CHALLENGES IN LAUNCHING A CLOUD-BASED AI MEDICAL SOLUTION.

INSTRUCTOR: DR. ZOYA KINSTLER, TA: TAKAYUKI IIDA

It was significant progress in artificial intelligence (AI) in healthcare when US Foods and Drug Administration (FDA) approved ViosWorks, a platform that uses elements from both Arterys and General Electric (GE) Healthcare in early 2017. The technology leverages cloud computing and deep learning for medical imaging. The Arterys component was first of its kind approved to aid doctors to diagnose heart problems (Marr, 2017). Unlike traditional medical imaging software, Arterys automates time-consuming analyses and tasks that are performed manually by clinicians today, while allowing physicians edit the automated contours if desired. It uses deep learning algorithms to implement a 4D Flow software that visualizes and quantifies the anatomy and blood flow in and around the heart (Idrus, 2017), hence significantly improving on GE Healthcare's magnetic resonance imaging (MRI) techniques. To be approved by the FDA, the solution had to pass rigorous assessments that some see as potential challenges for similar products needing acceptance in the market.

One of such challenges is being able to handle the three defining properties or dimensions of big data required by deep learning, usually referred to as the 3Vs: volume, variety, and velocity. Volume refers to the amount of data, variety the number of types of data and the velocity relates to the speed of data processing. These properties directly lead to run-time and model complexity. The sheer volume of data makes it often impossible to train a deep learning algorithm with a central processor and storage, because of the significantly large number of samples and parameters needed. Also, incompleteness and noisy labels due to diverse origins is a characteristic of high volume data. GE Healthcare's CEO John Flannery predicted a 50-fold increase in the flow of data from healthcare devices by 2020. ViosWorks is expected to capture as much as five gigabytes of data, compared to about 100 megabytes in a conventional MRI scan (Tansey, 2016). To handle that flow and increasing data size, a scalable storage solution was required. Arterys and GE Healthcare started off with Amazon AWS. However, eventually, data processing will be shifted to GE Health Cloud created late 2016.

The second dimension - variety, stems from the fact that data comes from different sources with a different distribution, formats, resolution, and types, which could introduce lots of conflicting information. Arterys' CTO, John Axerio-Cilies, said companies would be tempted to offer such tools directly to consumers like the Mole Mapper - a non-AI cellphones app that allows people to track suspicious moles and record or report any changes over time to health practitioners (Brouillette, 2017). Doing this is in line with the goal of making the new system cost-effective to be available to any patient around the world. If that is the case, FDA foresees such data variety a significant concern. Thus, a natural solution to address this is data integration to learn data representations from each data sources using deep learning methods - supervised or unsupervised methods or combination of both, and then integrating the learned features at different levels. Current experiments like in the case of Deep Boltzmann Machine (DBM) has shown this is possible (Chen & Lin, 2014), but it now depends on the needed abstraction level, efficiency, and effectiveness of the process based on business needs.

Generation of data at an extremely high speed and the need for such to be processed promptly are challenges of data velocity, with an added issue of data distribution changing over time - non-stationary. With GE Healthcare tweaking its traditional MRI scanners and capturing so much raw data on the heart that computers could not assemble into images that doctors could intuitively interpret, Arterys had to transform 2D slices of such into 3D animations. These animations now required parallel or distributed computing using clusters of CPUs or GPUs in increasing data training speed without sacrificing accuracy of the algorithms. An industry recommendation to learn from such data was to implement online learning approaches. Online learning learns one instance at a time, and the right label of each case will soon be available to be used for refining the model. This strategy mainly works for big data as some machines cannot hold the entire dataset in memory. A better approach is to use mini-batches to speed up learning and updates, instead of proceeding sequentially one example at a time, allowing a better balance in computer memory and runtime usage. In the case of the latter, it is necessary for the algorithm to learn the data as a stream since non-stationary data usually are separated into chunks with data from a small time interval. It was with the assumption that data close in time are piece-wise stationary. And, also may be characterized by a significant degree of correlation and, therefore, follow the same distribution (Chen & Lin, 2014). The cloud solution used allowed the implementation of all these.

The FDA wanted to make sure results of the tests from Arterys were on par with those generated by physicians. These however exceeded expectation by averaging about 10 to 15 seconds to produce a result for each case, which a professional human analyst would expect to spend between 30 minutes to an hour working on. This extreme efficiency was achieved by feeding in a thousand cardiovascular cases as training data and coming up with 10 million rules using supervised learning algorithms based on connections found in the data. Although the prediction was efficient and accurate, no one was sure what features and data point the algorithms used for classification. And, how the algorithms find the rules without any audit trail to explain its decisions, which results in the medical version of a term called deep learning's "black box" problem (Brouillette, 2017). However, a similar argument that Lithium, a drug whose exact biochemical mechanism in affecting mood has yet to be elucidated, but was approved by the FDA for treatment of bipolar disorder made such cases overlooked with the agreement that companies are allowed to keep the details of their algorithms confidential.

Fear of data privacy and security and medical ethics were other FDA concerns because of the cloud storage. It would be morally wrong to have people provide their health data for training purposes of the machines. Also, cloud service infrastructures are known to have multiple security issues because of the multi-tenant implementation. The solution was a system known as personal health information (PHI) service that stripped personal identifying information from the imaging data at the point of collection - a hospital. When accredited users of the system – doctors or other medical staff with authority to view personal records – log in, it grabs the imaging data and analytical results from Arterys's cloud, and the PHI from the hospital's secure server, and rebuilds it. Arterys itself never receives any information which can be used to identify individuals. Authenticating systems like this, backed by encryption and secure transfer protocols are likely to play an increasing role in overcoming problems inherent to storing and analyzing personal data. The FDA's approval is another significant step forward.

Partnership similar to what GE Healthcare and Arterys have in the market will not be the last. Companies like Siemens - a significant competitor with GE Healthcare in MRI, without a 4D Flow MRI system on the market already have similar systems in the works. Over the past 20 years, the FDA reported to have approved many other image analysis applications that rely on a variety of pattern recognition, machine learning, and computer vision techniques, and are currently racing to catch up with demand (Molteni, 2017). So, this is trending with great potential. Startups or established companies looking to go solo or in partnership in launching similar products in the market can learn from these challenges mentioned above. Understanding these beforehand helps corporations weigh options, plan and make necessary adjustments to reap benefits without necessarily being drowned by pitfalls.

References

Chen, X., & Lin, X. (2014). Big Data Deep Learning: Challenges and Perspectives. IEEE. http://ieeexplore.ieee.org/document/6817512/

Brouillette, M. (2015). Deep Learning is a Black Box, but Health Care Won't Mind https://www.technologyreview.com/s/604271/deep-learning-is-a-black-box-but-health-care-wont-mind/

Idrus, A. (2017). Arterys nabs second FDA OK for deep learning, Image Analysis Software. http://www.fiercebiotech.com/medical-devices/arterys-nabs-second-fda-ok-for-deep-learning-image-analysis-software

Marr, B. (2017). First FDA Approval for Clinical Cloud-Based Deep Learning In Healthcare https://www.forbes.com/sites/bernardmarr/2017/01/20/first-fda-approval-for-clinical-cloud-based-deep-learning-in-healthcare/#b78354d161c8

Molteni, M. (2017). Medicine is Going Digital. The FDA is Racing to Catch Up. https://www.wired.com/2017/05/medicine-going-digital-fda-racing-catch/

Tansey, B. (2016). Arterys, GE Healthcare to Roll Out Next-Gen MRI Scans of Heart. http://www.xconomy.com/san-francisco/2016/10/19/arterys-ge-healthcare-to-roll-out-next-gen-mri-scans-of-heart/