GRACA

GLOBAL RESEARCH ALLIANCE FOR CONGENITAL ANOMALIES

- Anorectal Malformations
- Cleft Palate
- Congenital Diaphragmatic Hernia and Eventration
- Congenital Hiatal Hernia
- Esophageal Atresia
- Gastroschisis
- Hirschsprung's Disease
- Intestinal Atresia
- Omphalocele
- Spina Bifida
- Tracheoesophageal Fistula

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Our Mission

The Global Research Alliance for Congenital Anomalies (GRACA) is dedicated to unifying and mobilizing a diverse network of medical professionals, researchers, governmental organizations, and congenital anomaly charities. Our mission is to establish international Standards of Care and Measurements of Morbidity and Mortality for children affected by surgically correctable midline Congenital Anomalies.

Through collaboration and innovation, we strive to accelerate research, enhance public awareness, and promote the development of life-changing treatments. GRACA's vision is a world where every child affected by a congenital anomaly receives the most advanced care and an opportunity for a healthy future. Our collective strength is a stairway to hope and survival, and our work is driven by a profound commitment to save and improve the lives of millions of children around the globe.

Introducing GRACA

The Global Research Alliance for Congenital Anomalies (GRACA), an initiative conceived on the counsel of the World Health Organization, is dedicated to assembling an international cohort of congenital anomalies organizations. The aim is to formulate a universal Standard of Care, as well as establish uniform measures of morbidity and mortality, benefiting millions of patients who share comparable medical challenges.

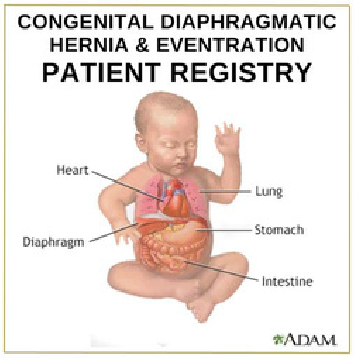
This global initiative is spearheaded by CDH International, which along with the Global Gastroschisis Foundation, played a vital role in GRACA's inception in 2020. Despite initial delays due to the pandemic, the alliance is now forging ahead with full momentum.

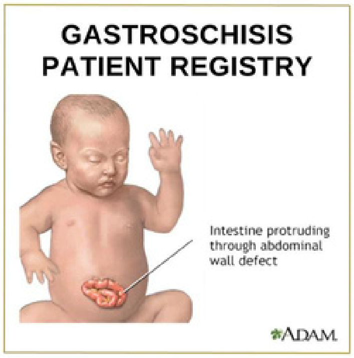
As the Fiscal Sponsor of GRACA, CDH International provides crucial support, including patient registries, and training to other patient communities, and acts as an intermediary with medical associations and government bodies.

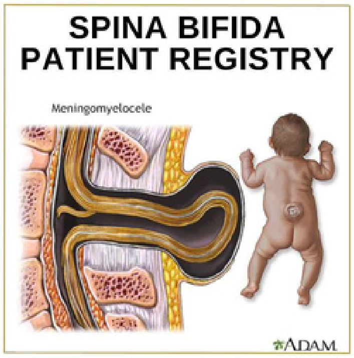
The Patient Communities

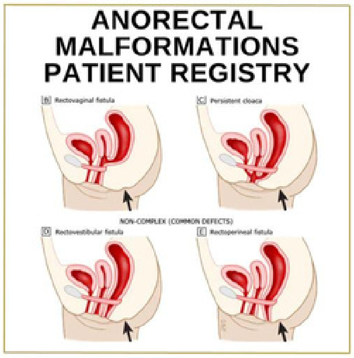
10 Congenital Anomalies were chosen based on the fact that they are formed around the same time of gestation, are all mid-line defects and are all surgically correctable.

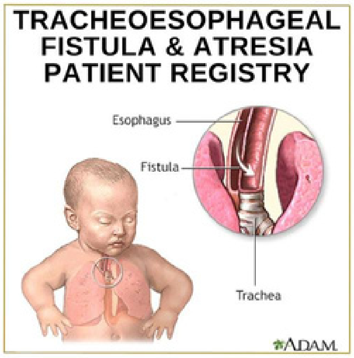
The first 6 Patient Registries will include the following Congenital Anomalies:

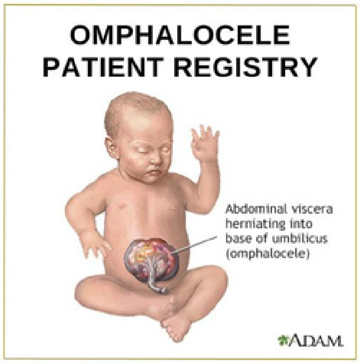












The remaining 4 will be added as soon as funding and time allows:

- Cleft Palate
- Congenital Hiatal Hernia
- Hirschsprung's Disease
- Intestinal Atresia

The Creation of GRACA

The Global Research Alliance for Congenital Anomalies (GRACA) was created by the founders of the world's largest charities for the 2 most common Congenital Anomalies treated with pediatric surgical care. Collectively, the leaders of these organizations have over 50 years of experience in patient advocacy, research, and awareness.

CDH International was founded by Dawn Ireland in 1995. CDHi runs the CDH Patient Registry with over 6500 patients in 74 countries, is a registered NGO in 6 countries, has raised over $2,000,000 and actively pushes all patient communities to collaborate to conserve resources and fund more research.

The Global Gastroschisis Foundation was founded by Meghan Hall Rauen in 2009 after the sudden death of her 3 and a half-month-old son, Avery, from Gastroschisis. The charity was originally named "Avery's Angels" but was renamed and restructured in 2021. It is the only charity for the anomaly and serves patient families worldwide.
Both organizations happened to start in the same town in North Carolina and both by mothers who lost their sons to congenital anomalies. Both organizations grew to become international powerhouses in patient advocacy and support. Dawn Ireland has mentored Meghan Rauen since the beginning of The Global Gastroschisis Foundation.

As both nonprofits grew and looked to help patients on a more international scale, they begin to represent these children in pediatric surgical groups, the rare disease sector and the congenital anomalies sector worldwide. And as the charities expanded their work, they both became very frustrated with the lack of adequate care for the patients in Lower and Middle-Income-Countries, the absence of Standards of Care and the dismissal of patient and family needs outside of the hospital.

CDH International was meeting with the World Health Organization to talk about creating a Standard of Care and Standard Measurements of Mortality and Morbidity for Congenital Diaphragmatic Hernia but saw such a great need for like Congenital Anomalies that it seemed completely natural to bring all the leaders in to help more of our children.

It never seemed responsible with either charity that one person or small group in one area of the world could dictate the care of 1000's of other patients without any real experience or collaboration. Patients in Europe did not receive the same medical care from country to country and certainly not the same care as that given in the US or South Africa or Venezuela. And the patient groups in all countries should be able to work together without any power struggles, membership fees, voting constraints, politics, etc.

Many discussions later, CDH International and the Global Gastroschisis Foundation decided to team up to help all their patients and more by creating a truly international, collaborative, supportive, and productive alliance for Congenital Anomalies patients that did focus on one hospital, country, continent or group. An alliance that did not exclude patients from LMIC's and did not exclude any nonprofits from helping to save these children.

Every single one of these children deserves a chance for survival and good quality of life and it will take every single nonprofit and other stakeholders working collaboratively to make that happen.

Then the WHO suggested that instead of focusing on just CDH, CDH International should pull the Congenital Anomaly patient communities together to potentially help millions of children.

So The Global Research Alliance for Congenital Anomalies (GRACA) was born.

"Graca" also means grace" in Portuguese and we think it is a wonderful description for this incredible endeavor.

Our Goals

- Patient Registries

Natural History Databases created, managed, and owned by patient communities.

- Research Collaborations

Data available to use with universities, hospitals, labs and governments for co-authored publications and studies.

- Patient Advocacy

Patient communities will have a seat at research tables to give a voice to what patients want and need in research.

- Standards of Care

Creating Standard Measurements of Mortality and Morbidity to build Standards of Care that will help save the lives of millions of children born with Congenital Anomalies.

Our Immediate Objectives:

- Recruiting Patient Communities

- Revamping the legacy CDH Forums to include other patient communities, providing them with a more secure alternative to social media for communication.

- Utilizing this platform to facilitate the transition of patients onto registries.

- CDH International will serve as a host, while each patient community will manage its forum with its own administrators and moderators.

- Adapting the framework of the CDH Patient Registry (with patient data removed) to develop Natural History Registries for each of the patient groups, none of which presently possess such registries.

- Offering these registries free to other communities, inclusive of a 10-hour training following setup.

Our Collaboration Model:

- WOFAPS will host the data, while CDH International handles the registry creation.
- One organization from each patient community will manage their respective Patient Registry.
- Individual patients retain data ownership. Neither GRACA, CDH International nor any organization claims it.
- All patient data is de-identified, with registries being fully compliant with HIPAA & GDPR regulations.
- These registries will provide valuable data to GRACA members and researchers to develop a minimal Standard of Care for Congenital Anomalies.

Partnerships

Currently, GRACA includes collaborations with noteworthy entities such as:

- CDH Community (CDH International and all Alliance of Congenital Diaphragmatic Hernia Organizations charities)
- Gastroschisis Community
- Omphalocele Community
- World Health Organization
- March of Dimes
- Kid's First Registry (NICHD)
- Centers for Disease Control and Prevention (CDC)
- The World Federation of Associations of Pediatric Surgeons (WOFAPS)
- Global Initiative for Children's Surgery (GICS)
- G-4 Alliance
- DHREAMS / Columbia University
- Zani Lab / University of Toronto
- University of Manitoba

We are excited to announce that many more communities, government organizations, surgical associations, and foundations are joining us and will be declared in the near future.

Research Impact:

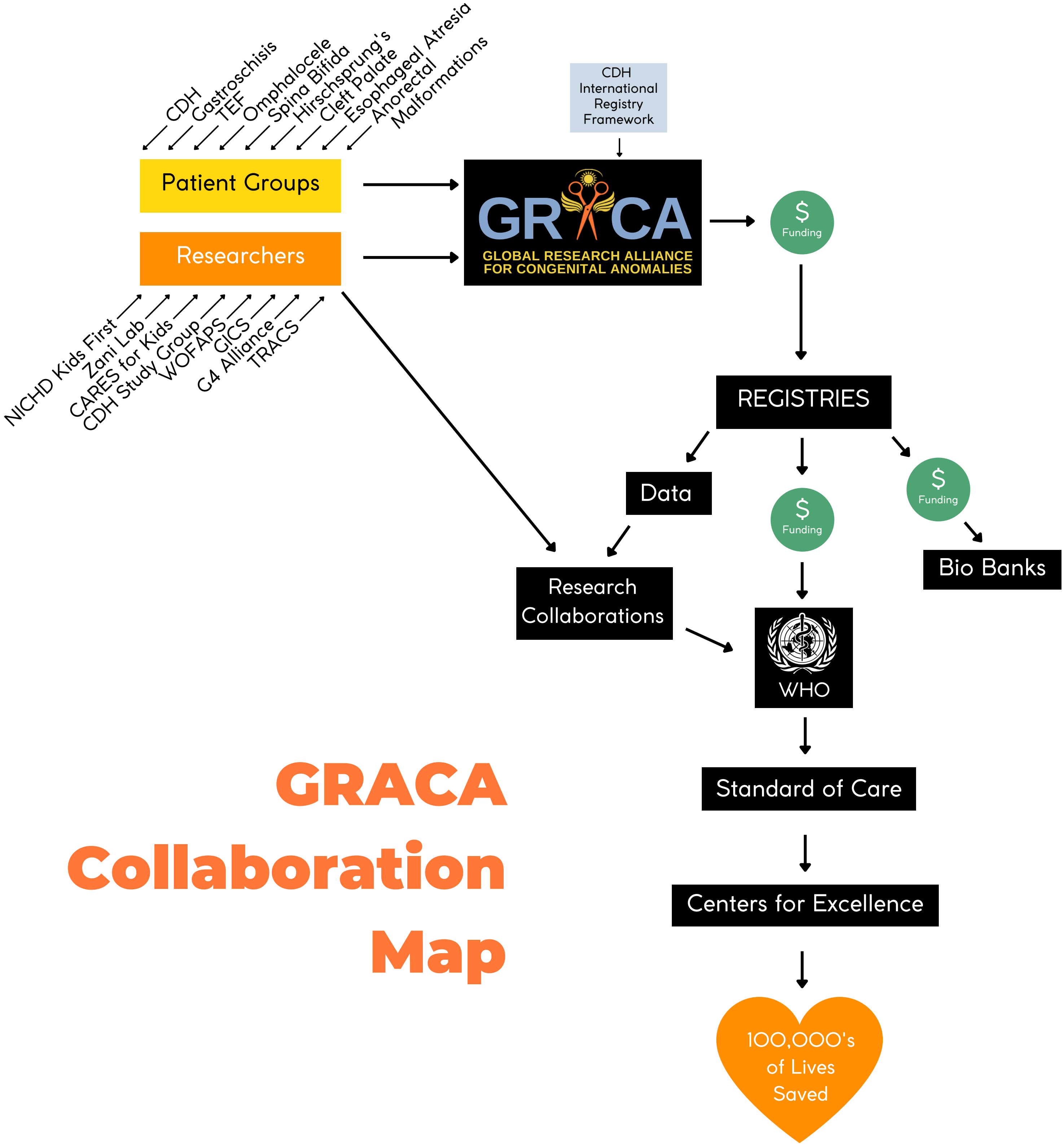
- By utilizing these registries, we can work closely with other registries to expedite research progress.
- Communities will have the opportunity to collaborate with universities, labs, and other registries on research projects.
- Registries are designed to be compatible with NIH, NHS, and ERN governmental registries.
- **The research opportunities created through GRACA will have the ability to help save and enhance the lives of millions of children born with Congenital Anomalies.**

A few other significant goals are in the pipeline and will be disclosed in due time.

As you can appreciate, this venture is an ambitious one but holds the transformative potential to safeguard and enhance the lives of millions of children.

We are presently seeking support from corporate entities and government sponsors to help bear the costs associated with these registries: their construction, security, training provision, and the recruitment of patients for participation.

GRACA Collaboration Map



CDH
Gastroschisis
TEF
Omphalocele
Spina Bifida
Hirschsprung's
Cleft Palate
Esophageal Atresia
Anorectal Malformations

Patient Groups

Researchers

NICHD Kids First
Zani Lab
CARES for Kids
CDH Study Group
WOFAPS
GICS
G4 Alliance
TRACS

CDH International Registry Framework

GRACA
GLOBAL RESEARCH ALLIANCE FOR CONGENITAL ANOMALIES

$ Funding

REGISTRIES

Data

$ Funding

$ Funding

Bio Banks

Research Collaborations

WHO

Standard of Care

Centers for Excellence

100,000's of Lives Saved

PROPOSED TIMELINE

Phase 1 - Establishing GRACA

1. Patient communities are recruited, led by one chosen nonprofit from each community.
2. All participating nonprofits and researchers are held to the standards of the GRACA Charter.
3. Funding is recruited, and budgets are established.

Phase 2 - Creating Patient Registries

1. Create a skeleton RedCAP registry for each Congenital Anomaly from the CDH Natural History Patient Registry that will be hosted on the WOFAPS server.
2. With a team of Medical Advisors, each Patient Community edits and builds its own Patient Registry.
3. Registries are translated into various languages with the help of AI and volunteers.
4. Registry Managers are trained.

Phase 3 - Recruiting Patients

1. Each Patient Community is educated about their registry and recruited to participate.
2. Registry managers assist patients and families.

Phase 4 - Begin Research Collaborations

Patient Communities establish relationships with researchers, governments, and other entities to use de-identified data for research, following all HIPAA and GDPR guidelines.

Phase 5 - Studies & Publications

Using data and University IRBs, studies and publications are created.

Phase 6 - Standard Measurements of Mortality & Morbidity

Working with the WHO, various Pediatric Surgery associations, and groups, the members of GRACA will work together to create Standard Measurements of Mortality and Morbidity. that will apply globally.

Phase 7 - Standards of Care

Working with established Boards and the WHO, the members of GRACA will work together to build basic Standards of Care that will help save the lives of millions of children born with Congenital Anomalies.

PROPOSED TIMELINE

Phase 1 (2023)	Establishing GRACA
Phase 2 (2024)	Creating Patient Registries
Phase 3 (2024 & ongoing)	Recruiting Patients
Phase 4 (2024 & ongoing)	Begin Research Collaborations
Phase 5 (2025 & ongoing)	Studies & Pubications
Phase 6 (2026)	Standard Measurements of Mortality & Morbidity
Phase 7 (2028)	Standards of Care

	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6	Phase 7
Anorectal Malformations						
Cleft Palate						
Congenital Diaphragmatic Hernia and Eventration	🟦	🟧	🟧	🟧		
Congenital Hiatal Hernia						
Esophageal Atresia						
Gastroschisis	🟨					
Hirschsprung's Disease						
Intestinal Atresia						
Omphalocele						
Spina Bifida						
Tracheoesophageal Fistula						

🟨 **BEGUN**

🟧 **IN PROGRESS**

🟦 **COMPLETED**

🟨 **BEGUN BY 1 OR MORE PATIENT COMMUNTIIES**

🟧 **BEGUN BY ALL PATIENT COMMUNTIIES**

🟦 **COMPLETED**

SUPPORTING THIS INCREDIBLY IMPORTANT WORK

At this time, GRACA will begin with 6 Patient Registries and as funding allows, we will expand to include all others.

Funds donated to the GRACA Initiative will cover:

- RedCAP Programming ($45,000 per year)
- Research Management ($45,000 per year)
- Security Costs for Registries
- Meeting Costs for Collaboration
- Medical Conferences & Research Presentations
- Medical Association Membership Fees

Funds designated for specific registries will go to help cover the costs of each Patient Community:

- Registry Set Up ($10,000)*
- Registry Training ($5000)*
- Ongoing Registry Management ($35,000 per year)
- Ads to Recruit Patient Participants
- Patient Education & Materials
- Annual Patient & Research Conference ($25,000)

For additional information, please reach out to us at research@cdhi.org.

** CDH International is not charging any fees to any other Patient Communities and will create the registries and train for free; however, CDH International is also a patient charity, and it will be a burden to absorb these costs, so any help is greatly appreciated.*

Management and Programing include all set-up programming, translation programming, collaborations, filings, abstracts, and serving on over a dozen research committees. More help is required so that CDH patients do not lose research and resources by using staff time on GRACA.
WOFAPS is graciously hosting the server at no cost.

PATIENT COMMUNITY FINANCIAL PROJECTIONS

COST	INITIAL COST PER CONGENITAL ANOMALY	FOR ADDITIONAL 9 YEARS	IN TOTAL PER CONGENITAL ANOMALY	IN TOTAL FOR 10 PATIENT COMMUNITIES
Registry Set Up	$10,000	0	$10,000	$100,000
Registry Training	$5000	0	$5000	$50,000
Ongoing Registry Managmenet	$55,000	$495,000	$550,000	$5,500,000
Ads and Marketing	$10,000	$45,000	$55,000	$550,000
Annual Patient Conference	$10,000	$90,000	$100,000	$1,000,000
Patient Education & Materials	$25,000	$10,000	$115,000	$1,150.000
TOTALS	$115,000	$640,000	$835,000	$8,350,000

CDH International is currently covering the cost of Registry Set Up and Training but is also a patient-led nonprofit with a small budget.

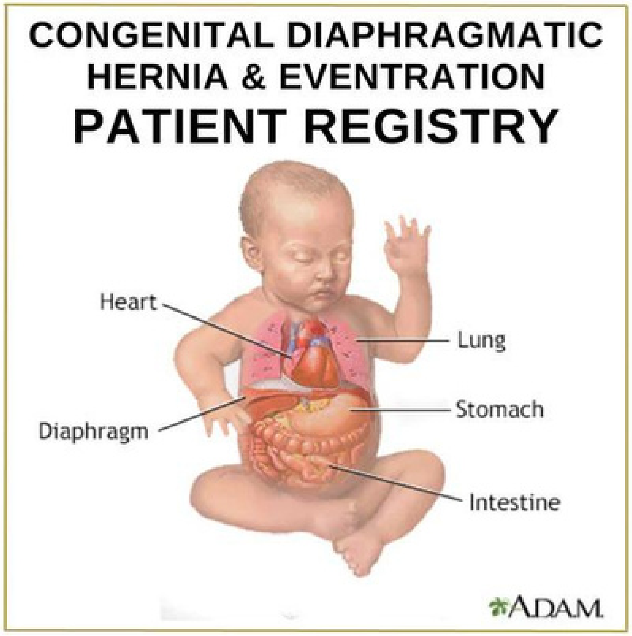
Our goal is to secure industry, government, and foundation sponsorships to defray the costs that most of these nonprofit organizations cannot afford to create this imperative research for their patient populations.

GRACA
FINANCIAL PROJECTIONS

COST	ONE-TIME COST	PER YEAR	FOR 10 YEARS
RedCAP Programming	0	$45,000	$450,000
Research Management	0	$45,000	$450,000
Security Costs	0	$10,000	$100,000
Meeting Costs for Collaboration (for 2 meetings)	$100,000	0	$100,000
Medical Conferences & Research Presentations	0	$100,000	$1,000,000
Medical Association Membership Fees	0	$10,000	$100,000
World Health Organization (WHO)	$800,000	0	$800,000
TOTALS	$900,000	$210,000	$3,000,000

CONGENITAL DIAPHRAGMATIC HERNIA PATIENT REGISTRY

Created: 1997
Status: Live
Cohorts: Over 7000
Managing NGO: CDH International
Publications: (0000-0002-5211-4005) - ORCID
Current Collaborations: 7
Participating NGOs: Members of the Alliance of Congenital Diaphragmatic Hernia Organizations (ACDHO)



Congenital Diaphragmatic Hernia

Congenital Diaphragmatic Hernia (CDH) is a congenital anomaly that occurs when a baby's diaphragm fails to form fully, allowing abdominal organs to enter the chest cavity and prevent lung growth.
1 in every 2500 babies is born with CDH. The cause is unknown.

Babies born with CDH undergo complicated surgeries and long hospital stays. In Higher-Income-Countries, the survival rate is approximately 50 to 80%. In Lower-to-Middle-Income-Countries, the survival rate is less than 1%. CDH International was founded to help find the cause, prevention and best treatments of Congenital Diaphragmatic Hernia while raising awareness and supporting patient families.

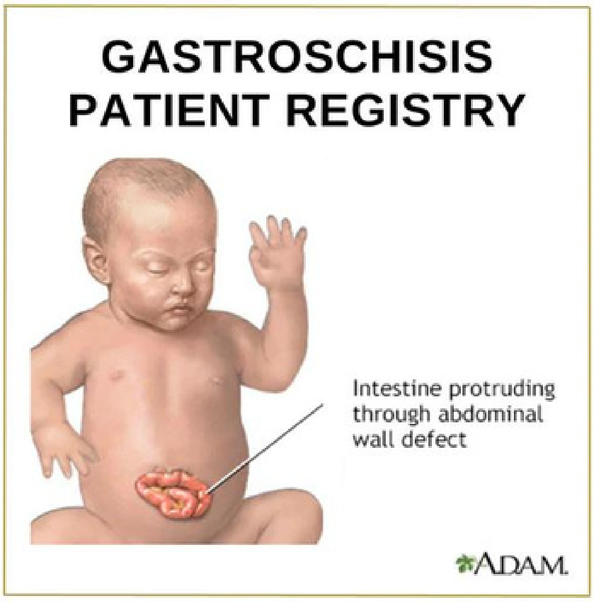
Congenital Diaphragmatic Hernia Patient Registry

- The CDH Patient Registry is a natural history database of over 4000 patients and basic information on over 7000 patients in 84 countries.
- Created in 1997, the CDH Patient Registry has over 800 queries collecting nearly 10,000 data points, researching prenatal exposures, family history, and full patient medical history from pre-pregnancy to current (at the time of participation) or death.
- Every patient over 1 year old or deceased can participate.
- Data from the CDH Patient Registry has been used in many studies and publications, some of which can be viewed at (0000-0002-5211-4005) - ORCID.

If you are a Congenital Diaphragmatic Hernia researcher, patient or family member who would like more information on how to participate or collaborate, please reach out to research@cdhi.org

GASTROSCHISIS PATIENT REGISTRY

Creation: 2023
Status: Estimated Live Date of October 1, 2023
Cohorts: Over 10,000
Managing NGO: The Global Gastroschisis Foundation
Publications:
Current Collaborations: 1



Gastroschisis

Gastroschisis is a relatively uncommon condition that occurs in approximately 1 in 5,000 live births. It is one of a group of birth defects known as abdominal wall defects, which occur very early in gestation and are characterized by an opening in the abdominal wall of the fetus.

Most cases of fetal gastroschisis involve the intestine and other abdominal organs herniating (protruding) through an opening (hole) in the abdominal wall and spilling out into the amniotic fluid around the fetus. This opening is usually found to the right of the belly button. As a consequence, the unprotected intestine becomes irritated, causing it to swell and shorten.

The longer the exposure to amniotic fluid, the more likely the intestine will become damaged. In addition, as the fetus continues to develop, the tight opening may squeeze the blood supply to the intestine or cause it to twist around itself. Either of these consequences can cause inflammation, intestinal blockage, loss or malfunction and lead to long-term feeding problems after the baby is born.

https://www.chop.edu/conditions-diseases/gastroschisis

Gastroschisis Patient Registry

The Gastroschisis Patient Registry is currently under construction and is a joint effort between the Global Gastroschisis Foundation, the Zani Lab at the University of Toronto, WOFAPS, and CDH International.

If you are a Gastroschisis researcher, patient or family member who would like more information on how to participate or collaborate, please reach out to info@averysangelstg.wpengine.com

FREQUENTLY ASKED QUESTIONS

Why is this so expensive?

Research costs are always expensive, and most costs cover the salaries of experts such as RedCAP programmers.

Education and recruitment costs are also expensive.

How are representative NGO's chosen?

The oldest established organization seems to be the organization with the most research experience and the largest membership.

These leaders represent the entire patient population and work with all other NGO's in their communities who sign the GRACA Charter. All patients will be represented.

Can a patient community fund it's own registry?

Absolutely.

Who will have access to the data?

Individuals will have access to their own personal data, and registry managers will have access.

Will patient data ever be sold?

Never. Or at least not without explicit patient permission and proceeds benefitting patients directly. No for-profit, non-profit or individual will financially benefit off of other peoples' patient data.

Who owns the data?

Patients own their own data. Registry Managers are simply stewards of the data.

Why is CDH International overseeing GRACA and building registries?

To save more children, including those born with CDH. CDH International does not financially benefit from GRACA.

How will this be funded?

Through donations, grants and sponsorships.

How can I help?

Donate, fundraise, volunteer, participate in research. Reach out to us to learn more at research@cdhi.org

THANK YOU

CONGENITALANOMALIES.ORG