Commercializing Digital Health Data
Ethical Considerations

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Codex4SMEs on line conference on Digital Health Data in Personalized Medicine, 11.5.2020

Bundesministerium für Bildung und Forschung

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getragen von:
Deutsches Krebsforschungszentrum
Universitätsklinikum Heidelberg
Thoraxklinik-Heidelberg
Deutsche Krebshilfe

Commercializing of Digital Health Data

What are we talking about?

- Warranting private-for–profit-companies **access** to **clinical** data from patients
- Warranting private-for–profit-companies **usage rights** with regard to clinical data
- Potential goals of usages: research and development, new products and patents, profit

- Commercialisation of clinical data as one way of sharing biomedical data

Data Sharing in biomedical sciences

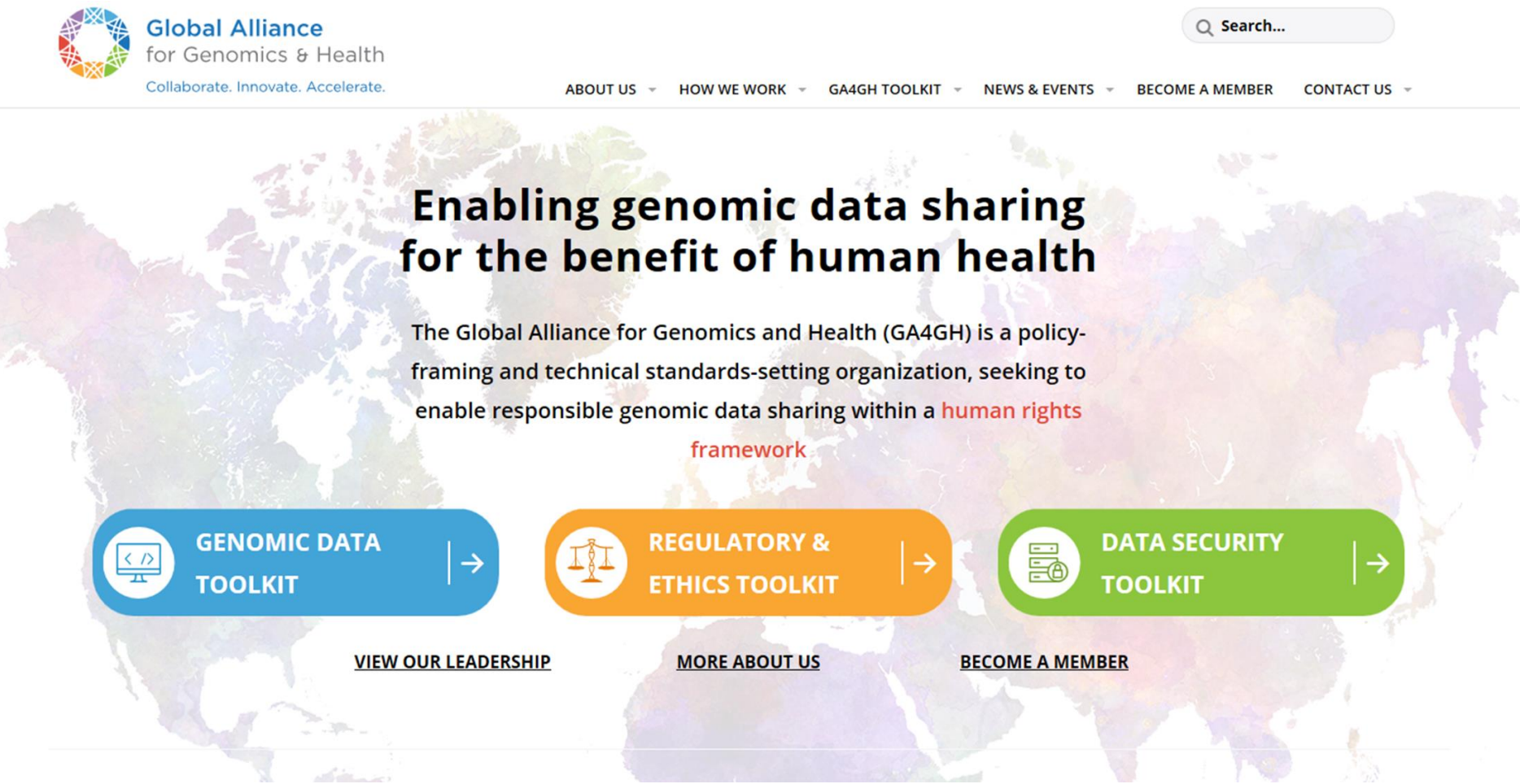
Some examples:

- Global Alliance for Genomics and Health
- ASCO CancerLinQ https://www.cancerlinq.org/

- Decipher
- ClinVar

- Patients like me

- Medical Informatics Initiative (Medizininformatik-Initiative; https://www.medizininformatik-initiative.de/de)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Enabling genomic data sharing for the benefit of human health
The Global Alliance for Genomics and Health (GA4GH) is a policy-framing and technical standards-setting organization, seeking to enable responsible genomic data sharing within a human rights framework
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Explore DECIPHER

It's free and you don't need to log in

DECIPHER is used by the clinical community to share and compare phenotypic and genotypic data. The DECIPHER database contains data from 25000 patients who have given consent for broad data-sharing; DECIPHER also supports more limited sharing via consortia. Have a look at the numbers.

Anyone can browse publicly-available patient data on DECIPHER and request to be put in contact with the responsible clinician. Why? Because sharing benefits everyone.

Explore DECIPHER's genome browser

Delve into the Human Phenotype Ontology

Join DECIPHER

Be part of the sharing community

Projects affiliated to DECIPHER can deposit and share patients, variants, and phenotypes to invite collaboration and facilitate diagnosis. Once deposited, you can use DECIPHER to identify and prioritise potential matches, and you can request notifications as soon as new matches arrive.

As well as influencing individual patient outcomes, use of DECIPHER has contributed to over 1000 published articles since 2004. It's still free, and you are in control of what data to make public.

Join now

Find out more

Already a member?

Log in to access your patient data

Email address

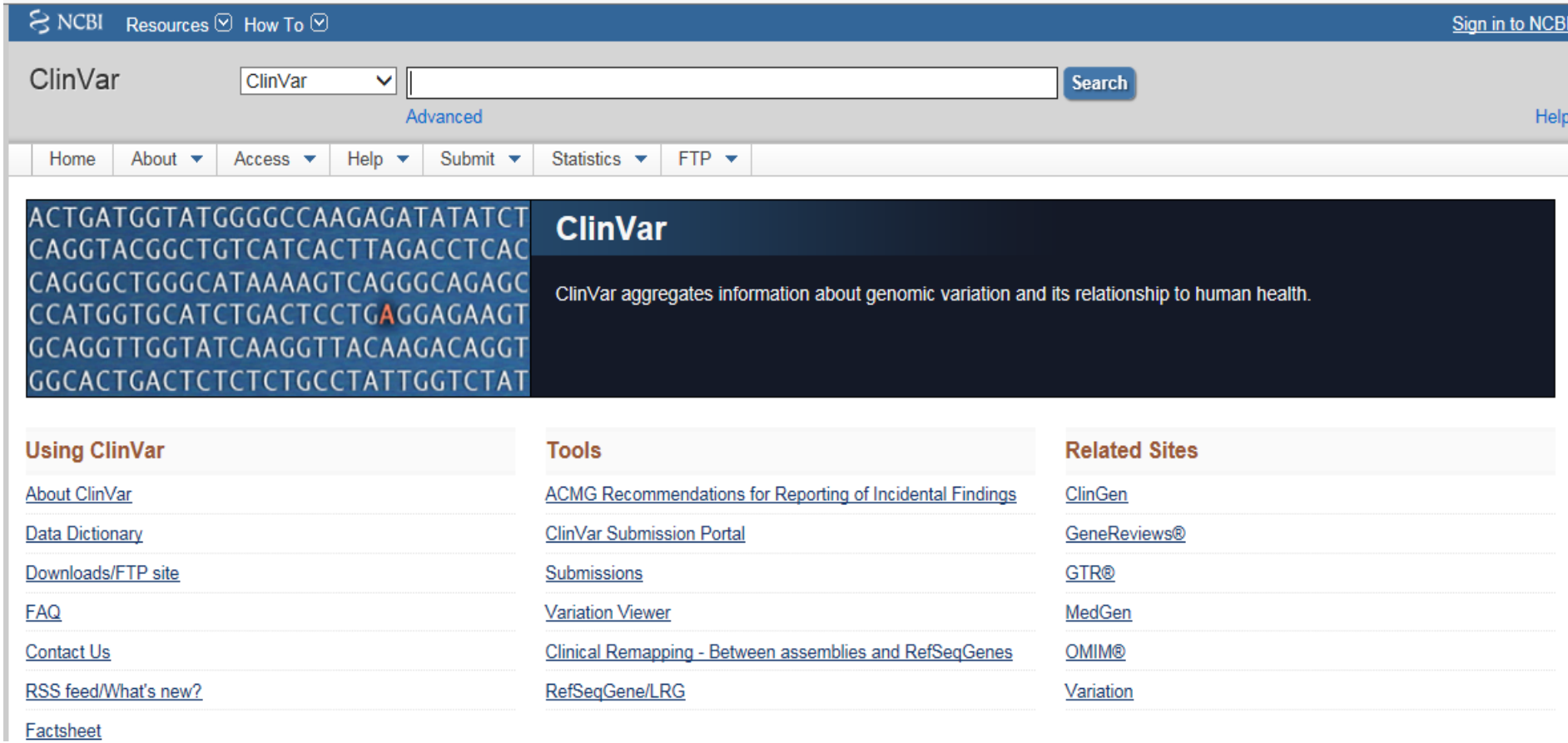
Email

Password

Password

Log in

Reset your password


NCBI Resources How To
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ClinVar
Search
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Home
About
Access
Help
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Statistics
FTP
ACTGATGGTATGGGGCCAAGAGATATATCT
CAGGTACGGCTGTCATCACTTAGACCTCAC
CAGGGCTGGGCATAAAAGTCAGGGCAGAGC
CCATGGTGCATCTGACTCCTGAGGAGAAGT
GCAGGTTGGTATCAAGGTTACAAGACAGGT
GGCACTGACTCTCTCTGCCTATTGGTCTAT
ClinVar
ClinVar aggregates information about genomic variation and its relationship to human health.
Using ClinVar
About ClinVar
Data Dictionary
Downloads/FTP site
FAQ
Contact Us
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Factsheet
Tools
ACMG Recommendations for Reporting of Incidental Findings
ClinVar Submission Portal
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Our digital health learning system uses the most advanced technologies to help you better understand wellness, aging, and disease. As new understanding emerges, you will gain access to tools, information and connections–to people like you–to find a clearer path forward to your own future health.

The German Medical Initiative (Die Medizininformatik Initiative)

- Overall Goal: creating IT and governance infrastructure to enable sharing of patient data for research purposes

- Several Federal Working Groups

- Working Group „Informed Consent“ (AG Consent)
  - Goal: a broad consent for Germany

  https://www.medizininformatik-initiative.de/de/mustertext-zur-patienteneinwilligung


Datei Bearbeiten Ansicht Chronik Lesezeichen Extras Hilfe
Startpage.com Suchergebnisse
Arbeitsgruppe Consent | Mediz
https://www.medizininformatik-initiative.de/de/zusammenarbeit/arbeitsgruppe-consent
MEDIZIN INFORMATIK INITIATIVE
ÜBER DIE INITIATIVE
KONSORTIEN
ZUSAMMENARBEIT
USE CASES
AKTUELLES
Arbeitsgruppe Consent
Die Arbeitsgruppe Consent befasst sich mit der Gestaltung der Einwilligungserklärung, die die Nutzung von Versorgungsdaten auch für künftige medizinische Forschungsfragen ermöglichen kann.
Ziele und Aufgaben
Ein wesentliches Ziel der Medizininformatik-Initiative ist es, routinemäßig im Rahmen der Patientenversorgung erfasste Patientendaten für eine wissenschaftliche Nutzung und für die Verbesserung der medizinischen Versorgung verfügbar zu machen. Diese wissenschaftliche Nutzung ist nur zulässig, wenn die Patientin oder der Patient explizit ihre oder seine Erlaubnis gegeben hat. Für die Erstellung einer Patienteninformation und
Zusammenarbeit
Nationales Steuerungsgremium
Dialogforum
Scientific Advisory Board

Medizininformatik-Initiative

Begleitstruktur – Koordinationsstelle des Nationalen Steuerungsgremiums

Arbeitsgruppe Consent
Mustertext Patienteneinwilligung

(Stand 16.04.2020)

Version 1.6d

Passage of the Patient Information of the MI-I

- **„1.2 Wie werden Ihre Patientendaten wissenschaftlich genutzt?**

Ihre Patientendaten können Universitäten, Forschungsinstituten und forschenden Unternehmen auf Antrag für medizinische Forschungszwecke zur Verfügung gestellt werden. Diese Daten dürfen vom Empfänger nur zu dem vorbestimmten und beantragten Forschungszweck genutzt und nicht zu anderen Zwecken weitergegeben werden. Ihre Patientendaten [falls zutreffend: und gespendeten Biomaterialien] werden ausschließlich für wissenschaftliche Zwecke genutzt; sie werden nicht verkauft. [Die/Das Name der behandelnden Einrichtung] kann aber für die Bereitstellung qualitätskontrollierter Daten von den jeweiligen Nutzern eine angemessene Aufwandsentschädigung erheben.“

Governance for research use of clinical data:
Example from the Medical Informatics Initiative

1. Information and consent process (through broad consent)

2. Evaluation (review) of research project by Ethical Review Board

3. Evaluation of data usage request by Data Access and Usage Committees („DACOs“ or „UACs“)

→ Need for ethical criteria to evaluate and decide upon commercialising usages of patients’ clinical data

What is at stake for Patients?

- Clinical data are personal and sensitive data
- Clinical data stem from a relation of trust and confidentiality: the physician-patient relation
- The patient-physician relation is about the patient's *individual* treatment and well-being
- Data leaks might lead to loss of privacy
- Data leaks might lead to personal harm through discrimination, tracking, tailored advertising etc.
- Patients are a vulnerable population

Patients' rights concerned by research use of their data

- Privacy / informational self-determination
- Protection against discrimination and harms
- Medical confidentiality
- Individual treatment
- Trust in physician and public heath care system

Specific ethical challenges of commercialising clinical data from patients

1. For-profit orientation
   → in tension with patients' altruistic motivation and overall common good orientation
   → in tension with the "public nature" of the data generating infrastructure of the data
   → public investments for private profits?

2. Non-disclosure policies of companies, e.g. development of patents
   → in tension with the core understanding of the public nature of scientific research
   → in tension with public good orientation

3. Globalized/multinational character of companies makes them not controllable for single states and legislation
   → contradicts accountability and transparency

4. (Perceived) poor reputation and lacking trustworthiness of private industries, e.g. pharmaceutical multinational companies
   → in tension with patients' core reason to share their data: trust in (academic) data users and research institutions

Threats and adverse scenarios

- Selling our patients' data to Google?

"deal between Google Deep Mind and the Royal Free London NHS Foundation Trust, which involved the transfer of identifiable patient records across the entire Trust, without explicit consent, for the purpose of developing a clinical alert app for kidney injury"

Health Technol. (2017) 7:351–367
DOI 10.1007/s12553-017-0179-1

CrossMark

ORIGINAL PAPER

Google DeepMind and healthcare in an age of algorithms

Julia Powles[1] · Hal Hodson[2]

Threats and adverse scenarios

- Selling our patients' data to Google and Co?

Washington has already made clear it wants unrestricted access to Britain's 55 million health records – estimated to have a total value of £10bn a year – as part of any post-Brexit trade agreement. Leaked details of meetings between US and UK trade officials late last year showed that the acquisition of as much UK medical data as possible is a top priority for the US drugs industry.

It is trust what counts

Editorial | Published: 11 March 2020

Patient trust must come at the top of researchers' priority list

Nature Medicine **26**, 301(2020) | Cite this article

1240 Accesses | **5** Altmetric | Metrics

Secondary use of patient health data can be a boon for medical research and development, but only if researchers can cultivate patient trust in the system.

Some potential ways to address challenges of the commercialisation of patient data

- Reality check: comparison between public/academic research and industry research with respect to Good Scientific Practice
- Expense allowances or other ways to involve private industries in costs for data sharing infrastructure
- Information and transparency
- Decentralised Computing (patients' data do not leave the hospital's IT infrastructure)
- Anonymization and other data protection techniques
- Patient involvement and participation
- Public-private partnerships
- State legislation

Thank you!

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