

ЭРҮҮЛ МЭНДИЙН ЯАМ









Диксон Памела Грахам

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Updates on Big Data, AI, and Digital Health: Use Cases and New and Emerging Regulatory Guidance

E-Health Convergences, Ministry of Health, Government of Mongolia April 2024

Pam Dixon Executive Director World Privacy Forum | <u>www.worldprivacyforum.org</u> <u>pdixon@worldprivacyforum.org</u> @privacyforum

@pamdi

Stucture of Presentation



I. Al-enabled research and precision medicine

II. Big Data & AI as a medical device; new work in virtual Big Data; evolving predictive analytic techniques using clinical data

III. Key regulatory and governance concerns and solutions



Big Data and AI in Digital Health: AI and **Precision Medicine**



RESEARCH AND AI -ENABLED PRECISION MEDICINE





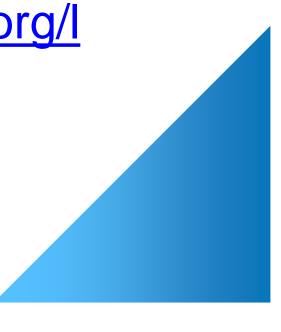
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Sensors

Health data sources can be standard or expanded. Now, some private sector data, or even virtual data based on aggregate clinical records is also being brought in for use in Al methods in health.

WHO: The health data ecosystem https://creativecommons.org/l

icenses/by-nc-sa/3.0/igo





TEMPUS

Improving patient care through high quality testing, clinical trial matching, and deep research data that powers scientific discovery

50%+

of all Academic Medical Centers in the US are connected to Tempus

50%+

of oncologists in the US connected to Tempus through sequencing, clinical trial matching, and research-enabled partnerships

90%

of the top 20 pharma oncology companies partner with Tempus

200+

biopharma partnerships

~6,000,000

de-identified research records to power scientific discovery to improve patient outcomes

26,000+

patients have been identified for potential enrollment into clinical trials in our network

Research and AI- Enabled Precision Medicine, **Two Key Areas:**

- Large libraries of clinical data and molecular data are being built using existing patient information. The clinical data is deidentified, and the AI is used to create advanced abstraction from electronic health records. NLP methods have advanced, and are being used to get more information out of clinical records.
- Techniques that combine comparing large molecular data libraries with large clinical data repositories, are driving advances.

• Tempus AI is a specific use case in this area.

- https://www.tempus.com (Example)
- KEY: This combination of Big Clinical Data and AI techniques in analyzing the data and molecules together is considered to be a medical device, as defined by the FDA. These devices are regulated and are listed on the FDA website.
- Part 3 of this presentation discusses how this regulation works. Note: this use case example was chosen because it is clear, and it has received FDA approval. Hundreds of these types of use cases now exist.





Research and AI- Enabled Precision Medicine, Citations:

- Additional information on this use case:
- Images, USCAP 2024
- Philadelphia (PA): AACR; Cancer Res 2024;84(6_Suppl):Abstract nr 6459.

Large Scale DNA Alteration Prediction from H&E Images Across Different Cancer Types Generalizing to External

 Xiaoyong Fu, Jordan Kardos, Paola Correa, Min Wang, Li, Jackson Egen, Shahed Iqbal. Molecular profiling of advanced non-small cell lung cancer in response to first-line immune checkpoint inhibitors and/or chemotherapy using multimodal real-world data [abstract]. In: Proceedings of the American Association for Cancer Research Annual Meeting 2024; Part 1 (Regular Abstracts); 2024 Apr 5-10; San Diego, CA.



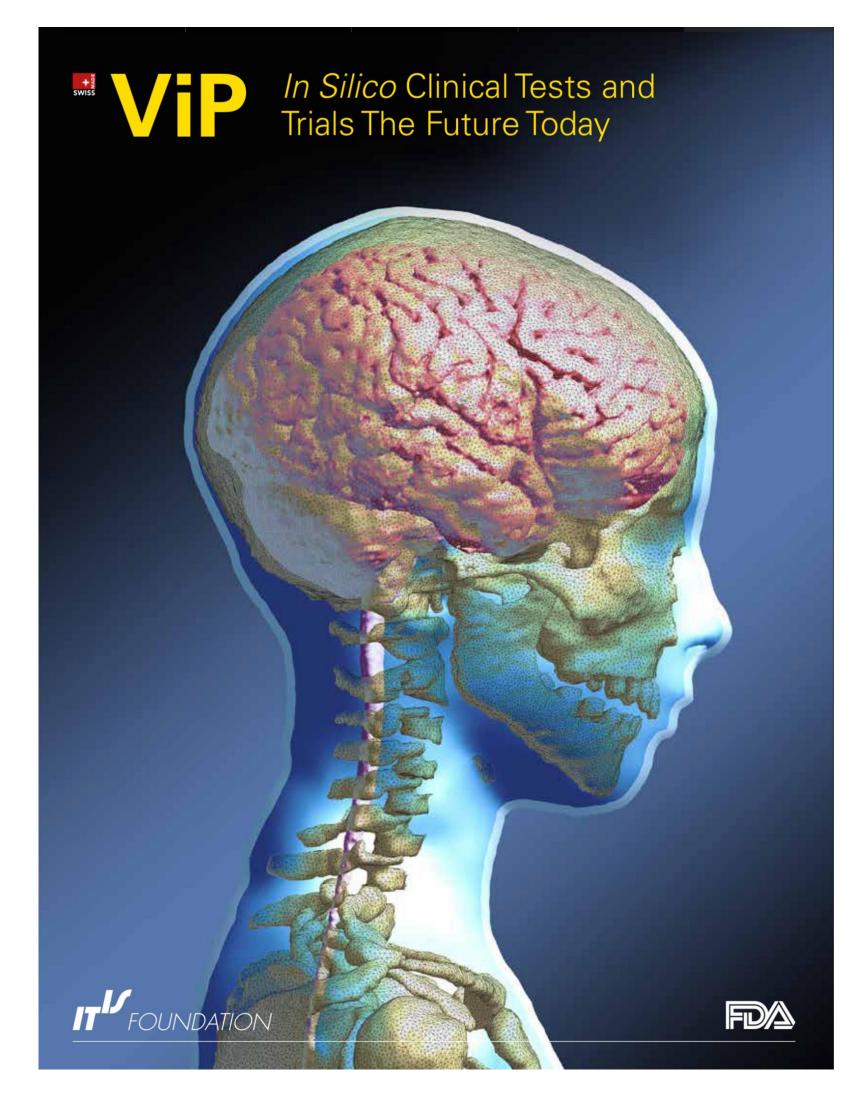
Big Data and Al in Digital Health: Predictive Analytics



PREDICTIVE **ANALYTICS USING** HEALTH DATA AT SCALE: virtual data, clinical data, and more







Virtual Big Data and AI:

One major category of Big Data involves AI / Predictive Analytics Performed on De-identified Clinical Data.

There is also a new category of Big Data: **virtualized data sets extracted from human research**. These are started with detailed MRI scans and reconstructed as computer-aided design objects.

This allows for new and very flexible and accurate health datasets that can be explanded to be used for population health research.





Resources for You (Medical Devices)

The Virtual Family: A Set of Anatomically Correct Wholebody Computational Models

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Catalog of Regulatory Science Tools to Help Assess New Medical Devices

Technical Description

The Virtual Family (VF) is a set of four highly detailed, anatomically correct whole-body models of an adult male, an adult female, and two children [1].

The four VF models are based on high-resolution magnetic resonance imaging (MRI) data of healthy volunteers. Organs and tissues of the VF 2.0 models are represented by three-dimensional, highly detailed computer-aided design (CAD) objects without self-intersections and gaps. The CAD objects allow the models to be meshed at arbitrary resolutions without loss of small features.

The following two VF model versions are available:

- VF 1.0: The VF 1.0 models include segmentation of approximately 80 high-resolution organs and tissues. The Virtual Family Tool can be used to discretize and export the CAD objects in a generic voxel-based format. All four VF 1.0 models and the Virtual Family Tool are provided free of charge (except for handling fees) to the scientific community for academic purposes only.
- VF 2.0: The VF 2.0 models consist of simplified CAD files optimized for finite-element modeling in any third-party platform. These models are based on a new, high-end generation of VF models that have been re-segmented at finer resolution to afford a higher degree of precision and anatomical refinement, as well as improved structural continuity of approximately 300 organs and tissues. For the purpose of simplification, these structures are combined into 22 high-resolution tissues. The VF 2.0 models are available free of charge (except for handling fees) to everyone.

*Virtual Family models (Age, Sex, Height, Weight, BMI)

The Virtual Family and Virtual Population Big Data Sets and Al research

The Virtual Population (ViP) consists of 15 high-resolution, full-body anatomical human models and three pregnant woman models. The models were developed from high-resolution magnetic resonance imaging (MRI) data of healthy volunteers and reconstructed as three-dimensional computer-aided-design (CAD) objects. The CAD format allows the models to be meshed at arbitrary resolutions without any loss of detail or small features. This allows extensive AI research using new kinds of synthetic data at the population level.

The ViP project began in 2005 with the development of the Virtual Family, a joint project between the IT'IS Foundation and the US Food and Drug Administration. Additional models were gradually generated to broaden the population coverage, forming ViP v1.. The v2.0 models, consisting of 22 simplified CAD files, were developed to support finite-element modeling in third-party commercially available platforms.

The newest generation VIP3.0 models, available since mid-2015, elevate computational simulations in 3D anatomies to an unprecedented level of detail and accuracy, with more than 300 tissues and organs per model, a resolution of 0.5 mm' throughout the entire body, and specific physical, physiological, and biological properties for all segmented tissues. (From US FDA and IT'IS Foundation.)





digital medicine npj

www.nature.com/npjdigitalmed

ARTICLE **OPEN** A large language model for electronic health records

Xi Yang^{1,2}, Aokun Chen^{1,2}, Nima PourNejatian³, Hoo Chang Shin³, Kaleb E. Smith³, Christopher Parisien³, Colin Compas³, Cheryl Martin³, Anthony B. Costa³, Mona G. Flores ³, Ying Zhang ⁴, Tanja Magoc⁵, Christopher A. Harle^{1,5}, Gloria Lipori^{5,6}, Duane A. Mitchell⁶, William R. Hogan $(1)^{1}$, Elizabeth A. Shenkman $(1)^{1}$, Jiang Bian $(1)^{1,2}$ and Yonghui Wu $(1)^{1,2}$

There is an increasing interest in developing artificial intelligence (AI) systems to process and interpret electronic health records (EHRs). Natural language processing (NLP) powered by pretrained language models is the key technology for medical AI systems utilizing clinical narratives. However, there are few clinical language models, the largest of which trained in the clinical domain is comparatively small at 110 million parameters (compared with billions of parameters in the general domain). It is not clear how large clinical language models with billions of parameters can help medical AI systems utilize unstructured EHRs. In this study, we develop from scratch a large clinical language model—GatorTron—using >90 billion words of text (including >82 billion words of de-identified clinical text) and systematically evaluate it on five clinical NLP tasks including clinical concept extraction, medical relation extraction, semantic textual similarity, natural language inference (NLI), and medical question answering (MQA). We examine how (1) scaling up the number of parameters and (2) scaling up the size of the training data could benefit these NLP tasks. GatorTron models scale up the clinical language model from 110 million to 8.9 billion parameters and improve five clinical NLP tasks (e.g., 9.6% and 9.5% improvement in accuracy for NLI and MQA), which can be applied to medical AI systems to improve healthcare delivery. The GatorTron models are publicly available at: https://catalog.ngc.nvidia.com/orgs/nvidia/teams/clara/models/ gatortron_og.

npj Digital Medicine (2022)5:194; https://doi.org/10.1038/s41746-022-00742-2

https://www.nature.com/articles/s41746 -022-00742-2.pdf

Predictive Analytics Performed on Clinical Data at Scale: The use of NLP Software and advanced Virtual Datasets

- Natural Language Programming software has changed clinical health data analysis, especially with the addition of Large Language Models.
- Example: Today's NLP software can pull **100 percent of** data from clinical charts. In the past, medical charts have been hard to analyze at scale because data is often hidden in the chart for various structuring and technical reasons. In the US use cases, NLP may be used to ensure quality control as well as for determining insurance risk.
- A landmark **Nature Digital Medicine** article describes how NLP combined with an AI Transformer (Large Language Model) took 90 billion words from de-identified clinical texts and used them for analysis. The article has been made available publicly free of charge See: https://www.nature.com/articles/s41746-022-00742-2.pdf

- Check for update





NVIDIA. NGC | CATALOG

Welcome Guest

Catalog > Models > GatorTron-OG

GatorTron-OG

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Overview

GatorTron-OG is a 345m-parameter cased Megatron checkpoint pre-trained on a dataset consisting of,

- 82B words of de-identified clinical notes from the University of Florida Health System,
- 6.1B words from PubMed CCO.
- 2.5B words from WikiText,
- 0.5B words from MIMIC-III itself.

The model is designed to provide improved language understanding for downstream clinical tasks. It was trained and is released with a 50K token customized clinical vocabulary trained on the above listed data distribution.

The model is released alongside GatorTron-S, a similar 345m-parameter cased Megatron checkpoint, but pre-trained on 22B words from the University of Florida SynGatorTron 5B NLG model (a Megatron GPT-3 model) as well as the full Pile dataset [1] and prompted to produce synthetic, de-identified discharge summaries using text sampled from MIMIC-III.

More Details

Please be sure to download the most recent version in order to ensure compatibility to the latest NeMo release. The following files are provided for each release:

- MegatronBERT.pt: pre-trained Megatron model weights,
- config.json: the config file used to initialize model network architecture in NeMo,
- vocab.txt: vocabulary file used to train the checkpoint,
- hparam.yaml: model configuration used to convert the Megatron checkpoints to NeMo format.
- MegatronBERT.nemo: pre-trained NeMo checkpoint.

De-Identification

De-identification of clinical notes was performed using the DeepDeID (LSTM-CRFs) tool on all University of Florida Health clinical notes through a named entity recognition task on defined classes containing PHI followed by dummy replacements (e..g, [**NAME**]). Details of the method are available in [1].

NLP/ Large Language Model Dataset:

- https://catalog.ngc.nvidia.com/orgs /nvidia/teams/clara/models/gatortro n_og.
- This model is trained on billions of de-identified clinical record data points.
- This model is available free of charge.





CLINICAL FRAILTY SCALE

1	1	VERY Fit	People who are robust, active, energetic and motivated. They tend to exercise regularly and are among the fittest for their age.
1	2	FIT	People who have no active disease symptoms but are less fit than category 1. Often, they exercise or are very active occasionally , e.g., seasonally.
t	3	MANAGING Well	People whose medical problems are well controlled , even if occasionally symptomatic, but often are not regularly active beyond routine walking.
•	4	LIVING WITH VERY MILD FRAILTY	Previously "vulnerable," this category marks early transition from complete independence. While not dependent on others for daily help, often symptoms limit activities . A common complaint is being "slowed up" and/or being tired during the day.
	5	LIVING WITH Mild Frailty	People who often have more evident slowing, and need help with high order instrumental activities of daily living (finances, transportation, heavy housework). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation, medications and begins to restrict light housework.

儲	6	LIVING WITH Moderate Frailty	People who need help with all outside activities and with keeping house. Inside, they often have problems with stairs and need help with bathing and might need minimal assistance (cuing, standby) with dressing.				
揻	7	LIVING WITH Severe Frailty	Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~6 months).				
ļ s i	8	LIVING WITH VERY SEVERE FRAILTY	Completely dependent for personal care and approaching end of life. Typically, they could not recover even from a minor illness.				
	9	TERMINALLY ILL	Approaching the end of life. This category applies to people with a life expectancy <6 months , who are not otherwise living with severe frailty. (Many terminally ill people can still exercise until very close to death.)				

SCORING FRAILTY IN PEOPLE WITH DEMENTIA

The degree of frailty generally corresponds to the degree of dementia. Common symptoms in mild dementia include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal



In moderate dementia, recent memory very impaired, even though they seeming can remember their past life events well. They can do personal care with prompting

In severe dementia, they cannot do personal care without help.

In very severe dementia they are often bedfast. Many are virtually mute.

lersion 2.0 (EN). All rights reserved. For permis lockwood K et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-49

The **Clinical Frailty Scale (CFS)** was introduced in the second clinical examination of the Canadian Study of Health and Aging (CSHA) as a way to summarize the overall level of fitness or frailty of an older adult after they had been evaluated by an experienced clinician (Rockwood et al., 2005).

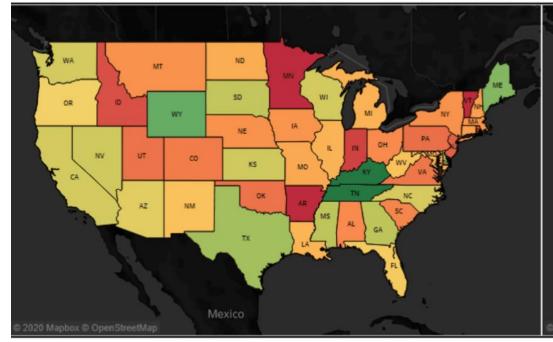
Al Use Case with clinical data: Patient Scoring or Health Scoring using de-identified and/or identified health data

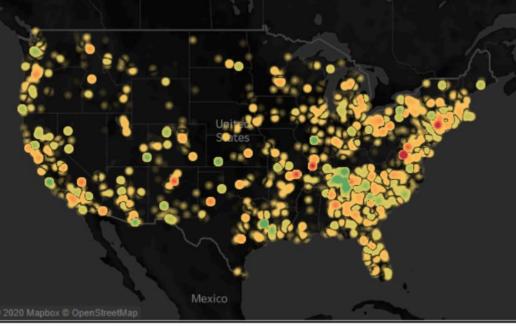
- This is not a new use case, in fact, this is classical Big Data analytics in health care. What is different is that techniques have improved.
- Key example: Frailty Score, sometimes called the Frailty Scale This score predicts how sick a patient is, and can predict the approximate death risk of a patient. There are now many versions of this score. Usually it uses hospital-wide clinical data as a base, some scales use larger data sets
- See: Priva Mendiratta et al, *Clinical Frailty Scale*, National Library of Medicine, 2023. https://www.ncbi.nlm.nih.gov/books/NBK559009/



Use Case: Predictive Analytics for health and the use of Private Sector Data or Commercial Data

verizon /	Date Range	Covid-19 Impact on Call Volume (Voice, Data Connectivity & Device Drivers)						
	Metric 1	Metric 2	Metric 3	Metric 4	Metric 5	Metric 6		
Post Covid Volumes	###	###	###	###	###	###		
Pre Covid Median	###	###	###	###	###	###		
Vol Difference from Median	###	###	###	###	###	###		
% Difference from baseline	###	###	###	###	###	###		





periencing call pressure (factoring city population

Top zip codes experiencing call pressure (factoring zip code populatio

		City Population	Post Covid Volumes	Pre Covid Median	Vol Difference from Median	City Call Pressure			Zip Population	Post Covid Volumes	Pre Covid Median	Vol Difference from Median	Zip Call Pressure
City 1	State A	###	###	###	###	###	^	Zip 1	###	###	###	###	###
City 2	State B	###	###	###	###	###		Zip 2	###	###	###	###	###
City 3	State C	###	###	###	###	###		Zip 3	###	###	###	###	###
City 4	State D	###	###	###	###	###		Zip 4	###	###	###	###	###
City 5	State D	###	###	###	###	###		Zip 5	###	###	###	###	###
City 6	State E	###	###	###	###	###		Zip 6	###	###	###	###	###
City 7	State F	###	###	###	###	###		Zip 7	###	###	###	###	###
City 8	State G	###	###	###	###	###		Zip 8	###	###	###	###	###
City 9	State H	###	###	###	###	###		Zip 9	###	###	###	###	###
City 10	State I	###	###	###	###	###		Zip 10	###	###	###	###	###

- Big Data Analytics for health purposes took a **historic** leap forward during the pandemic when private sector data was used for health data research.
- Example: Verizon and other telecommunication companies released aggregate mobile phone location and/or mobile usage data to track movement during the pandemic. This was revolutionary then, now it has become a more common practice. Before the pandemic, this was not an allowable use of private sector data.

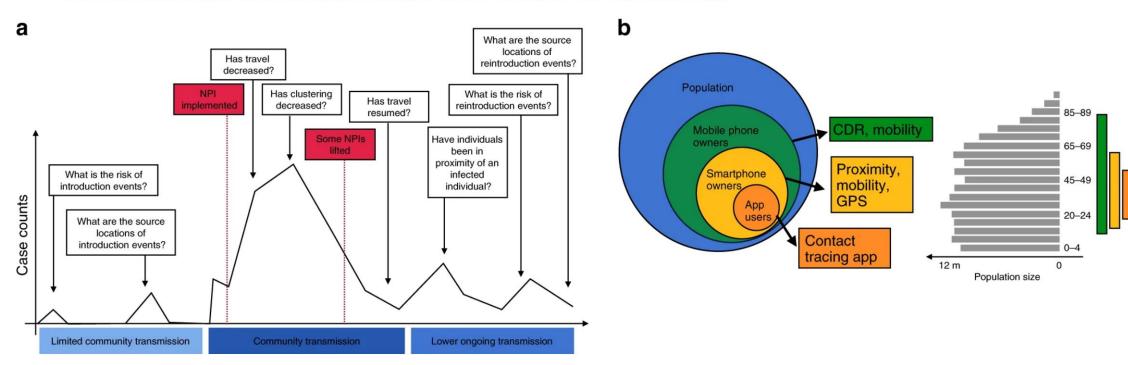
See Artur Strzelecki, Apple Mobility Trends Data in Human Mobility Patterns during Restictions and Prediction of COVID-19, National Library of Medicine, 2022.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9778143/





Fig. 1: The uses of mobile phone data to inform COVID-19 public health response and their possible biases.

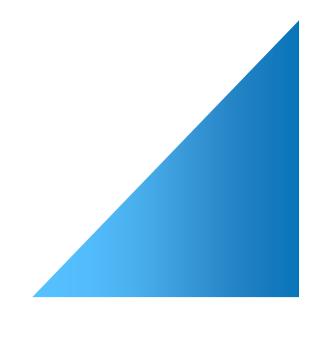


From: The use of mobile phone data to inform analysis of COVID-19 pandemic epidemiology

a Over the course of the epidemic, mobile phone data and applications may be relevant to help answer a number of important epidemiological questions needed to guide the implementation and evaluation of various interventions. **b** However, these data should be considered in light of ownership and use biases that may or may not limit generalizability to the overall population. Mobile phone owners and users only represent a subset of the population and may have additional age (shown here for a synthetic population for illustrative purposes), socio-demographic, or geographic biases. Applications that require the use of a smartphone or application may further limit the generalizability of these data since they represent smaller subsets of the user population.

Predictive Analytics performed on private sector Big Data can present nuanced challenges for health uses of the data

- Big data is very complex in all contexts, but especially health.
- The bias and errors that can happen in AI systems are often present in health contexts and can impact quality of data for use in clinical decision-making.
- See: Nature research publication detailing bias and other problems in the pandemic mobile geolocation data sets. Private sector Big Data provides many nuanced challenges which this article details.
- See: Ryra H. Grantz et al. *The use of mobile phone data to inform* analysis of COVID-19 pandemic epidemiology, Nature Communications, 2020. https://www.nature.com/articles/s41467-<u>020-18190-5</u> Open Access.











Big Data and Al Governance in Digital Health



BIG DATA and AI GOVERNANCE in the **HEALTH CONTEXT:** EMERGING METHODS AND GUIDANCE





Catalog of Regulatory Science Tools to Help Assess New **Medical Devices**





Update: January 12, 2024: The FDA is providing an updated <u>Regulatory Science Tool (RST)</u> <u>Catalog</u> that will provide additional tool search capability allow for additional capacity as the catalog continues to grow.

About the catalog of regulatory science tools

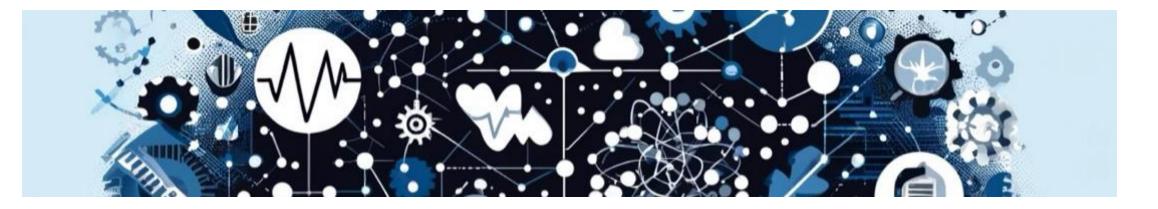
The Catalog of Regulatory Science Tools provides a peer-reviewed resource for medical device companies to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as Medical Device Development Tools and the FDA has not evaluated the suitability of these tools within any specific context of use. You may request feedback or meetings for medical device submissions as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email OSEL CDRH@fda.hhs.gov.

Health Big Data and AI is Regulated as a "Breakthrough Medical Device" by the US Food and Drug Administration, FDA.

- A database of all Breakthrough Medical Devices is kept and made available to the public with documentation. Additional information on the FDA database as AI and Big Data as "Medical Devices":
 - FDA Breakthrough Medical **Devices Database (AI)**: https://www.fda.gov/medicaldevices/how-study-and-market-yourdevice/breakthrough-devicesprogram#s1





Criteria	Description
First Criterion	The device provides for more effective treatment or diagnosis of life
Second Criterion	The device also meets at least one of the following:
	a. Represents Breakthrough Technology
	b. No Approved or Cleared Alternatives Exist
	c. Offers Significant Advantages over Existing Approved or Cle
	d. Device Availability is in the Best Interest of Patients

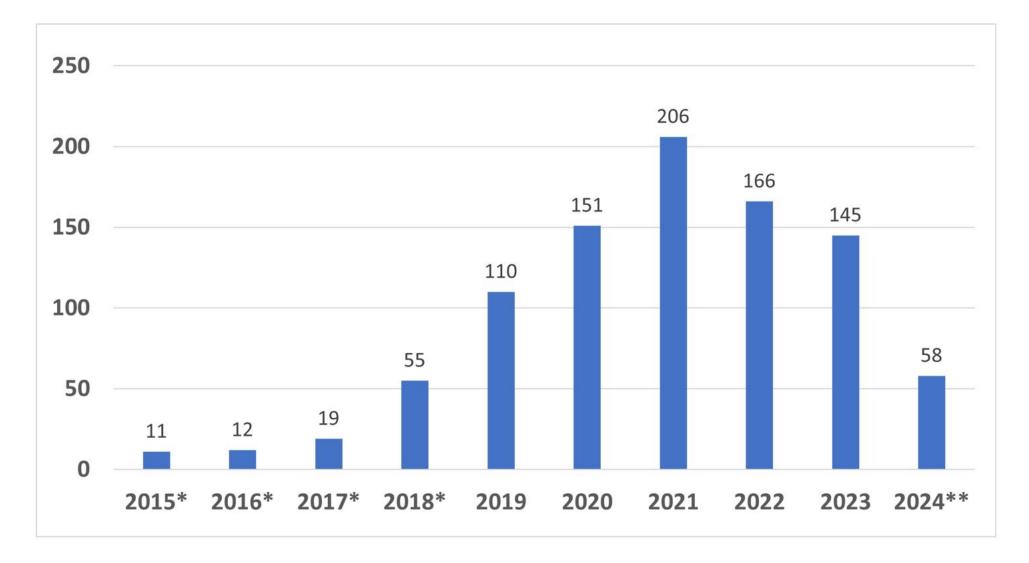
FDA Regulation of Big Data and Al as a **Breakthrough Medical Device**, continued:

- Criteria for being a Breakthrough Medical Device (AI + Big Data):
 - The device must provide effective treatment; and must also meet at least one of four additional criteria (see image to left)
 - Al tools in healthcare are "breakthrough" technology" and are now part of this program and have formal guidance applied to them.





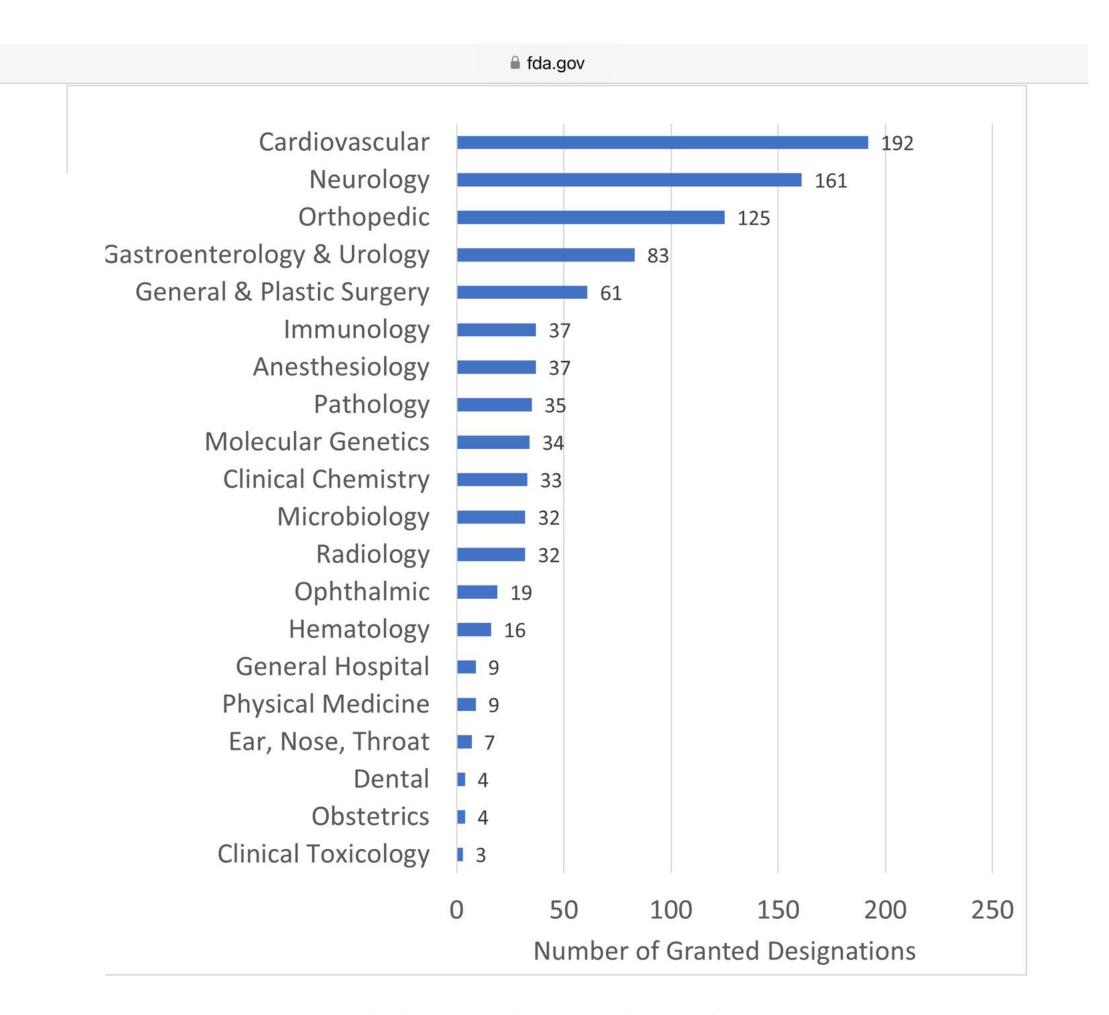
Graph 1: Number of Granted Breakthrough Device Designations by Fiscal Year



*Data includes devices that were designated under the precursor Expedited Access Pathway (EAP). Since the vision and designation criteria between the precursor EAP Program and the Breakthrough Devices Program are consistent, the FDA considers devices granted designation under the EAP to be a part of the Breakthrough Devices Program.

**Indicates the 2024 data are from October 1, 2023 through December 31, 2023.

How many Breakthrough tools, and in what areas?



ow many Breakthrough Devices have received arketing authorization?





Breakthrough Devices program: FDA, <u>https://www.fda.gov/medical-</u> <u>devices/how-study-and-market-your-</u> <u>device/breakthrough-devices-</u> program#s1

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🗎 fda.gov

奈 65% 🔳

CDRH and CBER Breakthrough Device Marketing Authorizations Data as of December 31, 2023

Total of 95 Marketing Authorizations, including 91 CDRH devices and 4 CBER devices

Search:		Show	entries
Manufacturer	Trade Name	Marketing Submission Number ≑	Marketing Submission Decision Date –
ENDOSOUND, INC.	ENDOSOUND VISION SYSTEM	<u>K232518</u>	12/27/2023
AUTOGENOMICS, INC.	AVERTD and AVERTD BUCCAL SAMPLE COLLECTION KIT	<u>P230032</u>	12/19/2023
MEDTRONIC, INC.	PULSESELECT PULSED FIELD ABLATION (PFA) SYSTEM	<u>P230017</u>	12/13/2023
BIOPORTO DIAGNOSTIC, INC.	PRONEPHRO AKI (NGAL)	<u>K232761</u>	12/7/2023
MEDTRONIC, INC.	SYMPLICITY SPYRAL RENAL DENERVATION SYSTEM	<u>P220026</u>	11/17/2023
RECOR MEDICAL, INC.	PARADISE ULTRASOUND RENAL DENERVATION SYSTEM	<u>P220023</u>	11/7/2023
PERFUZE, LTD.	MILLIPEDE 070 ASPIRATION CATHETER, PERFUZE ASPIRATION TUBE SET	<u>K232524</u>	10/18/2023
HISTOSONICS, INC.	EDISON SYSTEM	DEN220087	10/6/2023
ANUMANA, INC.	LOW EJECTION FRACTION AI-ECG ALGORITHM	<u>K232699</u>	9/28/2023
LAMINATE MEDICAL	Whole .	<u>DEN220026</u>	9/26/2023

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Examples:

New Search	Back to Search Results	
Device Definition	Image Acquisition And/Or Optimization Guided By Artificial Intelligence	
	A radiological acquisition and/or optimization guidance system is a device that is intended to aid in the acquisition and/or optimization of images and/or diagnostic signals. The device interfaces with the acquisition system, analyzes its output, and provides guidance and/or feedback to the operator for improving image and/or signal quality.	
Physical State	The subject software would utilize images acquired using an imaging system. The software can be installed on an existing imaging system, or can be operated on a computer that is connected to the imaging system.	
Technical Method	The device's algorithm would be based on the analysis of images and/or diagnostic data. The underlying algorithms used for providing guidance to the users may be based on deep learning methods, trained on images obtained by trained operators.	
Target Area	Human body	
Regulation Medical Specialty	Radiology	
Review Panel	Radiology	
Product Code	QJU	
Premarket Review	Office of Radiological Health (OHT8) Division of Radiological Imaging and Radiation Therapy Devices (DHT8C)	
Submission Type	510(k)	
Regulation Number	892.2100	
Device Class	2	
Total Product Life Cycle (TPLC)	TPLC Product Code Report	
GMP Exempt?	No	
Summary Malfunction Reporting	Ineligible	
Implanted Device?	No	
Life-Sustain/Support Device?	No	
Third Party Review	Not Third Party Eligible	

	Otification			- K
10 D	a construction of the second sec	& Listing Adverse Events Recalls PMA HDE C Emitting Products X-Ray Assembler Medsun Reports		
New Search			Back To Search	h Results
	Device Classification Name	reduced ejection fraction machine learning-bas	sed notification software	
	510(k) Number	K232699		
	Device Name	Low Ejection Fraction AI-ECG Algorithm		
	Applicant	Anumana, Inc. One Main Street, Suite 400 East Arcade, 4th Floor Cambridge, MA 02142		
	Applicant Contact	Suzanne Goodman		
	Correspondent	RQM+ 2251 San Diego Ave, Suite B-257 San Diego, CA 92110		
	Correspondent Contact	Alexia Haralambous		
	Regulation Number	870.2380		
	Classification Product Code	QYE		
	Date Received	09/05/2023		
	Decision Date	09/28/2023		
	Decision	Substantially Equivalent (SESE)		
	Regulation Medical Specialty	Cardiovascular		
	510k Review Panel	Cardiovascular		
	Summary	Summary		
	Туре	Traditional		
	Reviewed by Third Party	No		
	Combination Product	No		

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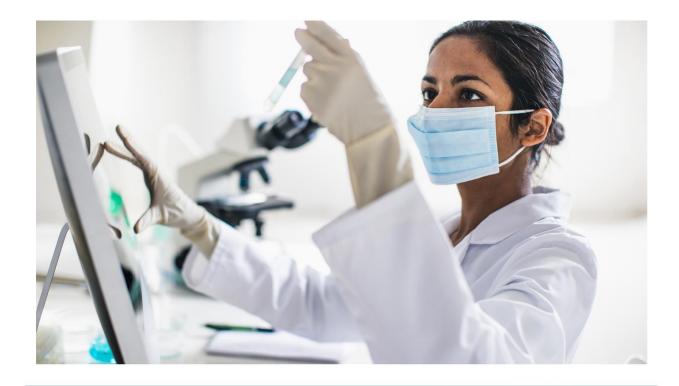
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Catalog of Regulatory Science Tools to Help Assess New Medical Devices





Update: January 12, 2024: The FDA is providing an updated <u>Regulatory Science Tool (RST)</u> <u>Catalog</u> that will provide additional tool search capability allow for additional capacity as the catalog continues to grow.

About the catalog of regulatory science tools

The Catalog of Regulatory Science Tools provides a peer-reviewed resource for medical device companies to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as <u>Medical Device Development Tools</u> and the FDA has not evaluated the suitability of these tools within any specific context of use. You may <u>request</u> <u>feedback or meetings for medical device submissions</u> as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email <u>OSEL_CDRH@fda.hhs.gov</u>.

The FDA also maintains a new (2024) catalogue of emerging Big Data and Al tools "medical devices"

- This area of AI in health is moving so quickly the FDA is now tracking pre-approval information.
- This is a new program with rich scholarly literature that is very recent.
- AI tools for health are classified as "medical devices" under the program.





GUIDANCE DOCUMENT

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

SEPTEMBER 2023

Download the Final	Guidance I	Read the	e Federal I	Register N	
		Final			
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Docket Number: FDA-2017-D-5966 Issued by:

Center for Devices and Radiological Health Center for Biologics Evaluation and Research Notice

The full FDA guidance for AI as a medical device is here:

https://www.fda.gov/regulatoryinformation/search-fda-guidancedocuments/breakthrough-devicesprogram





Example request for Breakthrough Device Designation:

https://www.fda.gov/regulatoryinformation/search-fda-guidancedocuments/breakthrough-devicesprogram

Appendix 1: Illustrative Example: Breakthrough Device Designation Request

This appendix provides an example of information that may be helpful to include in a request for designation into the Breakthrough Devices Program.

Background Information

Device Description: This section provides an overview of the product, including principles of operation (including device and/or drug components) and properties relevant to clinical function, if known. Images or engineering schematics are also encouraged for inclusion, as appropriate.

Indications for Use: This section presents indications for use for which you are requesting designation. The indications for use should clearly outline a patient population that meets the designation criteria.⁶¹

Regulatory History: This section details the history of previous FDA interactions and submissions, including feedback received and resolution of that feedback, as applicable. All relevant IDE, 513(g),⁶² and Q-Submission numbers should be included.

Designation Criteria

Criterion 1: Device "provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions."63

This section provides a discussion regarding how the first designation criterion is met by the proposed device and indications for use.

Criterion 2: Device meets one of the components of the criterion, listed below:

- (A) Device "represent[s] breakthrough technolog[y];"⁶⁴
- (B) "[N] o approved or cleared alternatives exist; "⁶⁵
- (*C*) Device "offer[s] significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long term clinical efficiencies; "66 or
- (D) Device availability "is in the best interest of patients."⁶⁷

⁶² See FDA Guidance "FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-a industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic.



⁶¹ See section 515B(b) of the FD&C Act (21 U.S.C. 360e-3(b)).

⁶³ See section 515B(b)(1) of the FD&C Act (21 U.S.C. 360e-3(b)(1)).

⁶⁴ See section 515B(b)(2)(A) of the FD&C Act (21 U.S.C. 360e-3(b)(2)(A)).

⁶⁵ See section 515B(b)(2)(B) of the FD&C Act (21 U.S.C. 360e-3(b)(2)(B)).

⁶⁶ See section 515B(b)(2)(C) of the FD&C Act (21 U.S.C. 360e-3(b)(2)(C)).

⁶⁷ See section 515B(b)(2)(D) of the FD&C Act (21 U.S.C. 360e-3(b)(2)(D)).





EXECUTIVE OFFICE OF THE PRESIDENT OFFICE OF MANAGEMENT AND BUDGET WASHINGTON, D.C. 20503

March 28, 2024

M-24-10

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM:

Shalanda D. Young Chalanda D. Young

SUBJECT: Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence

Artificial intelligence (AI) is one of the most powerful technologies of our time, and the President has been clear that we must seize the opportunities AI presents while managing its risks. Consistent with the AI in Government Act of 2020,¹ the Advancing American AI Act,² and Executive Order 14110 on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, this memorandum directs agencies to advance AI governance and innovation while managing risks from the use of AI in the Federal Government, particularly those affecting the rights and safety of the public.³

1. OVERVIEW

While AI is improving operations and service delivery across the Federal Government, agencies must effectively manage its use. As such, this memorandum establishes new agency requirements and guidance for AI governance, innovation, and risk management, including through specific minimum risk management practices for uses of AI that impact the rights and safety of the public.

Strengthening AI Governance. Managing AI risk and promoting AI innovation requires effective AI governance. As required by Executive Order 14110, each agency must designate a Chief AI Officer (CAIO) within 60 days of the date of the issuance of this memorandum. This memorandum describes the roles, responsibilities, seniority, position, and reporting structures for agency CAIOs, including expanded reporting through agency AI use case inventories. Because AI is deeply interconnected with other technical and policy areas including data, information technology (IT), security, privacy, civil rights and civil liberties, customer experience, and

https://www.congress.gov/116/plaws/publ260/PLAW-116publ260.pdf.

White House Regulation of Big Data and AI and Health; new guidance

https://www.whitehouse.gov/wp-content/uploads/2024/03/M-24-10-Advancing-Governance-Innovation-and-Risk-Management-for-Agency-Use-of-Artificial-Intelligence.pdf

Agencies must manage and mitigate the risks from the use of AI. This includes:

- Designating Chief AI Officers
- Convening an Agency Al Governance Body
- Making a compliance plan,
- Keeping use case inventories
- Reporting on AI Use Cases not subject to inventory, among other tasks.

Al that is used for health purposes has been designated as "safety impacting Al" and is required to undergo additional regulatory protections. For example, agencies working with Health and Al must

- Complete an AI Impact Assessment,
- Test the AI for performance in a real world context,
- Independently evaluate the AI, and
- Conduct ongoing monitoring,
- Regularly evaluate risks from the use of AI
- Mitigate emerging risks to rights and safety,
- Ensure adequate human training and assessment
- Provide additional human oversight, intervention, and accountability as part of decisions or actions that coul result in a significant impact on rights or safety.
- Provide public notice and plain language documentation.
- Among additional requirements.



¹ Pub. L. No. 116-260, div. U, title 1, § 104 (codified at 40 U.S.C. § 11301 note),

² Pub. L. No. 117-263, div. G, title LXXII, subtitle B, §§ 7224(a), 7224(d)(1)(B), and 7225 (codified at 40 U.S.C. 11301 note), <u>https://www.congress.gov/117/plaws/publ263/PLAW-117publ263.pdf</u>.

³ This memorandum accounts for public comments that OMB received following its publication of a draft version of this memorandum on November 1, 2023. OMB has separately published an explanation and response to public comments, available at https://www.regulations.gov/document/OMB-2023-0020-0001.



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@privacyforum



Resources and additional thoughts:

- World Bank Principles on identification for sustainable development https://id4d.worldbank.org/principles
- •OECD AI Recommendation and implementation manual http://www.oecd.org/going-digital/ai/principles/
- https://ico.org.uk/media/forprotection.pdf

Principles for Digital Development: <u>https://digitalprinciples.org</u>

•ICO Big Data Report, with sample PIA and DPIA for big data:

organisations/documents/2013559/big-data-ai-ml-and-data-





Updated considerations regarding health data flows and health data flow infrastructures:

Multi-jurisdictional: Health data flows are important at the local, national, regional, and international levels. (Post-pandemic changes).

High volume: The generation of public health data is so large and complex that it can no longer be saved or analyzed using conventional data processing methods. COVID-19 was a "Big Data" pandemic. It created changes in how health data is handled.

High velocity: The speed with which health data is generated, processed, and analyzed has increased dramatically. Ideally, the data processing will occur within fractions of a second, also known as "real time." This speed also requires greater automation of data and privacy governance.

High complexity: The diversity of data types and sources in health data is a challenge that still needs to be solved fully.

High sensitivity to design choices: there are many trade-offs in design choices (for example, in databases and in contact tracing), and it is crucial to work through all of the possibilities through the lifecycle of the data flows, uses, and storage.





Core considerations when thinking about Big Data:

The importance of detailed planning in order to do no harm and to provide benefit is central:

- planning in place.
- much larger technology and policy ecosystem
- Big data (and AI) implementations express values and ethics

Depending on how it is designed, implemented, and used, Big Data (and the AI and ML analysis it typically undergoes) can produce a wide range of consequences for individuals, groups of people, and institutions.

Beneficial consequences are the goal, but they require considerable work and planning. Negative consequences can result from improper planning, and can sometimes even happen where there has been good

Big data and AI does not exist in a vacuum: it is almost always a part of a

