

II INTERNATIONAL SUMMER SCHOOL

Rare disease and orphan drug registries

Day 4

18.09.2014

Patient unique identifier

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Patient unique identifier

DEFINITION

Patient unique identifier

A GUID strategy utilizes software which generates a unique ID random code, generated from personally identification information (PII) data

That unique ID is then attached to de-identified data from each participant, so it can be used by investigators to track data from the same individual participating in multiple studies

Patient unique identifier

MAIN CONCEPTS

Patient unique identifier

Concepts of the ID

What

Code Linked to PII (Personal Identifiable Information)

An element of the database

Why

It is reliable and can be shared easier than the PII

Confidentiality and patient rights

ELSI rules but in many cases because of the legal framework

Patient unique identifier

Personal Identifiable Information (PII)

- **PII**
 - Complete legal given (first) name of subject at birth
 - Complete legal additional name of subject at birth (If the subject has a middle name)
 - Complete legal family (last) name of subject at birth
 - Day of birth
 - Month of birth
 - Year of birth (####)
 - Name of city/municipality in which subject was born
 - Country of birth
 - Physical sex of subject at birth (M/F)
 - Registry ID - To help distinguish participants, from each of the different registries, the registry ID will be incorporated into the GUID.

Patient unique identifier

Concepts of the ID - 2

- **How**

- Integer, string or alphanumeric
- Computer program using some algorithm (one or double)
- Server or local PC

- **Where**

- The same machine that create the ID (checking duplicates)
- To be included in our own database

Patient unique identifier

Concepts of the ID -3

- **Other characteristics**
 - Reversible or not reversible
 - Reliable
- **Other related concepts**
 - Anonymous
 - Pseudoanonymous
- **Terms**
 - ID
 - GUID, GRDR-GUID, NDAR-GUID
 - HDID
 - ...

Patient unique identifier

TYPES OF IDs

Patient unique identifier

Options

- **National IDs**
 - Valid for national strategies
 - They do not allow interchanging with others out of the country
 - Not all countries use personal and unique IDs
 - The person is vulnerable
- **ID developed by a Research Network**
 - Only useful for specific purposes within the network
 - Need some investment by the network (security reasons)
 - Requires some IT developments
- **ID interoperable**
 - European projects and interoperability among health systems
 - E-Health

Patient unique identifier

European Projects: Interoperability

- The European eHealth Governance Initiative (**eHGI**)
- CALL for InterOPERability (**CALLIOPE**)
- Smart Open Services for European Patients (**epSOS**)
- Semantic Interoperability for Health Network (**SemanticHealthNet**)
- The eHealth European Interoperability Framework (**eHEIF**)
- The Healthcare Interoperability Testing and Conformance Harmonisation (**Hitch**)
- Thematic Network on Quality Labelling And Certification of EHR Systems (**eHR-QTN**)
- A step towards the electronic European Health Insurance Card (**NetC@rds**)
- Secure Identity Across Borders Linked (**STORK**)

European Project: STORK 2.0

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Username Reminder | Register Search

STORK 2.0 making access smarter.eu
SECURE IDENTITY ACROSS BORDERS LINKED 2.0

Home About the project Partners Work overview Links Results Press and Media

STORK eID Authentication

Authenticate here using your eID. Choose the country that issued your eID and click "submit" to continue.

Osterreich

Member States Get involved

Industry Group Get involved

Community of Interest

Home

What is STORK 2.0?

Secure idenTity acrOss boRders linKed 2.0 will contribute to the realization of a single European electronic identification and authentication area. It does so by building on the results of STORK, establishing interoperability of different approaches at national and EU level, eID for persons, eID for legal entities and the facility to mandate.

STORK 2.0 will be a step forward towards the creation of a fully operational framework and infrastructure for electronic identities and authentication in the EU. It does so through **STORK 2.0**

- Exploiting experiences from four cross border, cross sector pilots with real impact demonstrating the use and societal impact of the cross border, cross sector infrastructure developed
- Common specifications and building blocks for interoperable legal identities and mandates, on top of the interoperability infrastructure developed in STORK, following privacy rules (and advice from Art.29 Working Party) and enabling secure operation
- Solving within the scope of the pilots legal issues such as privacy/data protection, liability, different National regimes
- Acquaintance of the OAM models include attributes, legal entities and mandate components

STORK 2.0 11
3rd Industrial Reference Group Meeting @ World eID Congress

24 September 2014, Marseille, France

Find more about the event!

Upcoming Events

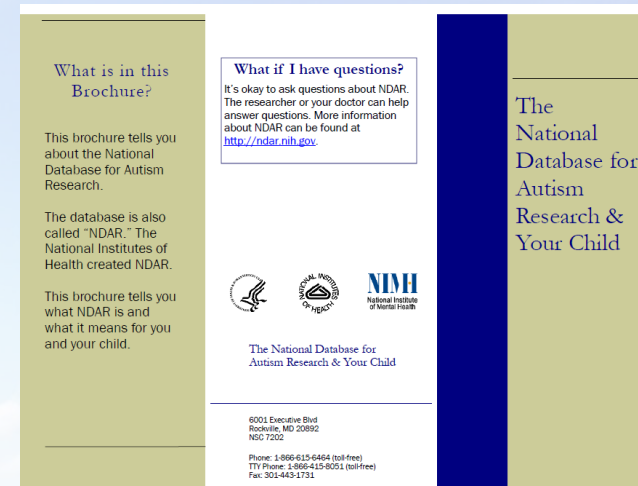
22/09/2014 @ 08:00 - World e-ID Congress

**Just for people whom resides in Europe
ID Structure: UK/SP/XXXXXXXX**

Patient unique identifier

Options - 2

- **Global IDs**
 - HDID
 - GUID-NDAR
 - GUID-GRDR



Patient unique identifier

HDID procedure

https://h001.ssl-redirect.de - Eigenschaften - Mozilla Firefox

On this page you are going to create the subject's study identifier, the **pseudonym**. In order to create it, you have to enter subject identifying personal data.

Remember, this data is **never** stored permanently or temporarily within the study's database. It is only used once to create a unique and secure pseudonym for the subject. All study data is only stored in connection with this pseudonym. The creation of a pseudonym can only be invoked within this web portal via a secure internet connection (SSL) and **only by** participating **site investigators**.

Subject Identification


First name:	<input type="text"/>
Date of birth:	<input type="text"/> . <input type="text"/> . <input type="text"/> <input type="button" value="7"/> (format "dd.mm.yyyy")
Birth name:	<input type="text"/>
Place of birth:	<input type="text"/>
Mother's maiden name:	<input type="text"/>

Please **print the data** after creation of the pseudonym for **your** confidential medical documentation. That is the only way to **re-identify** the subject's personal data.

Fertig h001.ssl-redirect.de

Patient unique identifier

GUID-GRDR



The screenshot shows the NIH/NCATS GRDR website. At the top, there are navigation links for 'U.S. Department of Health & Human Services' and 'National Institutes of Health'. Below this is the NIH logo and the text 'National Center for Advancing Translational Sciences' and 'The NIH/NCATS GRDRSM Program Global Rare Diseases Patient Registry Data Repository'. A navigation bar contains links for 'Home', 'About Registries', 'Program Overview', 'Common Data Elements', 'Resources', 'GUID', and 'News & Events'. The main content area features a photo of a child with 'Giant Congenital Melanosis' and a text box stating 'GRDRSM - a data repository by the patients for the patients, to improve the quality of life of millions suffering from rare diseases'. To the right, it describes the program's goal to build a rapid-learning health program and includes the quote 'Rare Diseases have no borders! They don't affect individuals, they affect entire families.' Below this is a section titled 'About The NIH/NCATS GRDRSM Program' with three paragraphs of text. The final section is 'Collaborating Organizations' with logos for 'DConnect', 'GERDS Registry', 'Instituto de Salud Carlos III', and 'SpainRDR'.

U.S. Department of Health & Human Services | National Institutes of Health

NIH National Center for Advancing Translational Sciences | The NIH/NCATS GRDRSM Program Global Rare Diseases Patient Registry Data Repository

Home | About Registries | Program Overview | Common Data Elements | Resources | GUID | News & Events

Giant Congenital Melanosis
Photo: Al Azhar University

GRDRSM - a data repository by the patients for the patients, to improve the quality of life of millions suffering from rare diseases

The NIH/NCATS GRDRSM Program
The GRDR program aims to build a rapid-learning health program, and develop large global data sets of patients with rare diseases incorporating data from electronic health records (EHRs). The goal is to accelerate development and uses of new knowledge to improve the health and quality of life for millions of people.

*Rare Diseases have no borders!
They don't affect individuals, they affect entire families.*

About The NIH/NCATS GRDRSM Program

The goal of the NIH/NCATS Global Rare Diseases Patient Registry Data Repository (GRDR) program is to serve as a central web-based global data repository that aggregates coded patient information and clinical data to be available to investigators to conduct various biomedical studies, including clinical trials. The aim of the program is to advance research for many rare diseases and apply to common diseases as well.

Data is collected and aggregated from rare disease registries in a standardized manner, linking the registry data to Common Data Elements (CDEs) using nationally accepted standards and standard terminologies. The aim is that through standardization, registries will be interoperable to enable exchange and sharing of data. Each registry will be free to develop its own survey questions according to patient preference and the nature of the disease.

To protect patient privacy, only coded data is collected and aggregated into the GRDR database. Global Unique Identifier (GUID) will be assigned to each patient's data (when applicable). The GUID will enable tracking and following of patients over time and across diseases, registries, studies and countries. In addition, the GUID will facilitate linking patient's clinical information to the corresponding biospecimens data set. Patient recruitment for subsequent study will be facilitated only through the contributing registry (home registry).

NIH/NCATS has developed policies for data submission and data access to make the data available to the rare disease community. NIH/NCATS also plans to establish a governance system for the GRDR Program, including data governance for the GRDR data repository. The GRDR program uses an open-science methods and data that are standardized to nationally accepted terminologies, rendering the GRDR interoperable with other national data initiatives. [More ...](#)

Collaborating Organizations

DConnect | GERDS Registry | Instituto de Salud Carlos III | SpainRDR

Patient unique identifier

PROCEDURE

Patient unique identifier

GRDR-GUID Procedure 1

- **The specific GUID client-program will be provided by the NIH/NCATS**
 - **to load the PII**
 - **generate hashcodes**
 - **send the hashcodes (not PII) to the GUID server.**
- **The NIH/NCATS GUID server will return the GUID to the registry**
 - **who will assign it to the participant's de-identified medical information**

Patient unique identifier

GRDR-GUID Procedure 2

- **Once the GUID is assigned to the medical data it will be uploaded into the GRDR which will be housed on Amazon cloud protected by**
 - **HIPAA (Health Insurance Portability and Accountability Act)**
 - **compliance with the FISMA (Federal Information Security Management Act)**

Patient unique identifier

HIPAA

U.S. Department of Health & Human Services
HHS.gov *Improving the health, safety, and well-being of America*

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Health Information Privacy

Office for Civil Rights | Civil Rights | **Health Information Privacy**

[OCR Home](#) > [Health Information Privacy](#)

HIPAA

- [Understanding HIPAA Privacy](#)
- [HIPAA Administrative Simplification Statute and Rules](#)
- [Enforcement Activities & Results](#)
- [How to File a Complaint](#)
- [News Archive](#)
- [Frequently Asked Questions](#)

PSQIA


- [Understanding PSQIA Confidentiality](#)
- [PSQIA Statute & Rule](#)
- [Enforcement Activities & Results](#)
- [How to File a Complaint](#)

Health Information Privacy

The Office for Civil Rights enforces the HIPAA Privacy Rule, which protects the privacy of individually identifiable health information; the HIPAA Security Rule, which sets national standards for the security of electronic protected health information; the HIPAA Breach Notification Rule, which requires covered entities and business associates to provide notification following a breach of unsecured protected health information; and the confidentiality provisions of the Patient Safety Rule, which protect identifiable information being used to analyze patient safety events and improve patient safety.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security and Breach Notification Rules

Learn about the Rules' protection of individually identifiable health information, the rights granted to individuals, breach notification requirements, OCR's enforcement activities, and how to file a complaint with OCR.



What's New

- [New Guidance on HIPAA and Same-sex Marriage](#) - 9/17/14
- [OCR issues 2011-2012 HITECH Act Reports to Congress](#) - 6/10/14
- [Security Risk Assessment Tool Released](#) - 3/28/14
- [New Guidance on HIPAA Privacy Rule and Sharing Information Related to Mental Health](#) - 2/20/14
- [Spanish Language Model Notices of Privacy Practices](#) - 2/13/14
- [Digital Privacy Notice Challenge open through April 7](#) - 2/10/14
- [HHS Strengthens Patients' Right to Access Lab Test Reports](#) - 2/3/14
- [HIPAA Privacy Rule and the National Instant Criminal Background Check System \(NICS\)](#)

Patient unique identifier

FISMA



The screenshot shows the NIST Computer Security Division website. At the top, there is a search bar for CSRC and navigation links for CONTACT and SITE MAP. The main header identifies the Computer Security Division and Computer Security Resource Center. A navigation menu includes CSRC Home, About CSD, Projects / Research, Publications, and News & Events. The current page is titled "FEDERAL INFORMATION SECURITY MANAGEMENT ACT (FISMA) IMPLEMENTATION PROJECT" and is part of a breadcrumb trail: CSRC HOME > GROUPS > SMA > FISMA. A left sidebar lists various FISMA resources such as Detailed Overview, Risk Management Framework (RMF), and Security Controls. The main content area features a sub-header "Our Vision" with a list of six bullet points detailing the project's goals, such as developing standards for information categorization and security requirements. A "Leading To..." section at the bottom indicates the project's aim to implement cost-effective, risk-based information security.

NIST National Institute of Standards and Technology
Information Technology Laboratory

SEARCH CSRC: GC

CONTACT SITE MAP

Computer Security Division
Computer Security Resource Center

CSRC Home About CSD Projects / Research Publications News & Events

FISMA

Detailed Overview
Risk Management Framework (RMF)
RMF Steps / FAQs / Guides
Applying the RMF to Federal Information Systems Course
Security Categorization
Security Controls
Security Assessment
Authorization and Monitoring
Security Configuration Settings
Industrial Control System Security
Compliance
Resources
News
Events
Schedule
FAQs - FISMA Project

CSRC HOME > GROUPS > SMA > FISMA

FEDERAL INFORMATION SECURITY MANAGEMENT ACT (FISMA) IMPLEMENTATION PROJECT

Protecting the Nation's Critical Information Infrastructure

Our Vision

To promote the development of key security standards and guidelines to support the implementation of and compliance with the Federal Information Security Management Act including:

- + Standards for categorizing information and information systems by mission impact
- + Standards for minimum security requirements for information and information systems
- + Guidance for selecting appropriate security controls for information systems
- + Guidance for assessing security controls in information systems and determining security control effectiveness
- + Guidance for the security authorization of information systems
- + Guidance for monitoring the security controls and the security authorization of information systems

Leading To...

- + The implementation of cost-effective, risk-based information security

FISMA NEWS

(Aug. 28, 2014) - NIST announces the release of [Draft Special Publication 800-53, Revision 4, Appendix H](#), International Information Security Standards, Security Control Mappings

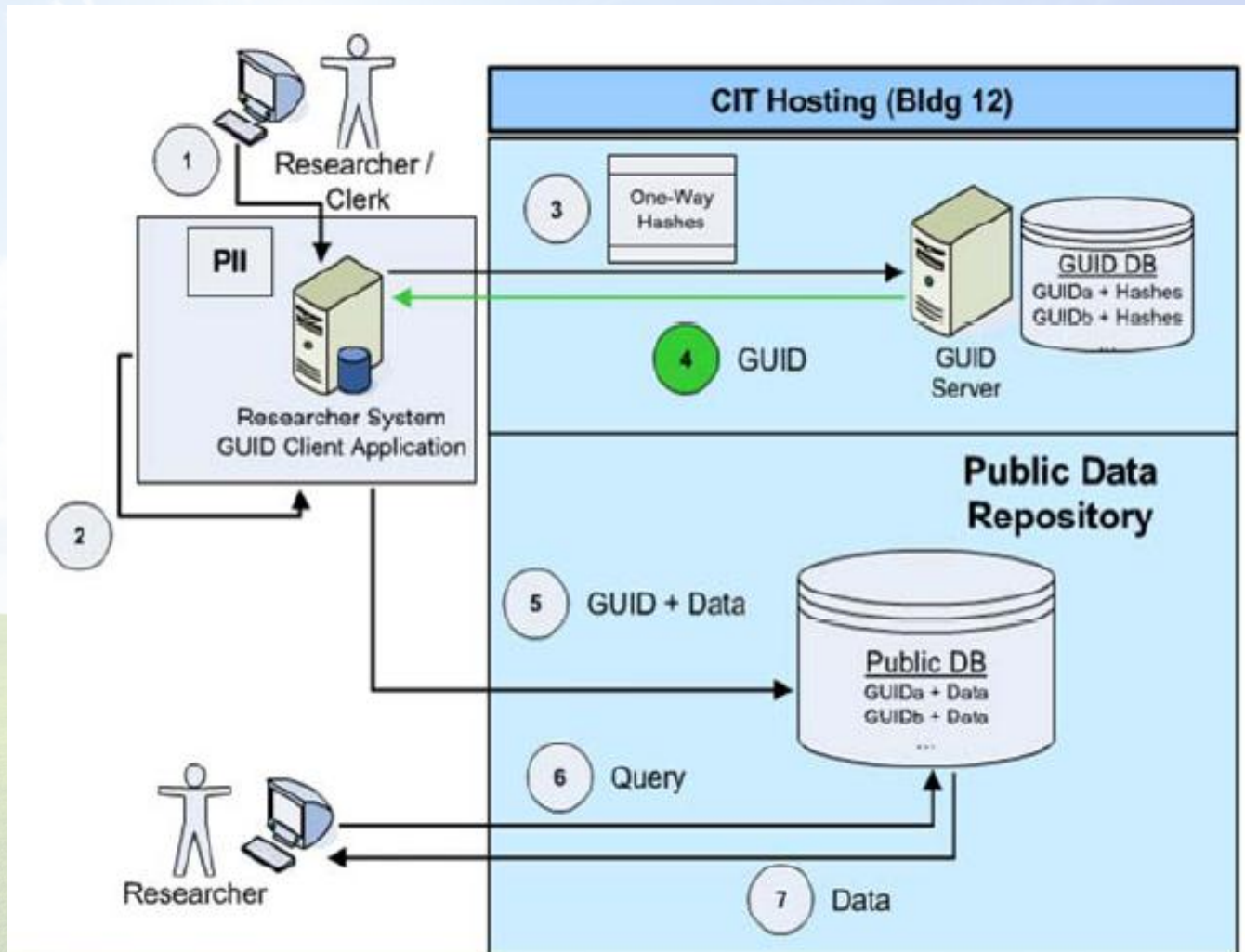
Patient unique identifier

GRDR-GUID Procedure 3

- **Requirements to protect the privacy and confidentiality of the participants and ensure the security of data against natural or man-made threats**
- **The process of assigning a GUID keeps direct patient identifiers from ever being transmitted or stored in the NIH/NCATS.**

Patient unique identifier

GRDR-GUID



Patient unique identifier

Example Batch CSV with Select PII Input Data

**ID,FIRSTNAME,MIDDLENAME,SUBJECTHASN
OMIDDLENAME,LASTNAME,MOB,DOB,YOB,
COB,SEX**

**Local_id1,John,Quincy,NO,Public,1,1,2007,
Washington,M**

**Local_id2,Jane,,YES,Smith,2,2,2006,Baltimore
,F**

Patient unique identifier

Software

GUID Client [Functions] [About]

Required Fields	Please enter subject's information (PII):	Please confirm (re-enter) the subject's information
1. Complete legal given (first) name of subject at birth	1. John	John
2. Does the subject have a middle name?	2. <input type="radio"/> Yes <input checked="" type="radio"/> No	<input type="radio"/> Yes <input checked="" type="radio"/> No
3. Complete additional (middle) name or names at birth	3.	
4. Complete legal family (last) name of subject at birth	4. Smith	Smith
5. Day of birth [1-31]	5. 1	1
6. Month of birth	6. JANUARY	JANUARY
7. Year of birth [####]	7. 2001	2001
8. Name of city/municipality in which subject was born	8. New York	New York
9. Country of birth	9. UNITED STATES	UNITED STATES
10. Physical sex of subject at birth [M/F]	10. <input checked="" type="radio"/> Male <input type="radio"/> Female	<input checked="" type="radio"/> Male <input type="radio"/> Female
Optional Fields		
11. Government Issued or National ID	11.	
12. Country issuing Government-Issued or National ID	12.	
GUID	[Empty field]	

Patient unique identifier

Providing the GUID

Please enter subject's information (PII):

Please confirm:

1. (First) name of subject at birth: John

2. (Middle) name? Yes No

3. (Middle) name or names at birth:

4. (Last) name of subject at birth: Smith

5. **GUID Generation Successful**

6. New GUID: TBIDEMOAT524WRK

7. (Month) of birth: JANUARY

8. (Day) of birth: 1

9. (Year) of birth: 2004

10. (City) in which subject was born: New York

11. (Country) of birth: UNITED STATES

12. (Sex) at birth [M/F]: Male Female

13. (National) ID:

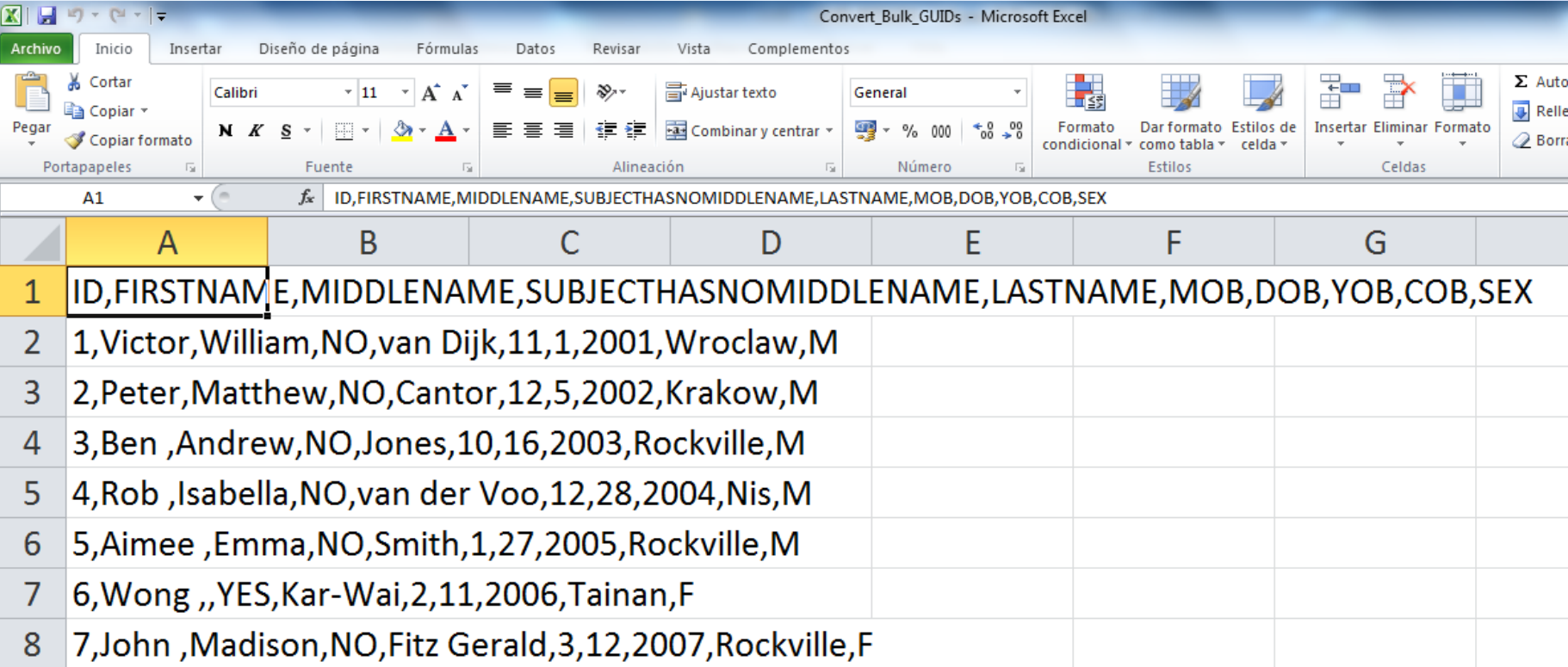
14. (Date) of issue or National ID:

Buttons: Generate GUID, Copy GUID, Copy GUID and PII, Clear / New, Exit

	A	B	C	D	E	F	G	H	I	J	K
1	GUID	First Name	Middle Name	Last Name	Subject has middle name?	Month of Birth	Day of Birth	Year of Birth	City of Birth	Country of Birth	Physical Sex at Birth
2	TBIDEMOZU773HV5	JOHN	PATRICK	SMITH	Yes	APRIL	4	1944	BOSTON	US	Male
3											

Patient unique identifier

Example Batch CSV with Select PII Input Data



Convert_Bulk_GUIDs - Microsoft Excel

Archivo Inicio Insertar Diseño de página Fórmulas Datos Revisar Vista Complementos

Calibri 11 Fuente Alineación General Número Estilos Celdas

A1 ID,FIRSTNAME,MIDDLENAME,SUBJECTHASNOMIDDLENAME,LASTNAME,MOB,DOB,YOB,COB,SEX

	A	B	C	D	E	F	G
1	ID,FIRSTNAME	MIDDLENAME,SUBJECTHASNOMIDDLENAME,LASTNAME,MOB,DOB,YOB,COB,SEX					
2	1,Victor,William,NO, van Dijk,11,1,2001,Wroclaw,M						
3	2,Peter,Matthew,NO,Cantor,12,5,2002,Krakow,M						
4	3,Ben ,Andrew,NO,Jones,10,16,2003,Rockville,M						
5	4,Rob ,Isabella,NO, van der Voo,12,28,2004,Nis,M						
6	5,Aimee ,Emma,NO,Smith,1,27,2005,Rockville,M						
7	6,Wong ,,YES,Kar-Wai,2,11,2006,Tainan,F						
8	7,John ,Madison,NO,Fitz Gerald,3,12,2007,Rockville,F						

Patient unique identifier

Some tests using my personal data

FIRST OPTION: RIGHT DATA

GRDRDEMONT807GM1,MANUEL,,SURNAME,No,MMM,DD,YYYY,MADRID,ES,
Male,,

SECOND OPTION: REPLACING MANUEL WITH MANOLO. In this case some advertisement was arisen (see the message in the figure below)

GRDRDEMOBK946JVG,MANOLO,, SURNAME,No, MMM,DD,YYYY,MADRID,ES,
Male,,

THIRD OPTION: I INCLUDED SOME MISTAKE IN THE YEAR OF BIRTH

GRDRDEMONT807GM1,MANUEL,, SURNAME,No, MMM,DD,YYYX,MADRID,
ES, Male,,

FOURTH OPTION: RIGHT DATA WITH EXTRA INFORMATION

GRDRDEMONT807GM1,MANUEL,, SURNAME,No, MMM,DD,YYYY,MADRID,ES,
Male,ID NATIONAL,ES

Patient unique identifier

Some tests using my personal data

The screenshot shows a web form for generating a Patient Unique Identifier (GUID). The form is titled "Please enter subject's information (PII):" and "Please confirm (re-enter) the". The form contains several input fields and radio buttons. A dialog box titled "Close PII Match Found" is overlaid on the form, displaying a warning message: "The PII that you have entered is a close match to another GUID in the system. The field that does not match is: First Name Value: MANOLO. Are you sure the PII entered is found on the subject's birth certificate?". The dialog box has two buttons: "No. Edit Data." and "Yes. Generate New GUID.". The form also includes a "Generate GUID" button and other options like "Copy GUID", "Copy GUID and PII", "Clear / New", and "Exit".

Please enter subject's information (PII):

Please confirm (re-enter) the

1. MANOLO

2. Yes No

MANOLO

Yes

Close PII Match Found

The PII that you have entered is a close match to another GUID in the system.
The field that does not match is:
First Name Value: MANOLO
Are you sure the PII entered is found on the subject's birth certificate?

No. Edit Data. Yes. Generate New GUID.

Generate GUID Copy GUID Copy GUID and PII Clear / New Exit

Patient unique identifier

NDAR-GUID



NATIONAL INSTITUTES
OF HEALTH

NDAR

National Database
for Autism Research

Serving the autism research community



GUID Tool

Click to Play

© ▶ ◀ ⏪ ⏩ 🔍 🌐

Patient unique identifier

MAIN OUTCOMES

Patient unique identifier

National Database
for Autism Research
research community

NDAR-GUID OUTCOMES

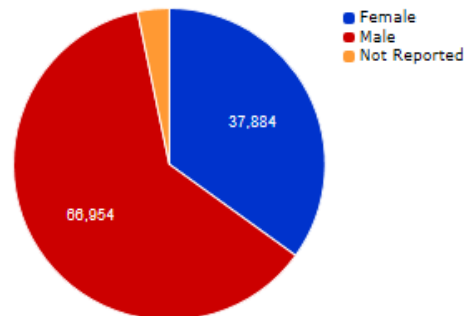
Tools Cloud Contribute Request Access Policy Tutorials About FAQ

The National Database for Autism Research (NDAR) is an NIH-funded research data repository that aims to accelerate progress in autism spectrum disorders (ASD) research through data sharing, data harmonization, and the reporting of research results. NDAR also serves as a scientific community platform and portal to multiple other research repositories, allowing for aggregation and secondary analysis of data.

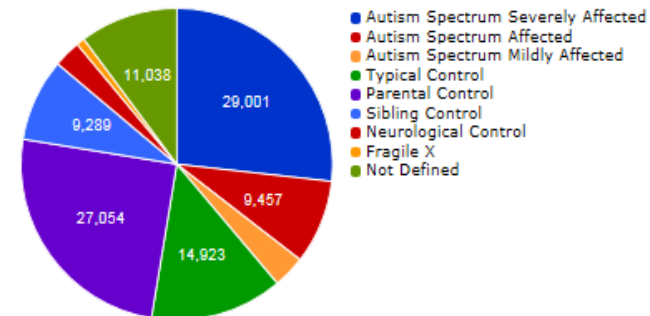
Data Distribution

108,386 subjects by age, 77,575 individuals

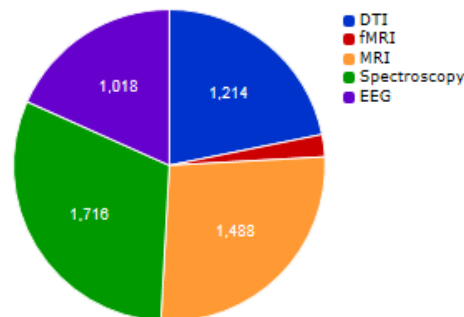
Gender¹



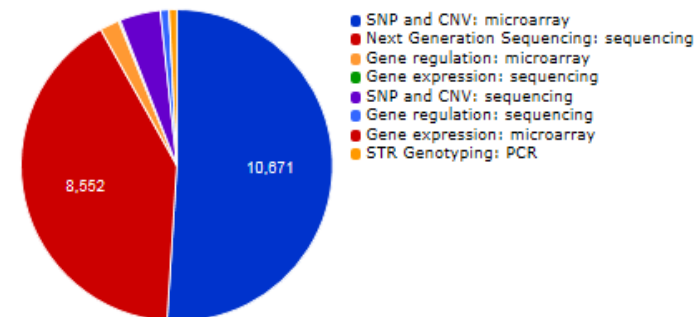
Phenotypic¹



Neuroimaging



Genomic



¹ Numbers reported are subjects by age

Patient unique identifier

SUMMARY

Patient unique identifier

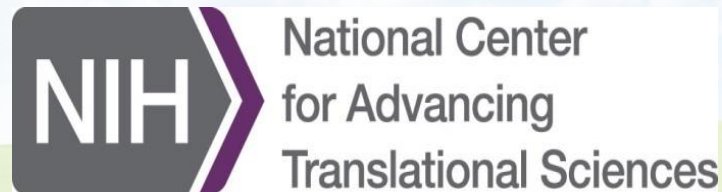
CONCLUSIONS

- **The implementation of an ID into RD registries allows to the researchers building capacities**
 - **Share the information with others**
 - **Interoperate among databases**
 - **Protect their patients**
 - **Facilitate the patient's collaboration**
- **GRDR-GUID is the most robust ID strategy for sharing data worldwide**
- **To use the GUID has some sense if they are linked to other research strategies, which provide valid outcomes for patient lives**

Patient unique identifier

Thank you

mposada@isci.es



ORDR
Office of Rare
Diseases Research

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Resources for Clinical and Translational Research