab	Etesevimab	QRZ9874	<input type="text"/>	<input type="text"/>
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose 2



Last Warning for Consent or No Consent

- Click “OK” to add a DIR consent.
- Click “Cancel” to save the immunization without a DIR consent.
- For more info on consents, see the “Online Disaster Reporting” video at <https://www.dshs.texas.gov/immunize/immtrac/User-Training/>.

immtrac.dshs.texas.gov says

This client currently does not have a Disaster Information Retention (DIR) Consent Form on file. Click "OK" if the client has provided a signed DIR consent form, or click "Cancel" to save the immunization without a DIR consent form.

OK

Cancel



If “OK” was Chosen on Previous Slide, Here You Can Add a DIR Consent.

Select the option:

- Option #1: Add Consent Form(s) and attributes for this client
 - First Responder *(no additional consent required)*
 - Adult Family Member of a First Responder *(no additional consent required)*
 - Disaster Information Retention Consent Form *(additional consent form required)*
- Option #2: Withdraw Consent for this client

Display Form

Update Client

Edit Client



Cancel

[Click here to obtain a blank copy of the ImmTrac2 Consent forms.](#)



Client's Imm Record Updated with 1 Dose Bamlanivimab and Two Doses of Etesevimab (Same Lot)

Immunization Record Tracking Schedule

Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
Bamlanivimab	09/25/2021	65Y 2M		Bamlanivimab monoclonal antibody [Bamlanivimab ®]	Full				Yes	
Etesevimab	09/25/2021	65Y 2M		Etesevimab monoclonal antibody [Etesevimab ®]	2				Yes	



Adding Bamlanivimab and Etesevimab if Pulling Etesevimab from TWO Different Lots.

Enter New Immunization

* Date Administered 09/01/2021

Prescribed By

Remove	Immunization	* Trade Name	* Lot #	Vaccine Eligibility	Prescribed By
<input type="checkbox"/>	Bamlanivimab	Bamlanivimab	ABC123		
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose Full
<input type="checkbox"/>	Etesevimab	Etesevimab	DEF456		
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose Full
<input type="checkbox"/>	Etesevimab	Etesevimab	GHJ789		
	* Manufacturer	LIL-Eli Lilly and Company	Body Site	Route	Dose Full



Adding Bamlanivimab and Etesevimab – Override Warning

Click the selection boxes on the right and click "Save Selected".

WARNING!

You are attempting to enter potential duplicate immunization records.

	Admin Date	Vaccine Group	Trade Name	Lot #	Date Entered	Hist?	Selected
Incoming:	09/01/2021	Etesevimab	Etesevimab	DEF456		N	<input checked="" type="checkbox"/>
Incoming:	09/01/2021	Etesevimab	Etesevimab	GHJ789		N	<input checked="" type="checkbox"/>

To make corrections to your entries, click Make Edits.

To OVERRIDE the system and save the DUPLICATE immunizations, check the incoming immunizations you want to save and click Save Selected.

Make Edits

Save Selected



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A “Validation Errors” message is displayed.
Click “OK”.

New Immunization Validation Errors


Validation Errors

- Trade Name is a required field. Please select a value.
- Manufacturer is a required field. Please select a value.
- Lot Number is a required field. Please enter a value.
- Please enter information in all required fields with an asterisk (*)



On the Third Row (Which Is Blank), Click the “Remove” Box on the Left Side of that Row, then Click Save.

Enter New Immunization

* Date Administered 09/01/2021 

Prescribed By

Remove	Immunization	* Trade Name	* Lot #	Vaccine Eligibility	Prescribed By
<input type="checkbox"/>	Etesevimab <input type="text"/>	Etesevimab <input type="text"/>	DEF456 <input type="text"/>	<input type="text"/>	<input type="text"/>
	* Manufacturer LIL-Eli Lilly and Company <input type="text"/>	Body Site <input type="text"/>		Route <input type="text"/>	Dose Full <input type="text"/>
<input type="checkbox"/>	Etesevimab <input type="text"/>	Etesevimab <input type="text"/>	GHJ789 <input type="text"/>	<input type="text"/>	<input type="text"/>
	* Manufacturer LIL-Eli Lilly and Company <input type="text"/>	Body Site <input type="text"/>		Route <input type="text"/>	Dose Full <input type="text"/>
<input checked="" type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	* Manufacturer <input type="text"/>	Body Site <input type="text"/>		Route <input type="text"/>	Dose Full <input type="text"/>



Another “Duplicate Immunization” Warning is Displayed.

Make sure “Selected” boxes are checked, and click Save Selected.

WARNING!

You are attempting to enter potential duplicate immunization records.

	Admin Date	Vaccine Group	Trade Name	Lot #	Date Entered	Hist?	Selected
Incoming:	09/01/2021	Etesevimab	Etesevimab	DEF456		N	<input checked="" type="checkbox"/>
Incoming:	09/01/2021	Etesevimab	Etesevimab	GHJ789		N	<input checked="" type="checkbox"/>

To make corrections to your entries, click Make Edits.

To OVERRIDE the system and save the DUPLICATE immunizations, check the incoming immunizations you want to save and click Save Selected.

Make Edits

Save Selected



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If Client Signed a DIR Consent, Add the DIR Consent Now.

- Click “OK” to add a DIR consent, otherwise,
- Click “Cancel” to save the immunization without a DIR consent.

immtrac.dshs.texas.gov says

This client currently does not have a Disaster Information Retention (DIR) Consent Form on file. Click “OK” if the client has provided a signed DIR consent form, or click “Cancel” to save the immunization without a DIR consent form.

OK

Cancel



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If “OK” was Chosen on Previous Slide, You Can Add a DIR Consent.

Select the option:

- Option #1: Add Consent Form(s) and attributes for this client
 - First Responder *(no additional consent required)*
 - Adult Family Member of a First Responder *(no additional consent required)*
 - Disaster Information Retention Consent Form *(additional consent form required)*
- Option #2: Withdraw Consent for this client

[Click here to obtain a blank copy of the ImmTrac2 Consent forms.](#)

Display Form





Update Client

Edit Client

Cancel



Client's Imm Record Updated with Different Lots of Etesevimab

Immunization Record					Tracking Schedule		ACIP 			
Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
Bamlanivimab	09/01/2021	65Y 1M		Bamlanivimab monoclonal antibody [Bamlanivimab ®]	Full				Yes	
Etesevimab	09/01/2021	65Y 1M		Etesevimab monoclonal antibody [Etesevimab ®]	Full				Yes	
	09/01/2021	65Y 1M		Etesevimab monoclonal antibody [Etesevimab ®]	Full				Yes	



Resources for Reporting Monoclonal Antibodies



Resources for COVID-19 Reporting

- Data exchange specifications for monoclonal antibody reporting will soon be available.

- Information for COVID-19 Vaccination Providers

<https://www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx>

- How to report disaster immunizations to ImmTrac2

<https://www.youtube.com/playlist?list=PL7xet9qFzOjVAa7qCZEHUIE0LtZJyxNVs>



Resources for Clinicians – Monoclonal Antibody Treatment - Part 1

- COVID-19 Monoclonal Antibody Eligibility – Treatment and Post Exposure Prophylaxis

<https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/mAb-eligibility-treatment-and-post-exposure-prophylaxis.aspx>

- COVID-19 Monoclonal Antibody Checklist for Subcutaneous and Intravenous Administration

<https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/COVID19-mAb-checklist-subcutaneous-intravenous-administration.aspx>



Resources for Clinicians – Monoclonal Antibody Treatment Part 2

- Subcutaneous Injection Instructions for REGEN-COV
<https://www.phe.gov/emergency/events/COVID19/therapeutics/Documents/REGEN-COV-SubQ-FactSheet-July2021-508.pdf>
- Treatment and Post-Exposure Prophylaxis of REGEN-COV
<https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/EMS-Template-Protocol-for-COVID19-mAbs-Administration.aspx>



Resources for Clinicians – Monoclonal Antibody Treatment Part 3

- Guides on Vaccination after Monoclonal Antibody Treatment administration

<https://www.cdc.gov/vaccines/COVID-19/clinical-considerations/COVID-19-vaccines-us.html>



Resources for Clinicians – Monoclonal Antibody Treatment Part 4

- Step-by-step instructions for placing a COVID-19 therapeutic order in VAOS

<https://www.dshs.Texas.gov/immunize/COVID19/COVID-19-Therapeutics-Job-Aid.pdf>

- **COVID-19 Support Line**

Call 833-832-7068, option “0” (zero) from 8:00 am – 5:00 pm Monday through Friday.





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Thank You!

From the Texas Immunization Registry

Q & A

ImmTrac2@dshs.texas.gov

Access, site registrations or renewals, etc.

ImmTracMU@dshs.texas.gov

Data exchange and promoting interoperability