ISSUE 9

Health Matters Bulletin

BY ***REBOOT HEALTH CONSULTANCY & ADVISORY SERVICES INC.***

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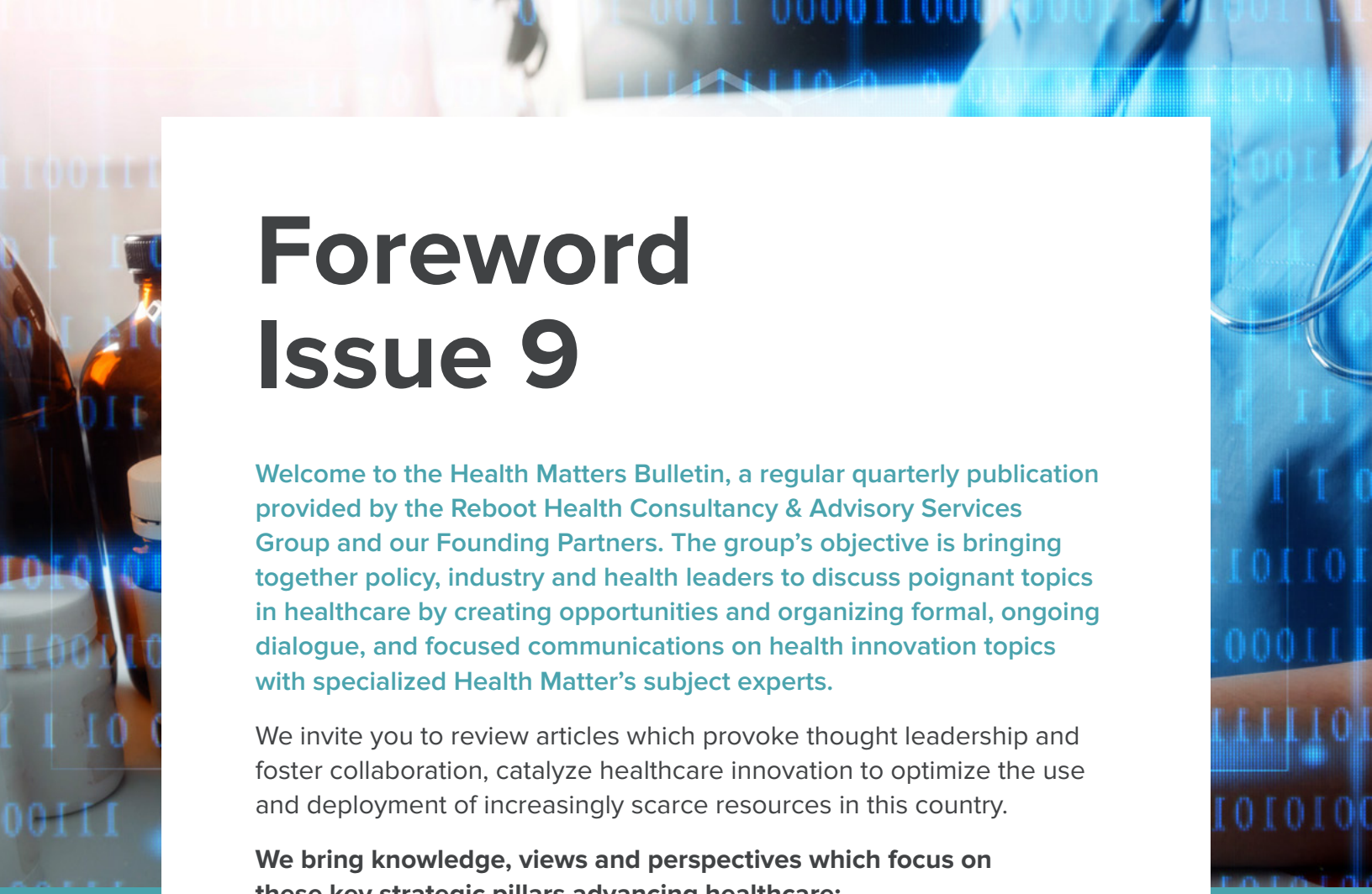

Foreword Issue 9

Welcome to the Health Matters Bulletin, a regular quarterly publication provided by the Reboot Health Consultancy & Advisory Services Group and our Founding Partners. The group's objective is bringing together policy, industry and health leaders to discuss poignant topics in healthcare by creating opportunities and organizing formal, ongoing dialogue, and focused communications on health innovation topics with specialized Health Matter's subject experts.

We invite you to review articles which provoke thought leadership and foster collaboration, catalyze healthcare innovation to optimize the use and deployment of increasingly scarce resources in this country.

We bring knowledge, views and perspectives which focus on these key strategic pillars advancing healthcare:

OUR KEY STRATEGIC PILLARS

- **Health Data Privacy, Policy and Security**
- **Personalized Medicine and Genomics**
- **Artificial Intelligence in Healthcare**
- **Value Based Healthcare, Operational Efficiency and Health Policy**
- **Health Innovation Development**

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Dementia Biomarkers are Changing AD Clinical Practice

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Alzheimer's disease (AD) is a devastating, incurable, neurodegenerative condition experienced by more than 600,000 Canadians.[1] More than 95% of cases are sporadic and occur late in life, with pathophysiological hallmarks of accumulated amyloid-β (Aβ) peptide and neurofibrillary tangles of tau protein in the brain.[2] Preclinical disease may be present for decades before the onset of clinical signs and symptoms which, once overt, typically progress over 8 to 10 years, ultimately leading to death from complications.[2]

DIAGNOSIS COMPLEXITIES

AD symptoms usually emerge after the age of 60 although people with certain rare genetic mutations may develop the disease earlier.[3] Currently and historically, AD diagnosis is confirmed post-mortem through brain autopsy, or based on clinical

symptoms, including cognitive testing, with a significant number of patients diagnosed when their disease has already advanced. A diagnosis of AD based on cognitive measures alone is only correct in 70% to 80% of cases. Even with imaging studies such as computed tomography (CT) and magnetic resonance imaging (MRI), or positron emission tomography (PET) the diagnosis might not be conclusive.[3]

In Canada, national guidelines for the diagnosis of AD suggest that most screening and clinical workup be completed by a primary care physician (PCP), and that more advanced diagnostics require referral to specialty clinics.[4]

However, studies suggest that less than half of those living with dementia receive a diagnosis, and many progress while they wait.[5] While clinical criteria have been the primary basis for the diagnosis of AD dementia, biological definitions of AD, based on biomarkers of Aβ deposition, pathologic tau, and neurodegeneration, have been used in research settings.[4]

NEW ERA OF DISEASE MODIFYING THERAPIES

Although historically, only symptomatic therapy is available and there have been no disease modifying treatment options for AD, a number of drugs aimed at modifying the disease in its earlier stages (i.e. mild cognitive impairment (MCI) due to AD and mild AD dementia) are currently under investigation or have recently reported promising results. This indicates that the treatment approach for patients in early stages of the disease should be different from the approach for those in later stages.[6,7,8]

Once approved, the long-awaited era of disease-modifying therapy for Alzheimer's disease would finally arrive and will substantially impact how the disease is managed. However, no national/provincial health-care system is ready to deliver these therapies to more than a fraction of patients who might be eligible as existing health system capacity constraints and the need for biomarker-driven diagnostics to confirm DMT eligibility are concerning.[9] Many of these treatments target Aβ peptide, two of which have received US Food and Drug Administration approval for AD treatment: aducanumab and lecanemab.[10,11]

ROLE OF BIOMARKERS

Aβ-targeted therapies require detection of Aβ aggregation and here is where biomarkers are of enormous use in Alzheimer's as they are objective measures, they are reproducible, and they are independent of the clinician's judgment. Aβ aggregation evidence can be detected using cerebrospinal fluid (CSF) or positron emission tomography (PET) to determine treatment eligibility.[12-16] A blood biomarker as evidence of Alzheimer's pathology might also become available in the future.

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These modalities have advantages and disadvantages in terms of cost, access, and acceptability. Upscaling access to CSF testing should be more cost-effective than PET and could provide evidence for both amyloid and tau pathology. CSF testing requires lumbar puncture capacity with trained nursing or medical staff, and laboratory staff and equipment for analysis and interpretation. Amyloid PET requires scanner and tracer availability, nuclear medicine physicians, and is expensive.

Unfortunately, low numbers of dementia specialists and limited access to imaging lengthen wait times for such services in Canada.[17] It was highlighted in the recent Canadian Conference of Dementia that, "expanding CSF biomarker access for Canadian patients while building stronger evidence for future blood-based biomarkers will lead to patients potentially eligible for DMTs receiving a diagnosis sooner".[18]

THE POWER OF KNOWING

Using a biomarker to provide timely diagnosis also brings other types of benefits for patients as shown in investigations done at UBC. Based on this research, many people who have Alzheimer's disease want to know their diagnosis, and diagnostic clarity seems to be the major motivator in their decision to undergo diagnostic testing. Patients and care partners use biomarker results to their benefit in making positive lifestyle changes and planning for their futures. Learning biomarker results behind this diagnostic certainty produce positive feelings in patients and caregivers. Knowing can provide a sense of relief and allow patients and families to plan ahead, seek support, make practical decisions, learn how to adapt to the symptoms and maintain or even improve quality of life.[19] Findings also demonstrated the value of early diagnosis in guiding medical care, even in the absence of disease-modifying therapeutics as substantial changes in clinical management were observed as a direct result of Alzheimer's disease biomarker testing. Appropriate use of AD drug therapies increased for biomarker-positive patients, and decreased for biomarker-negative patients, and the use of biomarkers decreased the need for costly brain imaging diagnostics.[20]

CONCLUSION

The key to transforming the life of people with Alzheimer's disease is to diagnose as early as possible and to intervene with the right care plans. New diagnostics tests, like CSF biomarker testing, has the potential to streamline a patient's journey, improving speed and access toward a confirmatory diagnosis, giving people with Alzheimer's disease and their caregivers more time to plan and prepare for the future.

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References: *References can be accessed **here**.*

Dr. Alonso Montoya is a highly experienced Neuropsychiatrist with a unique background in clinical research, biopharmaceutical medicine, and medical affairs with over 15 years of experience driving transformative change within healthcare in Europe and Canada. His therapeutic expertise spans several therapeutic areas including neurodegenerative, neurodevelopmental, and neuropsychiatric conditions, personalized care, and digital health.

Dr. Montoya undertook his psychiatry residency training at the National Institute of Neurology and Neurosurgery in Mexico, completed a clinical fellowship training in Neuropsychiatry at Harvard Medical School, and conducted his postdoctoral research in Functional Neuroimaging at McGill University. He is a published author with more than 40 peer-reviewed publications.

For the last years his focus has been helping to provide full spectrum solutions that meet the needs of people facing Alzheimer's and Multiple Sclerosis – from diagnostics through to impactful therapies and monitoring tools for all stages of disease – and currently leads the Neurodegeneration Biomarkers in Roche Diagnostics in Canada.

Early identification of disease and prevention, along with longevity and healthy aging are one of the most complex phenotypes being studied. There is great interest in investigating the ***Biology*** of healthy aging and longevity together with the ***Genetics*** of healthy aging and longevity. Working together with the leading experts in the area, there are plans to develop a Summit to discuss Healthy Aging and Longevity. If you are interested in hearing more or being involved, share your contact information **here**.

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Revolutionizing Healthcare Through Data-Driven Innovation

One of the goals that the organizers of the Annual Healthcare Summit (HCS) strive to achieve every year, is to deliver valuable thought-leading discussions that stimulate innovation and drive improvements in Healthcare. Changes in healthcare are remarkably slow compared with other industries. By some estimates it can take up to 20 to 25 years for healthcare systems to adopt newly developed technologies, even those approved by regulatory bodies like Health Canada. This rate of adoption brings a level of stagnation that only a crisis like the one experienced during the COVID-19 pandemic can overcome and then demonstrate that collaboration, learning and implementing new technologies fast can have life-saving outcomes. Improvements in how we approach the most dangerous of diseases like cancer have made remarkable progress over the years by adopting new technologies more rapidly with the desired outcome of saving lives and improving healthspan.

Data driven innovations that are adopted and employed by the health system and the practitioners enable efficiency and better clinical decisions. As presented at this year's summit and discussed at length, healthcare now faces one of the greatest technological advances with the emergence of generative artificial intelligence (AI) systems that can process and make sense of health data more similar to human processing than was previously possible. How these new advances in AI are adopted and the speed of implementation will determine how their potential to revolutionize healthcare is realized.

EMERGENCE OF THE COGNITIVE AGE – HOW AI IS DELIVERING BETTER HEALTHCARE

Generative AI systems or Large Language Models (LLMs) like GPT-4 have emerged with unparalleled adoption (over 100 million users three months after being launched) as they can discuss almost any topic at an almost human level. As presented by John Nosta, LLMs act as expansive digital libraries and interactive thought partners to solve challenges like those in healthcare. Distinctly different from other AI tools, the interaction with LLMs is beyond transactional. It is a nuanced dialogue facilitated by a new level of "technological intimacy." Like all data driven tools, LLMs rely on large amounts of quality data to make quality decisions. Accessing data will also need to be managed by regulators to ensure individual consent is received and personal privacy is respected and preserved. As these models evolve and as the data they access for training is curated as valid, they have the potential to further enrich our intellectual toolkit, offering new avenues for understanding health and disease and supporting practitioners and patients for better health outcomes. It is no surprise that John Nosta contends that AI and GPT are catalyzing the next industrial revolution.

The application of AI tools is not new to innovations in healthcare. Personal journeys through cancer detection and treatment provide clear examples on how patients benefit from the use of innovative and validated new technologies. Three courageous cancer patients took the stage at the summit and graciously recounted their journeys that in turn highlighted the benefits of employing AI in health. The early adoption of technology for these individuals was/is impactful on their health.

AI ENABLED PRECISION IMAGING AND THERAPY

Dr. Martin Dawes, Past Head of Family Medicine at UBC, had his metastatic myeloma first discovered when he lost his balance on a hike. Recognizing the risks, his doctor ordered a brain scan. The imaging of the tumours in his brain were enabled by AI assisted CAT scans that localized them with millimeter precision to allow for their careful surgical removal with minimal damage to surrounding normal tissue. Biopsies of the tumours were genetically sequenced and analyzed using AI assisted systems to identify the most appropriate targeted therapy. Gratefully, immunotherapy proved remarkably effective at picking up the malignant cells that had metastasized throughout and with laser-like

precision, guided Dr. Dawes' immune system to destroy the cancer. The design and development of the immunotherapeutic drug was supported by multiple AI systems. Dr. Dawes' positive outcome was in part supported by the employment of multiple AI systems in the detection and treatment of his cancer.

AI ANALYTICS AND DATA INTEROPERABILITY FOR TARGETED CARE

Dr. Soyean Kim, a Statistician whose work deals with healthcare IT infrastructure and technologies that support genomics-based innovation, was recently diagnosed with advanced stage 3 colorectal cancer. After suffering through the one-size-fits-all non-targeted chemotherapy applied by B.C.'s program, Dr. Kim sought a more targeted approach to treating her cancer. As a genetic researcher she recognized the need to gather the data about her tumours to successfully analyze and select a targeted treatment with a high likelihood of efficacy and fewer toxic effects. To do so, Dr. Kim had to get the oncogenomic sequencing done abroad as it is not common to Canadian Healthcare. Done at a high personal expense, Dr. Kim had the data on her tumour generated, but faced the next challenge of how to integrate the data with other data assets to find a treatment utilizing AI supported technologies. Due to the lack of interoperable data systems compounded by variable legislation and regulations across jurisdictions, coordinating the care abroad with that received in Canada continues to be a barrier. This also highlights the need for preserving control over personal health data and sharing one's own health data regardless of the jurisdiction and health provider. Dr. Kim continues her journey as she seeks the personalized care needed to defeat her cancer.

AI-POWERED MULTI-OMIC BLOOD ANALYSIS FOR EARLY DETECTION AND INTERVENTION

Dianne Balon, a Senior Executive for Healthcare in Alberta had been actively managing her health through a variety of means. She met regularly with her primary care physician and took additional preventive measures to avoid serious illness. She undertook annual molecular level blood assessments (**www.molecularyou.com**) that employed AI to analyze the data on her personal blood biomarkers to accurately determine her health status and provide lifestyle action plans to help lower her health risks. On her fourth analysis, while taking part in a long-COVID study, the AI-powered molecular blood analysis identified that she was at high risk for pancreatic cancer. Her primary care physician was notified, and in turn ordered MRI imaging be performed. The imaging indicated the presence of small lesions on her pancreas. The follow up biopsy indicated she had stage 1 pancreatic cancer consistent with the Molecular You assessment. Surgery was performed and she is now cancer free, and the molecular level analysis indicates the out-of-range biomarkers have returned to normative values.

[On behalf of the HCS organizers, we owe these individuals a great debt of gratitude for sharing their personal health journeys. Editors]

REVOLUTIONIZING HEALTHCARE THROUGH AI-ASSISTED ANALYSIS

Revolutionizing healthcare using personal patient data sets will require the continued rapid adoption of AI systems. Applying LLMs that are trained on accurate data sets that have been consented for use, so disease can be detected early (pre-symptomatic), and personalized prevention and/or personalized treatment strategies selected providing physicians with the knowledge to deliver best outcomes for patients and simultaneously deriving savings to our healthcare system. There are signs that the rate of adopting new innovations into healthcare is improving, however there remains significant potential for improvement in order to fully optimize the full potential that currently exists. Canada has world-leading expertise in AI, data consent management, molecular level analytics and genomic technologies. If it were willing and enabled rapid adoption of these technologies, Canada could lead the world in revolutionizing healthcare with predictive, preventive and personalized care providing an efficient system that engages practitioners, patients and payers.

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Molecular You allows organizations to assess and guide their people to better health, while providing individuals with unparalleled insight into their chronic disease risks. Based on a new type of blood test we can assess hundreds of biomarkers and translate the results into targeted lifestyle interventions, delivered through our easy-to-use digital platform. For more information, please visit. **www.molecularyou.com**

If you missed a session at the 23rd Annual Healthcare Summit, you can view the presentation files for some of our keynote speakers by visiting our event page **here**.

Stay tuned for more information on our 24th Annual Healthcare Summit scheduled for ***October 29th - 30th, 2024*** in Vancouver, BC.

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Data Trusts: A Paradigm Shift to Accelerate AI Research & Innovation

Image by Freepik

Is the Canadian health sector poised to lose out in the race to develop artificial intelligence (AI) technologies because we are not making health data more readily available for research and innovation in this country? In my view, the answer is a resounding yes. I have witnessed this through personal experience.

Faced with the constant pressures of overflowing emergency departments, long surgical waitlists and restoring aging infrastructure, hospitals and health authorities have little time and resources to innovate when it comes to improving access to data for research and innovation. We recognize research and innovation is necessary to overcome shortages in health human resources. In discussions around resolving the ever increasing healthcare demands, we point to AI and other healthcare technologies as an important part of the answer. But who is figuring out how to provide better access to the vast volumes of data that researchers need in order to develop those AI technologies and develop solutions?

The best analogy that I can think of when it comes to the plight of researchers trying to get access to health data to their work is that of young Oliver Twist who musters up the courage to ask for more food, only to be ridiculed and met with disdain. Although this may be a bit of an exaggeration, researchers and innovators are hungry for data and often times they must wait many months and even years for the data, if they receive it at all.

With the rapid pace at which AI development is taking place, this delay in data access is only going to hinder healthcare innovation in this country even more, and there is a critical need for change. One promising solution is a legal and data governance framework known as a “data trust”. A data trust is essentially taking the concept of the legal trust, where a third-party trustee is entrusted with administering assets for the benefit of beneficiaries, and applying it to data, as opposed to the usual money or real estate.

Having health institutions put their data in a trust so that it can be administered more effectively by an expert third party to support research and innovation makes sense from many different perspectives.

Firstly, it unburdens healthcare institutions from the task of developing and implementing better processes on their own. The complexity of managing the entire process to locate the data, de-identify, extract and curate it so it is research-ready is not only complicated, but costly. For example,when applying this to medical imaging data, it must be considered that these are notoriously large files and therefore more resource intensive to handle, requiring specialized expertise and capacity to do this well.

In addition, there is the business and legal side to manage. Consider, what is your data licensing model and strategy? It must help cover your resourcing costs, but cannot be so expensive that projects cannot proceed. How do you manage intake and track the progress of requests as well as invoice and collect payment? What form of data access agreement is appropriate to put in place with the external parties involved? How do you track the data that has been provisioned and ensure ongoing compliance with the data access agreement? What data governance framework do you have to establish to ensure proper oversight of the activity from a legal, privacy and ethics perspective? How do you ensure public trust and confidence in your process and activities, including addressing any patient consent requirements? These are just a few of the questions that must be answered and few healthcare institutions have figured these out today.

Secondly, the data trust model espouses a service delivery mentality that seeks to create a positive user experience for researchers that unburdens them as much as possible so they can focus on doing more robust research. Contrast this with today’s prevailing mindset, which is focused on cost and risk mitigation, i.e. provide the minimum data and only after they meet a long list of due diligence requirements. In my view, you can achieve service excellence without compromising privacy or security by designing your processes in the right way. There is no correlation between length of due diligence and increased privacy and security.

Thirdly, the data trust model supports the creation of a single process through which researchers can access data from all organizations who contribute data to the data trust. This would truly unlock the power and value of the health data that we have in this country. Imagine the possibilities if our AI development projects can have streamlined access to all the medical images they need from multiple sites across the country in a single data request and where all the cross-jurisdictional legal, privacy and data governance complexities are taken care of by the data trust services team. This is the promise that the data trust model holds: we can create a network of interoperable data trusts across the country, which effectively function like a "Data Supercharging Network" in order to securely "supercharge" research and innovation projects with high quality Canadian healthcare data.

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Steven Tam is senior legal and privacy professional who served as General Counsel & Chief Privacy Officer at Vancouver Coastal Health (VCH) for over 12 years. He led the development of the General Health Information Sharing Agreement (GHISA), a unified legal, policy and data governance framework signed in 2013 between the BC Ministry of Health and all BC health authorities that governs almost all sharing of health information across the province for provision of care, research, quality improvement and healthcare planning.

Most recently, he served as VCH's Chief Data Governance Officer where he worked to transform how data is strategically governed and managed so that higher quality data is made more accessible to clinicians, researchers and administrators to deliver better care and improve our healthcare system, while enhancing data security, privacy and ethical use of health data.

Pursuing the data trust model will require an unprecedented level of collaboration and cohesion amongst the research and innovation community to push for a fundamentally better way of stewarding healthcare data in this respect. It means stepping up to say that we are willing to invest in the time and resources to do this and engaging healthcare institutions to make it happen strategically and financially. Those who are daring enough to move forward together, contact Steven Tam (**stevencstam@gmail.com**).

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