



Disruptive Technologies: *How Life Sciences Companies Can Navigate an Evolving Legal & Regulatory Landscape*

**Association of Corporate Counsel,
2022 Life Sciences: At Home & Across
the Global**

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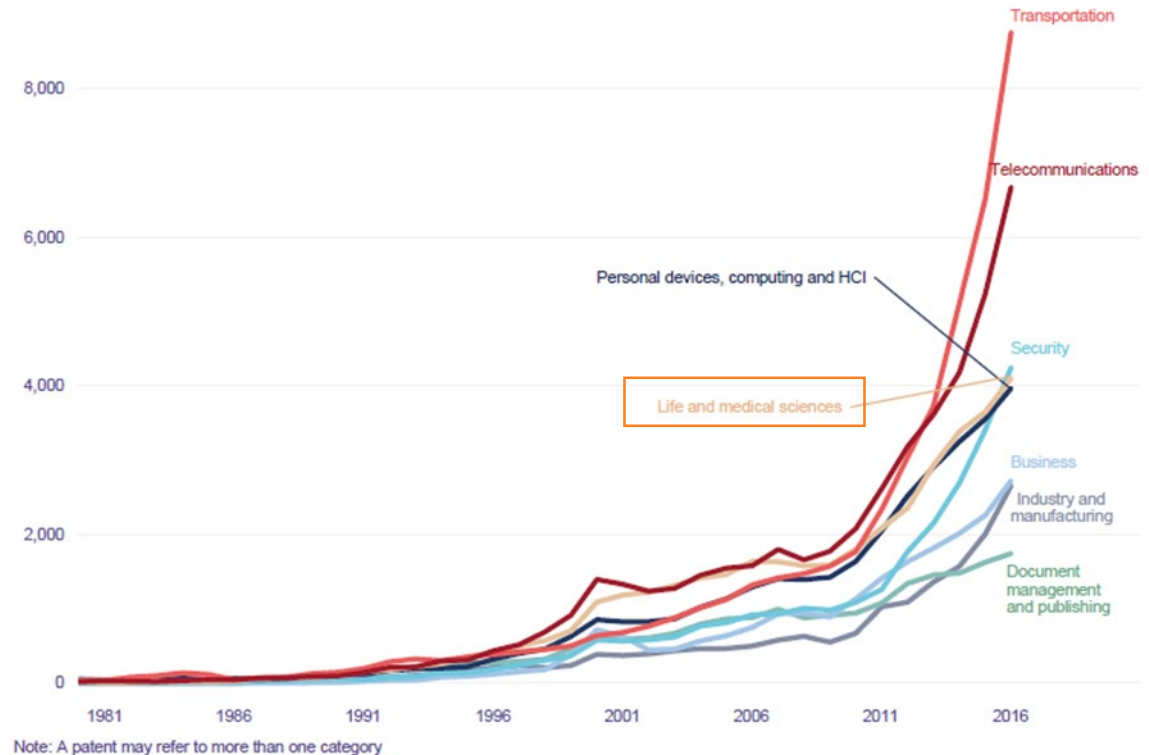
AI Technology in Life Sciences

International AI filing trend

“Patent families related to AI application fields emerged in the 1990s.”

“[D]eep learning showed an impressive average annual growth rate of **175 percent** from 2013 to 2016.”

Figure 3.18. Patent families for top application field categories by earliest priority year
Patent families related to AI application fields emerged in the 1990s, with transportation and telecommunications overtaking all other fields



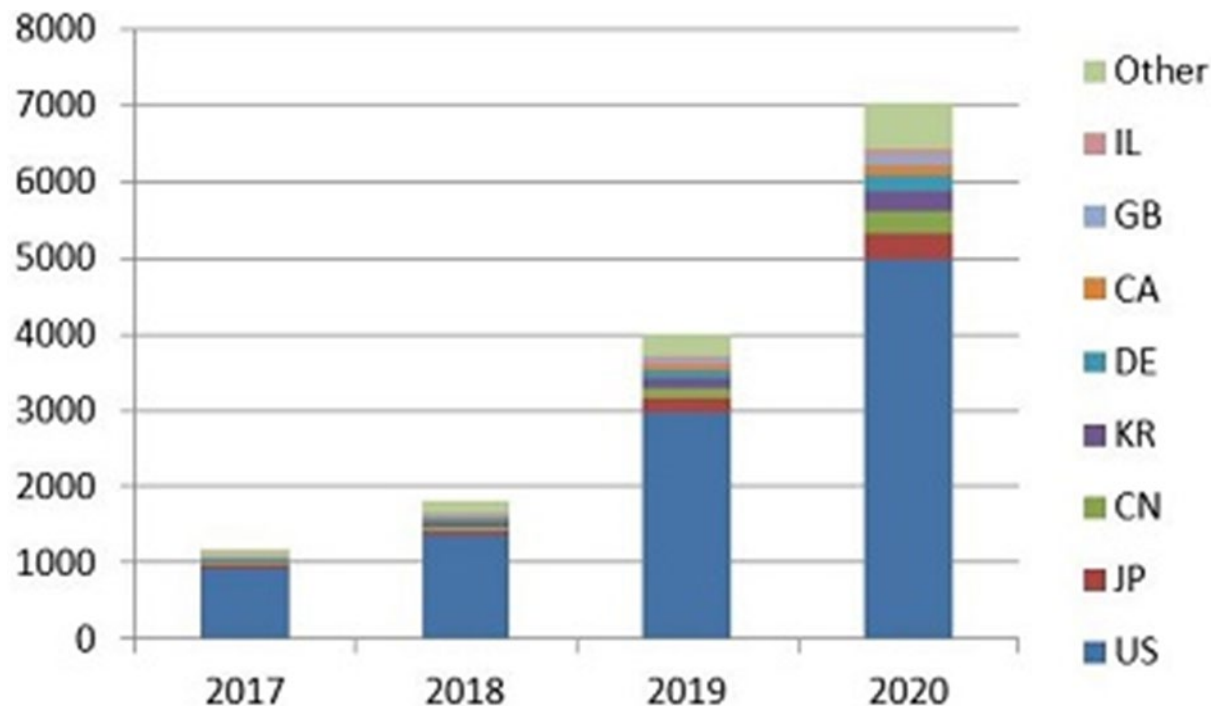
WIPO Technology Trends 2019: Artificial Intelligence, https://www.wipo.int/tech_trends/en/artificial_intelligence/

Recent AI filing trend in the U.S.

AI Patents in the U.S. by Applicant Country By Year

~8x increase in AI patents from 2017 to 2020.

Higher percentage of **non-U.S.** applicants.



United States: AI Patent Trends In The U.S. Patent Office: Is The U.S. Losing Its Lead?

<https://www.mondaq.com/unitedstates/patent/1041332/ai-patent-trends-in-the-us-patent-office-is-the-us-losing-its-lead>

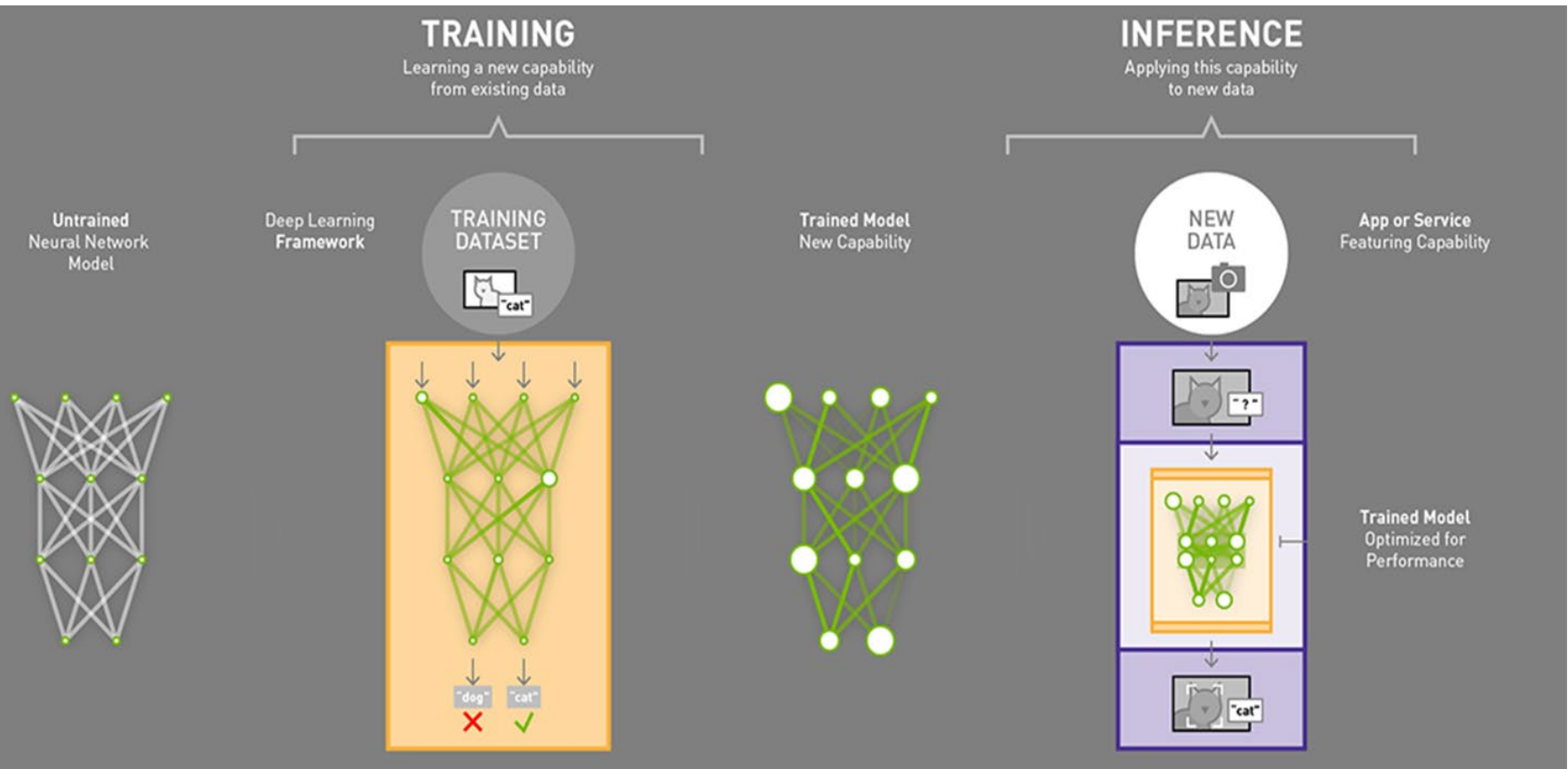
What can be patented?



<https://www.sharda.ac.in/blog/wp-content/uploads/2019/06/10-Practical-or-Theory-1024x536.jpg>

- **Application** of known AI to **specific fields and sectors**
 - E.g., achieving a new/better outcome using ML in various life sciences context (e.g., discovery of new drug, clinical trial design, medical devices, robotic surgery, medical imaging, precision medicine, healthcare and patient monitoring)
 - **Higher value** because it is likely to be detectable and can be broad
 - This is where we pursue most of the patent applications
- **New AI models and algorithms**
 - **Lower value** due to difficulty in detecting infringement
 - May be more difficult to patent without linking to a technical application

AI basics and where innovations can occur



Choice and configuration of the model (e.g., inputs, outputs, layers)

Structure / preprocessing of training data

How the trained model is used (e.g., making a diagnosis, administering a treatment, formulating clinical trials), outputs of the model (e.g., new chemical compounds)

Patent v. Trade secret v. Copyright

Patent

- Patents protect new, useful, and non-obvious ideas.
- **AI Examples:** an AI-based algorithm, a device executing AI techniques, a drug developed by AI, computer hardware configuration and optimization, etc.
- Need to file patent applications at various patent offices.

Trade Secret

- Trade secrets protect confidential information that provides a competitive advantage due to its secrecy.
- **AI Examples:** software code and other aspects of AI that can be kept confidential.
- Need to make a reasonable effort to maintain secrecy (e.g., by implementing trade secret policy).

Copyright

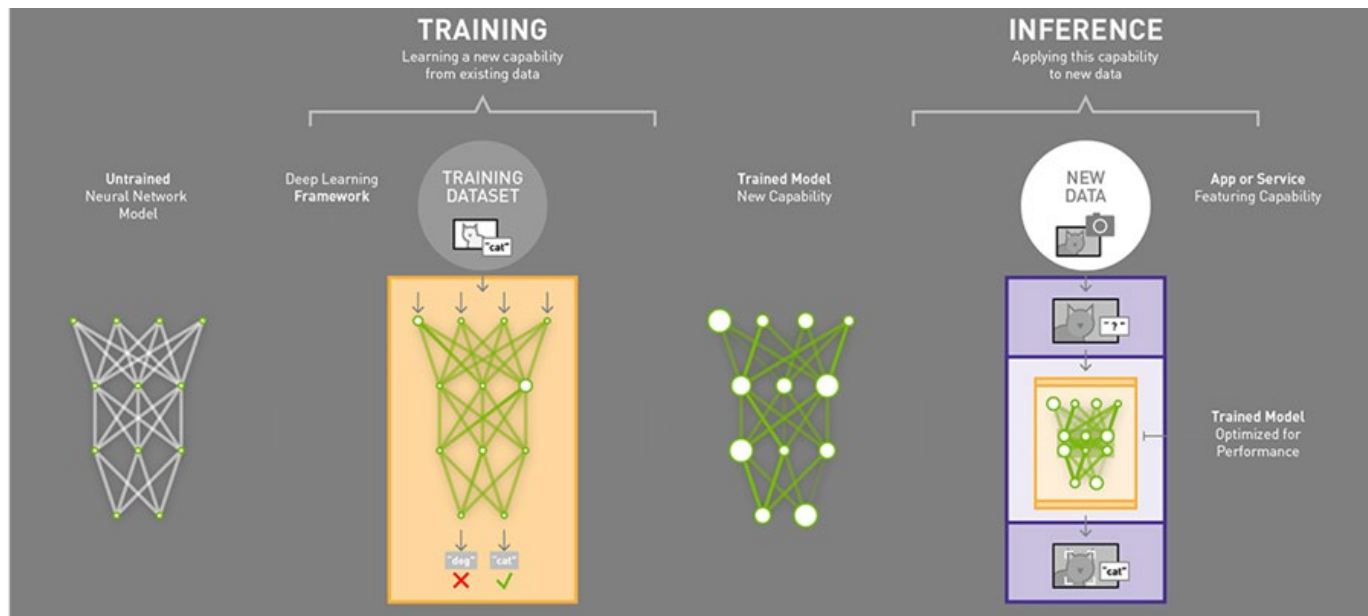
- Copyrights protect original textual works and visual or artistic expressions.
- **AI Examples:** software code, graphical user interfaces.
- Registration is optional.

Patent v. Trade secret

- A **hybrid** approach is typically advisable:
 - Patent: practical application of AI algorithms
 - Trade secret: low-level implementation details, fine-tuning, and optimization
- Patents are especially important in competitive fields such as AI
 - **Business Goals**
 - Obtain funding and increase valuation
 - Increase brand recognition
 - Value of a monopoly on the patented technology
 - **Competitive Landscape**
 - Independent development/reverse engineering
 - Defensive filings
 - **Feasibility of Trade Secret Protection**
 - Detectability: user-facing vs. internal, secret use
 - Pitching investors
 - Selling and marketing
 - Disclosure to development partners
 - Regulatory disclosure requirements
 - Whitepapers, conference presentations, blogs
 - Employee attrition
 - Hacking and cybersecurity

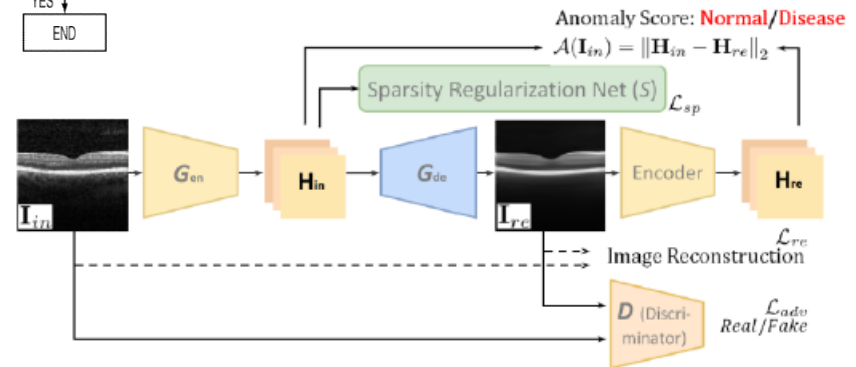
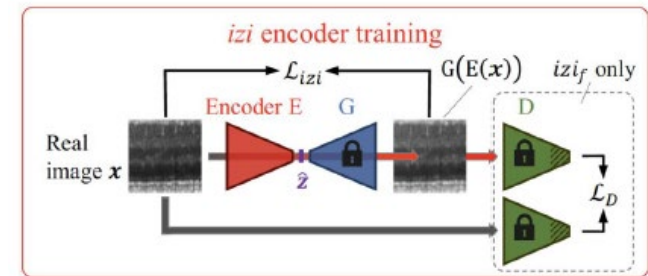
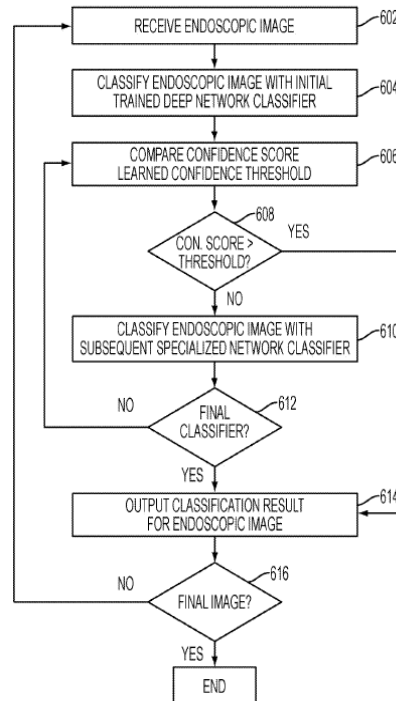
Preparing disclosure materials for AI inventions

- The patent application needs to teach the invention
 - Explain the delta: **state of the art** and how your invention improves on it
 - No magic black boxes
 - No academic papers
- Describe in detail each of the stages below that is new or different with your approach



Preparing disclosure materials for AI inventions

- Flow charts, flow charts, flow charts
- Diagrams
- Concrete Examples
- Technical Advantages
- Alternative Embodiments (what you/competitors could do)



FDA Regulatory Considerations

Software as medical device (SaMD)

A device is defined in the Federal Food, Drug, and Cosmetic Act as:

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is...
 - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals...and
 - which does not achieve its primary intended purposes through chemical action within or on the body of man

Some functions are explicitly excluded by law

Software that meets the criteria to be a device is called Software as a Medical Device (SaMD)

Non-device software in health/medical

The term device...shall not include a software function that is intended...

- (A) for administrative support of a health care facility, including...claims or billing information, appointment schedules...
- (B) for maintaining or encouraging a health lifestyle... (General Wellness Guidance)
- (C) to serve as electronic patient records...
- (D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings...
- (E) ...for supporting or providing recommendations to a health care professional [i.e., Clinical Decision Support software]...and...enabling such health care professional to independently review the basis for such recommendation that such software presents...unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system...(Clinical Decision Support Guidance)

21st century cures – software change

Five types of software excluded from “device” definition:

1. Administrative support of health care facility (inc. lab workflow)
2. Maintain or encourage a healthy lifestyle, unrelated to diagnosis, cure, mitigation, prevention, or treatment of disease or condition
 - ***FDA Wellness Guidance – unregulated/enforcement discretion***
3. Electronic patient records for transfer, store, convert formats, or display patient information (do not “interpret or analyze”)
 - ***FDA Mobile Medical Applications Guidance – enforcement discretion***
4. Transfer, store, convert formats or display lab test or device data; OR
 - ***FDA MDDS non-enforcement policy***
5. Clinical Decision Support Purposes
 - Display information about a patient,
 - Support or *provide* recommendations to health professionals AND
 - Enable HCP to independently review software recommendations
 - ***FDA CDS Draft Guidance***

SaMD risk characterization

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Figure 1: SaMD IMDRF risk categorization

Clinical Evaluation		
Valid Clinical Association	Analytical Validation	Clinical Validation
Is there a valid clinical association between your SaMD output and your SaMD's targeted clinical condition?	Does your SaMD correctly process input data to generate accurate, reliable, and precise output data?	Does use of your SaMD's accurate, reliable, and precise output data achieve your intended purpose in your target population in the context of clinical care?

Figure 3: IMDRF description of Clinical Evaluation components

Risk-based Policy for CDS using IMDRF Framework



Table 3. IMDRF type (I to IV) of SaMD products by state of healthcare condition and significance of information provided by the products to healthcare decision.^a

State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Summary of Regulatory Policy for CDS Software Functions				
IMDRF Risk Categorization	Can the User Independently Review the Basis?*	Intended User is HCP		Intended User is Patients or Caregivers
		FDA Regulation		FDA Regulation
Inform X Critical	Yes	Not a Device		Oversight Focus
	No	Oversight Focus		Oversight Focus
Inform X Serious	Yes	Not a Device		Oversight Focus
	No	Oversight Focus		Oversight Focus
Inform X Non-Serious	Yes	Not a Device		Enforcement Discretion**
	No	Enforcement Discretion**		Oversight Focus

Pre-certification (pre-cert) program

Proposed framework called “Digital Health Software Precertification (Pre-Cert) Program”

“Precertification Program” or “Pre-Cert” for short

Developers certified based on culture of quality and organizational excellence

Scope: any organization that intends to develop or market regulated software in the U.S.

Four components of the proposed program

Excellence Appraisal and Precertification	Streamlined Premarket Review Process
Review Pathway Determination	Real World Performance

Digital health center of excellence



Strategic Priorities:

AI/ML in SaMD; Cybersecurity; Wireless Devices and Pre-Cert Pilot

FDA AI whitepaper and GMLP

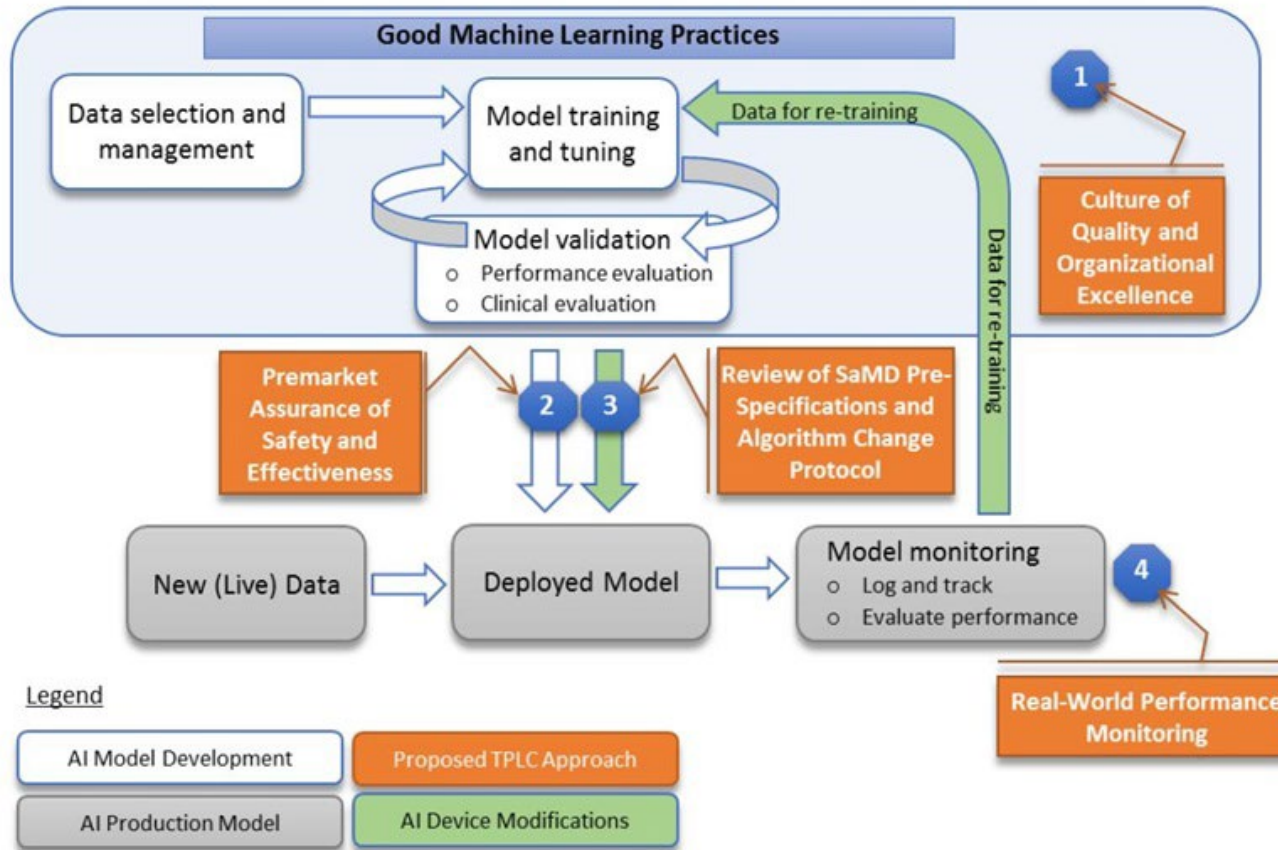


Figure 2: Overlay of FDA's TPLC approach on AI/ML workflow

Clinical decision support (exclusions)

“Decision Support” – 2 step process

(1) unless the software obtains or analyzes “a medical image or a signal from an IVD device or a pattern . . . from a signal acquisition system”

- sensors, data derived from medical devices

(2) And has the purpose

- Display/analyze information about a patient,
- Support or *provide* recommendations to health professionals AND
- Enable HCP to independently review software recommendations and not rely primarily on recommendations to make diagnosis or treatment decisions

Then, excluded from “device” definition

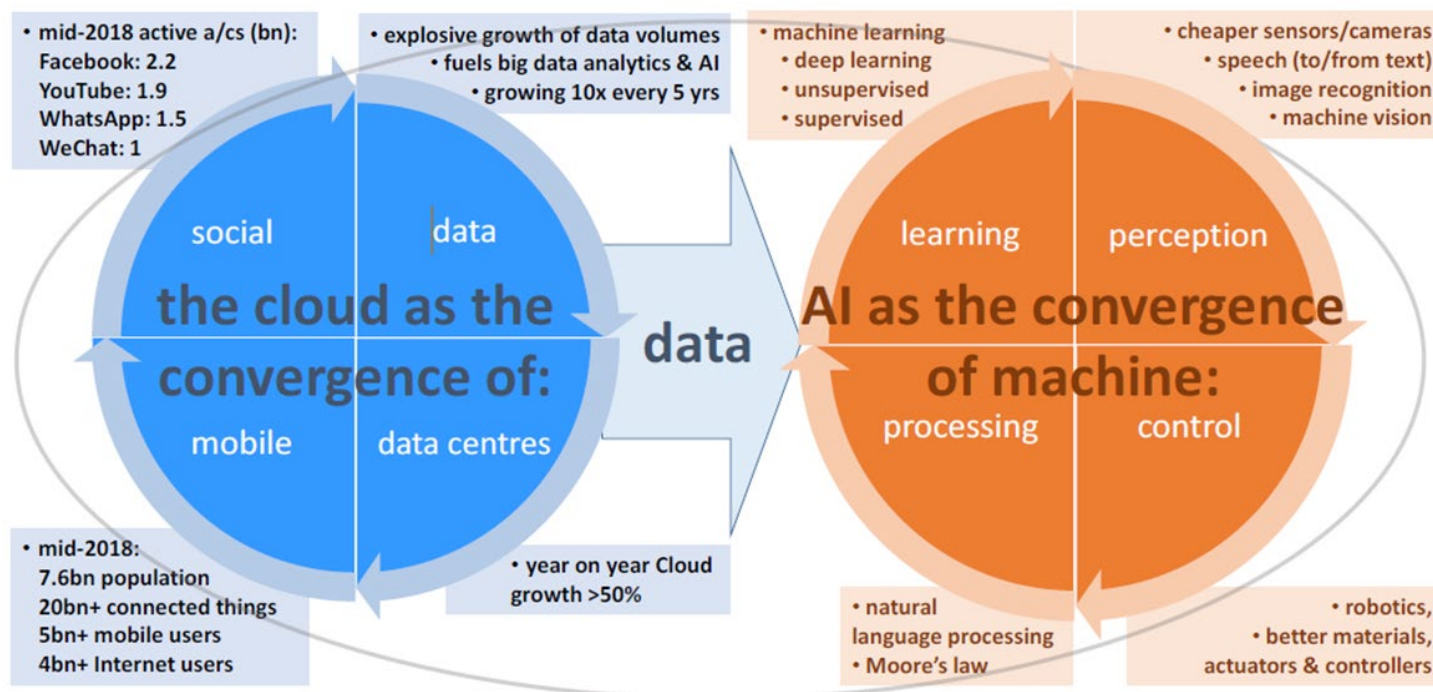
Artificial intelligence in SaMD

- Examples:
 - AI/ML that processes/analyzes physiological signals to detect patterns that occur at the onset of physiological instability and generates alarms,
 - AI/ML that uses images taken by a smartphone camera to provide detailed information to dermatologists on physical characteristics of a skin lesion, and
 - AI/ML that analyzes chest X-rays to evaluate feeding tube placement, detect incorrect placement, and perform triage for radiologists
- FDA envisions a “predetermined change control plan” in premarket submissions. This plan would include the types of anticipated modifications—referred to as the “Software as a Medical Device Pre-Specifications”—and the associated methodology being used to implement those changes in a controlled manner that manages risks to patients—referred to as the “Algorithm Change Protocol.”

Implementation in Life Sciences Transactions

The cloud and AI

- **Developments in AI have been fueled by the growing ability to collect, store and process huge amounts of digital data – fueled by the growth of the cloud**
 - “Volume, velocity and variety”
- **Today – more than 20bn sensors connected to internet, 5bn mobile phone users, 4bn internet users and 2.5bn social media users**



The government and AI

- On 11 February 11 2019, President Trump signed an executive order directing the U.S. government to prioritize artificial intelligence in its research and development spending
 - Follows various conferences at Government level to discuss AI and introduction in Dec. 2017 of proposed FUTURE of AI Act of 2017.
- In late March 2020, the White House announced the launch of the Covid-19 High Performance Computing Consortium to bring together industry leaders in AI with national laboratories and academics to “significantly advance the pace of scientific discovery in the fight to stop the virus.”
 - Google (a consortium member) has shared computationally predicted structures of viral proteins generated by its AI platform on open access databases in an effort to speed up the process of identifying a vaccine.
- On 26 April 2018, the UK’s Department for Business, Energy & Industrial Strategy published a policy paper outlining an initiative to “put the UK at the forefront of the artificial intelligence and data revolution”
- On 25 April 2018, the European Commission announced a series of measures to put AI to use in the EU and boost its competitiveness
- In 2020, FDA authorized marketing of first cardiac ultrasound software that uses AI to guide user.
- In 2021, the US FDA, Health Canada, and the UK’s MHRA jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP).
- In 2021, the WHO warned that AI technologies come at a risk in a report titled “Ethics and Governance of Artificial Intelligence for Health”.
- In 2021, FDA authorizes marketing of first device that uses AI to help detect potential signs of colon cancer.

Exponential growth in use of AI

- AI (together with the growth of the cloud) is emerging as a key driver of the “fourth industrial revolution” following the shift brought about by steam, electricity and computing
- **Key Statistics:**
 - Singapore, Brazil, Australia, Canada, and India experienced the fastest growth in AI hiring from 2015-2019.
 - In the U.S., the State of Washington has the highest relative AI labor demand – almost 1.4% of total jobs posted are AI jobs. After Washington, California (1.3%), Massachusetts (1.3%), New York (1.2%), D.C. (1.1%).
 - In 2019, global private AI investment was over \$70B
 - Start-up investments \$37B+
 - M&A \$34B+
 - IPOs \$5B
 - Investment in AI Start-ups globally increased from \$1.3B in 2010 to over \$40B in 2018.
 - Largest investment categories:
 - Autonomous vehicles \$7.7B
 - Drug, Cancer and Therapy \$4.7B
 - Facial Recognition \$4.7B
 - Video Content \$3.6B
 - Fraud Detection and Finance \$3.1B
 - The AI Index 2019 Annual Report, AI Index Steering Committee, Human-Centered AI Initiative

Types of commercial transactions

Contact Tracing: New York City and Salesforce have partnered to build a Covid-19 contact tracing program complete with a call center and customer relationship and case management system to better track the spread of infection.

Community Tracing Collaborative: Massachusetts has partnered with Partners Health in a Covid-19 Community Tracing Collaborative.

Tracking and Tracing: The Kingdom of Bahrain has launched a Covid-19 tracking program that relies on GPS tracking electronic bracelets and a Covid-19 contact tracking app. The system alerts a government monitoring station when an infected individual leaves isolation or if the bracelet loses its connection. Additionally, Ministry of Health officials may randomly send picture requests to which self-isolating individuals must respond with a photo that clearly shows their face and bracelet.

Data Sharing Collaborations: Facebook has rolled out three maps through its Data for Good program aimed at tracking the potential spread of Covid-19. The maps, based off of aggregated Facebook data, will be shared with research and public health organizations.

AI use cases in the time of Covid-19

Patient Care: A predictive model from Epic (a health records company) was recently added to its service offerings to help doctors intervene with life saving care before hospitalized patients deteriorate. The model predicts which patients are getting worse and will need more care. It evaluates patients' risks of getting sicker in real time by tracking thousands of pieces of data generated by heart rate, blood pressure, temperature, and other monitors. Stanford Health, Confluence Health, and others are using the model.

Treatments and Vaccines: Northwestern University researchers are using AI to speed up the search for Covid-19 treatments and vaccines. The AI-powered tool makes it possible to prioritize resources for the most promising studies, and ignore research that is unlikely to yield benefits. The tool replaces the human scoring system used to evaluate large volumes of research.

AI use cases in the time of Covid-19

Research Programs: The MIT-IBM Watson AI Lab is funding AI research projects in a variety of areas to address the health and economic consequences of Covid-19

- Early detection of sepsis
- Effects of targets lockdowns on the economy and public health
- Which materials make the best face masks
- Effect of re-purposed drugs on Covid-19
- Privacy risks associated with contact tracing and other apps
- Overcoming manufacturing and supply hurdles
- Using EMRs to find a treatment
- Finding better ways to treat Covid-19 patients on ventilators

Contractual considerations in AI deals

IP Ownership and Protection

- While each AI discipline is different in its specific implementation, a number of themes are common to many modern AI Systems that given rise to particular IP questions:
 - By replicating aspects of human cognition, AI systems have the potential to engage in acts of content creation – *can an AI system be an author of a work?*
 - Many AI systems, in particular those using machine learning techniques, undergo a training process in which they develop their own decision-making capabilities / algorithms and rules by practicing decision making and using feedback to improve future decisions – *if the algorithms change over time, is the original author the owner of the developed algorithms?*
 - Training AI systems often requires large volumes of training data to ensure the system develops its decision-making algorithms based on the data that reflects the full range of scenarios it may encounter in operation – *if a third party owns the data, who is the output of the system owned by?*
 - AI systems are often used to sift through large volumes of input data to detect statistical features or patterns – *is the author the person who designed the AI system? The author/source of the input data? Neither?*

Contractual considerations in AI deals (2)

- In drafting AI contracts, companies must specify:
 - Who owns the data?
 - Who owns the test results?
 - Who owns discoveries made using AI programs?
 - Was the AI developed in house or using a third party – what are the corresponding ownership rights?

Defining the framework

- AI contracts require clear contractual provisions describing ownership of machine learning systems and related developments.
- As machine learning systems become more autonomous, issues relating to ownership where no clear identifiable author exists will increase (e.g., ownership of computer-generated works).
- IP Definitions:

“Framework” means (i) the deep-learning framework embodied in or used to generate the [Software] or any portion thereof, which has been trained by [Service Provider] or any of its affiliates, or any of its or their licensors, service providers, agents or contractors, solely or jointly with [Service Recipient], including all technology embodied therein or used to generate any portion thereof, and (ii) all code, configuration files and other input materials used in connection with training such framework (excluding any data provided by [Service Recipient]).

“Labelling Technology” means any technology created or developed in the course of processing, formatting, labelling and/or modifying any data, regardless of origin or source, into a format compatible for ingestion into any input layer or mechanism of the deep-learning framework or the [Software], where such processing, formatting, labelling and/or modification has been conducted by or with any assistance or input from [Service Provider] or any of its affiliates, or any of its or their licensors, service providers, agents or contractors.

Datasets

Value of datasets

- The success of a machine learning algorithm often depends on the unique datasets that can be fed into the system to train the framework.
- Typical approach:
 - Service recipient provides input data for training and owns such data.
 - Consider whether service provider may need a license to use/modify such data.
 - Service provider assists service recipient in “preparing data” and configuring for input into the core framework.
 - Consider whether service recipient may need a license to use/access service provider’s documentation/specifications for data preparation purposes.
 - Service recipient and service provider jointly own output data or separately define scope of ownership and use rights as to output data.
 - Consider how ownership rights as to output data can be allocated between service provider and service recipient.
 - Consider license rights that each party may need to grant to the other for continued use of output data.

Sample language

The Framework and Labelling Technology, and related documentation, are proprietary to [Service Provider] or its licensors and all applicable rights in and to the Framework and Labelling Technology, and related documentation, including but not limited to, rights in confidential and trade secret material, rights in databases or data, trademarks, service marks, patents, copyrights and other intellectual property or proprietary rights, will be [Service Provider's] or its licensors' sole property. The license granted under this Agreement provides only the right of limited use with respect to such Framework and Labelling Technology and related documentation as expressly permitted by the terms and conditions of this Agreement, and no other right, title or interest in or to any other rights of [Service Provider] or its licensors is granted.

In consideration of the licenses granted by [Service Provider] pursuant to this Agreement, [Service Recipient] hereby irrevocably assigns, conveys, grants and transfers, and agrees to assign, convey, grant and transfer, to [Service Provider] and its successors and assigns, all right, title and interest of every kind and character throughout the world that [Service Recipient] may acquire or possess in or to any portion of the Framework and/or Labelling Technology, to the full extent of its rights or interest therein (if any).

Liability concerns

- **Shift in liability concerns:**
 - Current contracting models generally account for failures based on human error
 - SLAs focus on standardizing level and quality of service personnel
 - Data protection and security provisions often backed by audit and inspection rights, focusing on oversight and monitoring of human error
 - Liability exclusions address human-based errors, including gross negligence and willful misconduct
 - AI/machine learning services have different failure concerns
 - General risk associated with use of framework in its development stage
 - Greater risk of large-scale “catastrophic” failures, as errors may accumulate rapidly and be caught less frequently
 - Lack of oversight into internal processes of framework and how it functions with newly input data
 - Less control of data ingested into framework, including risk of pollution with “bad” training data

Liability concerns: contractual allocation

- **Questions to consider from a contractual perspective**
 - Who is liable for the acts of the AI framework (e.g., the core algorithm owner, the data provider, the user)?
 - On what basis will liability need to be decided (e.g., vicarious liability, strict liability)?
 - What types of failure modes must the service provider protect against?
- **Suggested contractual protections for service provider**
 - Broad liability disclaimers that account for:
 - errors and inaccuracies resulting from use of the core algorithm,
 - loss or corruption of service recipient's data through use of algorithm,
 - service recipient's reliance and actions based on output of algorithm.
 - Strict capping of liability and disclaiming of indirect and consequential damages
 - No obligations to indemnify service recipients for any harm incurred through use of algorithm
 - Limitations on service recipient's remedies (e.g., limited to service provider's making commercially reasonable efforts to correct errors)

Liability: Sample language

Sole remedy:

[Service Provider's] sole liability and [Service Recipient]'s exclusive remedy under any warranties set forth herein, shall be for [Service Provider] to attempt, through commercially reasonable efforts, (i) to correct such non-performance of the [Software] or (ii) to provide materials to implement such correction, including updates, patches, error corrections and workarounds, at [Service Provider's] election. The foregoing remedies are available only if [Service Recipient] discovers the above warranty breach during the [Warranty Period] and [Service Recipient] notifies [Service Provider] promptly in writing of such discovery.

Notwithstanding the foregoing, [Service Recipient] acknowledges and agrees that due to nature of the [Software] and of the tools and processes used to develop the [Software] and the underlying technology thereof, a certain degree of error or inaccuracy is inevitable, and that [Service Provider] therefore makes no guarantee or warranty, and hereby expressly disclaims, both during the [Warranty Period] and thereafter, any guarantee or warranty that (x) the results, output or other data provided through or generated by the [Software] (the "Results") will be error-free, accurate, complete or reliable, (y) the quality of the [Software] and/or the Results will meet [Service Recipient]'s requirements or expectations (other than to the extent expressly set forth in the related documentation) or (z) any of the foregoing will be corrected. No advice, support or other communication provided by [Service Provider] or its affiliates, or any of its or their employees, licensors, service providers, agents or contractors, shall create any express or implied warranty with respect to the [Software] or any Results. [Service Recipient] fully understands and acknowledges that [Service Recipient]'s use of the [Software] and Results is at its own risk and that [Service Recipient] will be solely responsible for any damage to property or loss of data that results from use of the [Software] or any Results.

Liability: Sample language

Disclaimer of other warranties:

EXCEPT FOR THE EXPRESS, LIMITED WARRANTY PROVIDED HEREIN, [SERVICE PROVIDER] MAKES NO WARRANTIES, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, WITH RESPECT TO ANY [SERVICE PROVIDER] MATERIALS, OR THE RESULTS OR ANY OTHER MATERIALS PROVIDED OR GENERATED HEREUNDER. [SERVICE PROVIDER] SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ACCURACY AND NONINFRINGEMENT AND THOSE ARISING FROM A COURSE OF DEALING, USAGE OR TRADE, AND ALL SUCH WARRANTIES ARE HEREBY EXCLUDED TO THE FULLEST EXTENT PERMITTED BY LAW.

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Liability: Sample language

Limitation on liability:

IN NO EVENT SHALL [SERVICE PROVIDER'S] LIABILITY ARISING UNDER THIS AGREEMENT EXCEED THE AMOUNT PAID BY [SERVICE RECIPIENT] FOR THE APPLICABLE [SERVICE PROVIDER] MATERIALS PROVIDED TO [SERVICE RECIPIENT]. [SERVICE PROVIDER] WILL NOT BE LIABLE TO [SERVICE RECIPIENT] FOR (A) ANY DECISION MADE OR ACTION OR NON-ACTION TAKEN BY [SERVICE RECIPIENT] IN RELIANCE UPON ANY RESULTS, (B) ANY CONSEQUENTIAL, INCIDENTAL, SPECIAL, INDIRECT, PUNITIVE, OR EXEMPLARY DAMAGES, INCLUDING WITHOUT LIMITATION, LOST PROFITS, BUSINESS, CONTRACTS, REVENUE, GOODWILL, PRODUCTION, ANTICIPATED SAVINGS, LOSS OF DATA, OR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, OR (C) ANY CLAIM OR DEMAND BY [SERVICE RECIPIENT], IN EACH CASE, HOWEVER CAUSED AND (TO THE FULLEST EXTENT PERMITTED BY LAW) UNDER ANY THEORY OF LIABILITY (INCLUDING NEGLIGENCE) EVEN IF [SERVICE PROVIDER] HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. [SERVICE RECIPIENT] ACKNOWLEDGES AND AGREES THAT [SERVICE PROVIDER] WOULD NOT HAVE ENTERED INTO THIS AGREEMENT OR MADE AVAILABLE TO [SERVICE RECIPIENT] ANY [SERVICE PROVIDER] MATERIALS PROVIDED TO [SERVICE RECIPIENT] IN THE ABSENCE OF THESE LIMITATIONS AND THAT THE AMOUNTS PAYABLE HEREUNDER ARE BASED IN PART ON THESE LIMITATIONS, AND FURTHER ACKNOWLEDGES AND AGREES THAT THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

**HORRISON
FOERSTER**

**Thank you +
Q&A**

