Patient Data Sharing Program Toolkit

- Program Talking Points and Overview
- Social Media Posts
- Informational Flyer
- Links to general videos
  - Adding a “How To” Video
- Group Specific Webinar
- Press Release Sample
- Email Reminders
- Adding Your Registry to the ClinGen Website

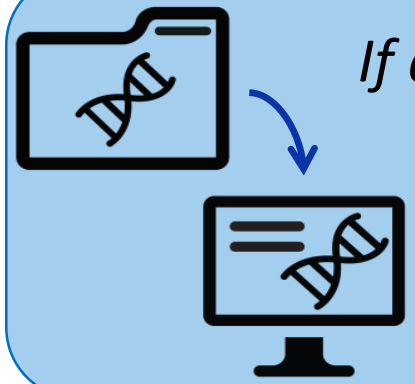
rev. March 2019

Talking Points

General information about the program, need for data sharing, etc.

ClinGen Data Sharing Program Talking Points:

- ClinGen, an NIH-funded resource, is working to better understand the relationship between genetics and health to improve patient care and research. This effort relies on gathering more information through data sharing.
- Team members from ClinGen are working with ***PIN Name*** to give you the option share your anonymous genetic and health information with others from who will use it to improve patient care and genetic testing.
    - Why is data sharing needed?
        - When a genetic change (variant) is found for the first time, often little is known about it. It may be unclear if that genetic change causes health concerns. Data sharing can help us better understand these genetic changes and can help others get clearer genetic testing.
        - Even if a genetic variant is well understood, data sharing helps increase understanding of a condition's features, which may help identify possible interventions and treatments.
        - The more information collected, the better researchers will understand how genes affect health and, ultimately, how best to care for patients.
        - As we learn more about genetic changes, their relationship with health and disease (interpretation) may change. Individuals that share data through ClinGen can decide if they would like to receive updates about their genetic test results from the ClinGen team.
    - Data sharing is safe and secure. Only deidentified information (meaning that it does not include your name, birthday, or other identifiers) is shared through the program.
- To share your data, you don't have to do much more than you already are to participate in ***PIN NAME***.
    - You will be asked to:
        - Complete the ClinGen Data Sharing Program Consent
        - Upload a copy of your genetic testing report
        - Decide whether you would like to receive updates to your test results from the ClinGen team.
        - In the future, we may ask you to potentially complete optional, additional health history questions



If a registry participant opts in, they would be asked to **upload a copy of their genetic testing report to their registry account** for the ClinGen genetic counselors to review.

ClinGen team may contact participants or ask participants to complete additional, optional survey(s).

ClinGen's team will review participants' genetic test reports to pull out information about any variants reported.

ClinGen's team will submit de-identified genetic and health information collected from the registry to publicly available databases.

ClinGen Expert Panels and Curation Groups can have access to this deidentified data.

These groups have the option to receive updates regarding data sharing.

Social Media Posts

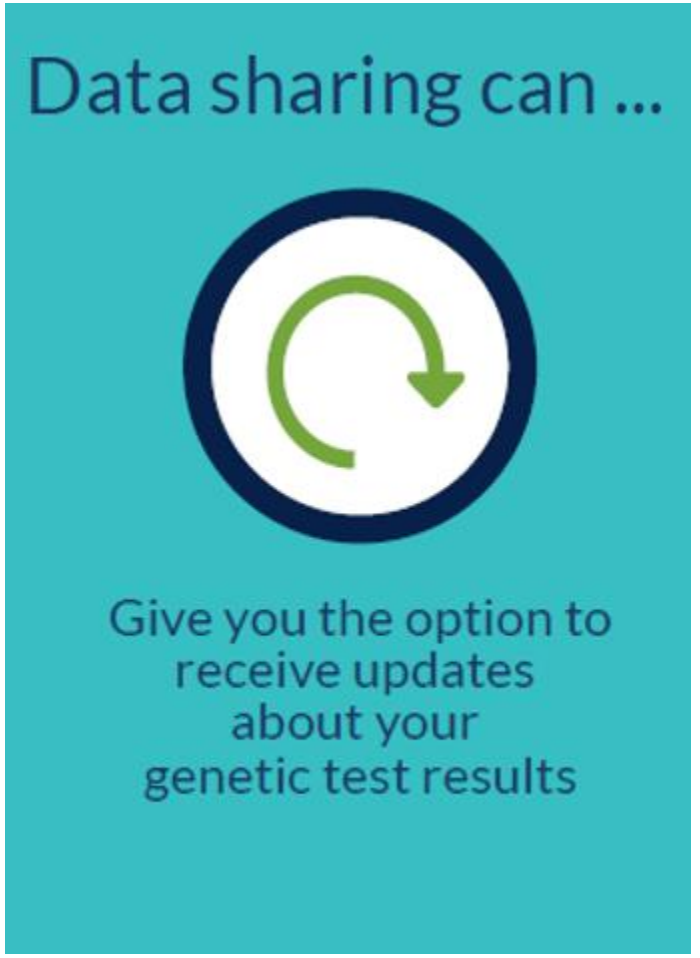
Social media is a great way to engage potential participants and family. Included are sample posts and graphics for posts.

Consider posting once a week!

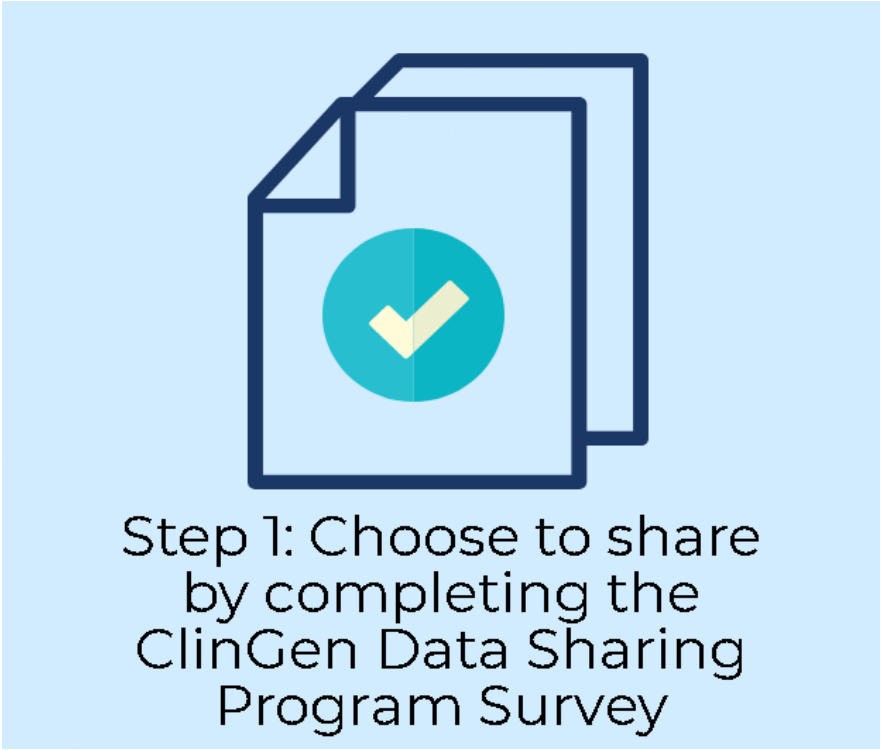
Visit the PIN NAME (LINK) to help us by sharing your data. We need your help and sharing is safe and secure! Spread the word with others in the CONDITION NAME communities by sharing this post! Learn more here.

Visit the PIN NAME (LINK) to share your data safely and securely. Choose to share by taking the ClinGen Data Sharing Program Survey in your registry account. Help push research forward! Learn more here.

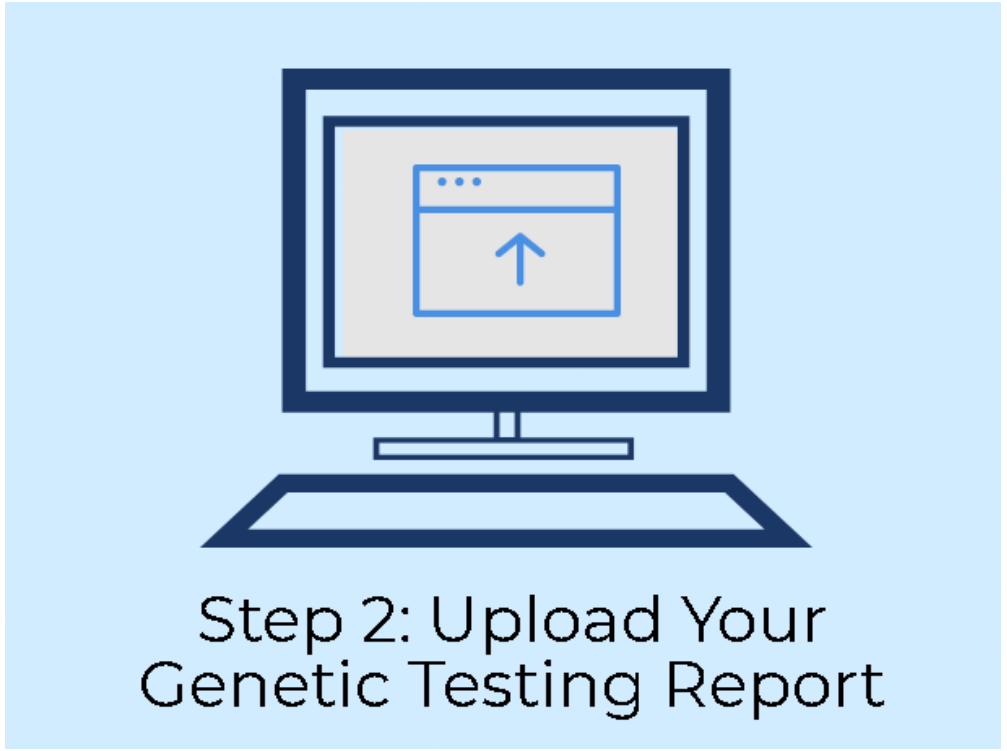
Visit the PIN NAME (LINK) to share your data. If you choose to share your data safely and securely, you can sign up to get updates as more is learned about your genetic test results.



Visit the PIN NAME (LINK) (PIN) to help us by sharing your genetic and health data! Sharing is safe and secure.



Visit the PIN NAME (LINK) to help us by sharing your genetic and health data! If you have signed up to share, don't forget the second step! Upload a copy of your genetic test results.



Visit the PIN NAME (LINK) to help us by sharing your genetic and health data! If you have signed up to share, don't forget the second step! Upload a copy of your genetic test results. Don't know how to upload your report watch this short video:

https://www.youtube.com/watch?v=3qQIKHurUTE&t=27s

Through the PIN NAME (LINK), you can share your genetic and health information securely and safely. From other registries, we know that families can share genetic data that may not otherwise be available to researchers and clinicians!

Informational Flyer

The informational flyer can be customized with your group’s name and logo.

As a member of a Patient Insights Network, you are contributing your information to help increase our knowledge and improve patient care!

Now, there is an easy way to make your data work even harder to help researchers.

ClinGen, an NIH-funded resource, is working to understand the relationship between genetics and health to improve patient care and research. This effort relies on gathering more information through data sharing.

Your Patient Insights Network is working with ClinGen to help people like you share their genetic and health information.

Data sharing can ...

Help us better understand genetic changes and can help others get clearer genetic test results

Increase our understanding of a condition's features, which may help identify possible interventions and treatments

Give you the option to receive updates about your genetic test results

Learn more here: http://bit.ly/ClinGenData

Contact us with questions:
ClinGen at datashare@clinicalgenome.org
The PIN Coordinator at coordinator@pin.invitae.com

Informational Videos

These videos provide an overview of the program. The consent form links to them, but they also can be used as recruitment tools and to answer questions about the program.

bit.ly/datasharevideo

more »

more »

more »

more »

more »

more »

Brief How-To Video

http://bit.ly/2C5Reu8

Group Specific Webinars

The team at ClinGen that is facilitating data sharing would be happy to set-up a live or recorded webinar for scientific advisory committees, board member, or potential participants.

Sample Webinar – CureCADASIL Participants

- http://bit.ly/2VC3Ctm

- Webinar can be customized for each group and can be delivered live, through a recording, or possibly as an in-person discussion at a family meeting.

Press Release Sample Language

Given that ClinGen is an NIH funded research initiative, there are restrictions regarding logo and name use. The following is sample wording from a previous release that describes the program and ClinGen.

All press releases need to be reviewed and approved by ClinGen. Please consider this when drafting the release and allow for extra time to review.

_____ is working with Geisinger, a National Institutes of Health (NIH) Clinical Genome Resource (ClinGen) grantee to share genetic and health information from. Geisinger, as a ClinGen grantee, plans to help rare disease patient advocacy groups collect and share genetic and health information to increase our understanding of genomics. Through their existing registry, _____ will participate in the Patient Data Sharing Program to have certified genetic counselors review and share participants' de-identified genetic and health information. Registry participants are able to direct whether or not they would like their de-identified data shared. Data sharing can help support ClinGen's efforts to better understand the relationship between genetics and health. It can help clarify uncertain genetic testing results and provide more information about a condition to inform treatment and management.

About ClinGen & ClinVar

ClinGen is an NIH-funded effort dedicated to identifying clinically relevant genes and variants for use in precision medicine and research. ClinVar is a freely accessible, public archive of reports of the relationships among human variations and phenotypes hosted by the National Center for Biotechnology Information (NCBI) and funded by the Intramural National Institutes of Health (NIH). ClinGen investigators work closely with NCBI regarding the development and functionality of ClinVar and to support data deposition from many sources including genetic testing laboratories, researchers, and patients.

Email Campaign

An email campaign is programmed in to the registry and can be viewed on the following slides. If additional newsletters or emails are desired, this can be discussed.

Invitation to Participate

Invite #1 – Invitation to Participate

Sent 1 week after registration in a PIN program offering the program. Participants are automatically removed from further emails once they have taken the ClinGen Informed Consent survey.

[Includes the PIN Logo for the program to which the receiver belongs]

Subject: Invitation to Participate in ClinGen Data Sharing Program
Dear [Account Holder First Name],

The Invitae Patient Insights Networks PIN (Patient Insights Network) is working with the Clinical Genome Resource (ClinGen) to invite you to choose to share your genetic and health information to help us better understand the relationship between genetics and health. Based on your survey answers, it appears that you have had genetic testing, so please read on to learn about an opportunity to share your de-identified information.

Why is this data sharing needed?
When a laboratory finds a genetic change (variant) for the first time, often little is know about it. Even if a genetic variant is well understood, data sharing helps increase understanding of a condition's features, which may help identify possible interventions and treatments. The more information collected, the better researchers will understand how genes affect health and, ultimately, how best to care for patients.

Why participate?
• Help clinicians, researchers, and other patients by increasing our understanding of your condition
• Have the option to receive updates about your genetic test results when there may be new information
• Make a difference by helping others with the same condition get more definitive results from genetic testing

What do I need to do?
You would not have to do much more to participate! To review the consent and opt to share your data, simply:
1. Login to your account at: Invitae Patient Insights Networks.
2. Review and complete the ClinGen Data Sharing Program informed consent survey.
3. Upload a copy of your genetic testing report to your account, if you have not already.

Individuals that choose to participate will have their de-identified genetic and health information shared to help us better understand the relationship between genetics and health. In the future, we may ask you to complete optional, additional questions through your account. Learn more by watching our short videos here.

For questions about this opportunity to share your data, call or email ClinGen at datashare@clinicalgenome.org or 570-214-1721 (toll free 855-322-7683).

Having difficulty or have questions about your account? Contact the PIN Coordinator at coordinator@pin.invitae.com.

Thank you,

Invitae Patient Insights Networks Coordinator

Invite #2 – Invitation to Participate

Sent 3 weeks after registration in a PIN program offering the program.
[Includes the PIN Logo for the program to which the receiver belongs]

Subject: Please Participate in ClinGen Data Sharing Program
Dear [Account Holder First Name],

The Invitae Patient Insights Networks PIN (Patient Insights Network) is working with the Clinical Genome Resource (ClinGen) to invite you to choose to share your genetic and health information to help us better understand the relationship between genetics and health. Based on your survey answers, it appears that you have had genetic testing, so please read on to learn about an opportunity to share your de-identified information.

Why is this data sharing needed?
When a laboratory finds a genetic change (variant) for the first time, often little is known about it. Even if a genetic variant is well understood, data sharing helps increase understanding of a condition's features, which may help identify possible interventions and treatments. The more information collected, the better researchers will understand how genes affect health and, ultimately, how best to care for patients.

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What do I need to do?
You would not have to do much more to participate! To review the consent and opt to share your data, simply:
1. Login to your account at: Invitae Patient Insights Networks.
2. Review and complete the ClinGen Data Sharing Program informed consent survey.
3. Upload a copy of your genetic testing report to your account, if you have not already.

Individuals that choose to participate will have their de-identified genetic and health information shared to help us better understand the relationship between genetics and health. In the future, we may ask you to complete optional, additional questions through your account. Learn more by watching our short videos here.

For questions about this opportunity to share your data, call or email ClinGen at datashare@clinicalgenome.org or 570-214-1721 (toll free 855-322-7683).

Having difficulty or have questions about your account? Contact the PIN Coordinator at coordinator@pin.invitae.com.

Thank you,

Invitae Patient Insights Networks Coordinator

Invite #3 – Invitation to Participate

Sent 4 months after registration in a PIN program offering the program.
[Includes the PIN Logo for the program to which the receiver belongs]

Subject: An Opportunity to Participate in ClinGen Data Sharing Program
Dear [Account Holder First Name],

The Invitae Patient Insights Networks PIN (Patient Insights Network) is working with the Clinical Genome Resource (ClinGen) to invite you to choose to share your genetic and health information to help us better understand the relationship between genetics and health. Based on your survey answers, it appears that you have had genetic testing, so please read on to learn about an opportunity to share your de-identified information.

Why is this data sharing needed?
When a laboratory finds a genetic change (variant) for the first time, often little is known about it. Even if a genetic variant is well understood, data sharing helps increase understanding of a condition's features, which may help identify possible interventions and treatments. The more information collected, the better researchers will understand how genes affect health and, ultimately, how best to care for patients.

Why participate?
• Help clinicians, researchers, and other patients by increasing our understanding of your condition
• Have the option to receive updates about your genetic test results when there may be new information
• Make a difference by helping others with the same condition get more definitive results from genetic testing

What do I need to do?
You would not have to do much more to participate! To review the consent and opt to share your data, simply:
1. Login to your account at: Invitae Patient Insights Networks.
2. Review and complete the ClinGen Data Sharing Program informed consent survey.
3. Upload a copy of your genetic testing report to your account, if you have not already.

Individuals that choose to participate will have their de-identified genetic and health information shared to help us better understand the relationship between genetics and health. In the future, we may ask you to complete optional, additional questions through your account. Learn more by watching our short videos here.

For questions about this opportunity to share your data, call or email ClinGen at datashare@clinicalgenome.org or 570-214-1721 (toll free 855-322-7683).

Having difficulty or have questions about your account? Contact the PIN Coordinator at coordinator@pin.invitae.com.

Thank you,

Invitae Patient Insights Networks Coordinator

Adding Your Registry to the ClinGen Website

Once your registry submits to ClinVar, you can request that your registry be added to the ClinGen website.

http://bit.ly/registrydata

Requirements:

- Registry submissions are submitted to ClinVar as ‘Phenotyping Only’ submissions
- Registry submits at least once per year adding new variants and updating variants as necessary
- Registry has attested to submitting at least 75% of all variants submitted to their registry in the last year
- Registry submits all categories of variants (pathogenic, uncertain, benign, etc.) that are reported on participants’ genetic testing reports

Registries Meeting Minimum Requirements for Data Sharing with ClinVar

ClinGen considers the sharing of variant interpretations essential for supporting genomic medicine and a critical part of quality assurance for accurate genetic and genomic testing. Open and transparent sharing allows peer-review and knowledge dissemination to ensure the highest quality care of patients.

Here, we identify patient registries who meet a minimum standard of data sharing with ClinVar:

- Registry submissions are submitted to ClinVar as ‘Phenotyping Only’ submissions
- Registry submits at least once per year adding new variants and updating variants as necessary
- Registry has attested to submitting at least 75% of all variants submitted to their registry in the last year
- Registry submits all categories of variants (pathogenic, uncertain, benign, etc.) that are reported on participants’ genetic testing reports

To apply for status, or to update your status, patient registries can apply here.

Questions about the criteria? Contact clingen@clinicalgenome.org.

		Additional Achievements			
Patient Registry	Meets requirements	Submitted >100 variants	>75% from past 5 years[1]	Classification updates to participants[2]	Participant matching mechanism[3]
GenomeConnect	✓	🏅	🏅	🏅	🏅

Some requirements and additional achievements based on self-reported data by laboratory

* Most recent submission pending ClinVar processing
[1] >75% of classified sequence and/or copy number variants from past 5 years submitted
[2] Actively provides participants with the option to receive information from the registry about potenital updates to their varaint classifications at the reporting laboratory
[3] Registry provides participants with the ability to match with others based on genetic information (gene or variant)