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## Genes for sale?

**Other countries have statutory bodies that oversee their national genomics medicines programmes, but not Ireland. For the first time, we can reveal the extent of the harvesting of Irish genetic data by the for-profit company Genuity, which has dozens of link-ups with Irish hospitals, universities and health organisations**

**By Killian Woods  
and Barry J Whyte**

**I**n the middle of last year, Simon Harris got a striking lesson on Ireland's place in the genomics medicine revolution. It came during a discussion with Nicola Blackwood, the Under Secretary of State for Health in Britain, on the potential for collaboration between the two jurisdictions.

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Professor Orla Hardiman says Ireland is 'putting profit before people with its genomic medicine strategy'

What we have yet to do is put in place the kinds of structures that our European neighbours assembled before embarking on national genome initiatives

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Such discussions make sense given this technology allows researchers the ability to gather large volumes of genetic data and, from them, derive new diagnostic tools and new therapies for previously intractable (and often fatal or severely life-limiting) diseases.

Harris's discussion, however, threw up something of a red flag. Blackwood had "made an assumption" that Genomics Medicine Ireland was "the public-funded equivalent in Ireland of Genomics England".

In fact, it is no such thing. Genomics Medicine Ireland is owned by private investors, while Genomics England is the state-owned entity that oversees Britain's genomics medicine programme.

In short, Blackwood had mistaken a private, for-profit company as an arm of the state - an issue that was already something of a bigbear for the Department of Health where senior officials knew that it was "not unusual for international stakeholders, particularly those in the UK, to assume that Genomics Medicine Ireland is equivalent to Genomics England".

The exchange with Blackwood is revealed in Department of Health documents obtained as part of a months-long investigative collaboration between the Business Post and Noteworthy, the community-led investigative platform from TheJournal.ie.

Department's concerns The same documents show senior civil servants had already told Harris that "the department would have concerns as to the extent to which GMI presents itself as a national project when it is a private predominantly foreign-owned operator".

And while Harris "merely clarified [with Blackwood] when it arose that this is not the case in Ireland", he clearly returned home somewhat nonplussed by the whole matter and told officials that he wanted to speed up the creation of a national genomics programme.

A \$400 million investment to fund its plan to sequence the genomes of 400,000 people in Ireland.

At that stage, she said the company had already collected tens of thousands of samples. Last week, the firm declined to provide an update on this figure.

The company had also started to make significant money from selling access to the genomic data it was gathering. In 2018, the firm's revenue hit \$11.6 million - a tenfold increase compared to the previous year.

So confident was Jones that she told the Business Post the company would be going for an initial public offering on the stock market within the next two years.

In 2018, the company's public relations firm asked the then Taoiseach Leo Varadkar to give his endorsement to the company's research programme in order to foster the "perception externally... that the government is embracing the efforts... as the country's genomic initiative".

Varadkar agreed, recording a video in which he did precisely that, describing GMI as "a real success story" that had "experienced impressive growth".

He also referenced the fact that the state's strategic investment fund was a significant investor in the firm - to the tune of €66 million to date.

The endorsement, the company's funding and millions in revenue put serious momentum behind a business that has prospered in the vacuum left by state inaction.

The investigation team confirmed that, in total, nine hospitals have struck research deals with the company, including Beaumont, Tallaght, St James's Hospital, St Vincent's University Hospital, Galway University Hospital, University Hospital Limerick, Temple Street and Crumlin Hospital.

Further links were discovered with Mercy Hospital Cork, Mater University Hospital, Cork University Hospital and Portlucan University Hospital.

As part of arrangements discovered, the investigation team has also confirmed that Genuity Science provided funding to ten Irish facilities, including hospitals and universities. Many institutions, including University College Cork and University Hospital Limerick, declined to confirm if funding was received because it was "commercially sensitive".

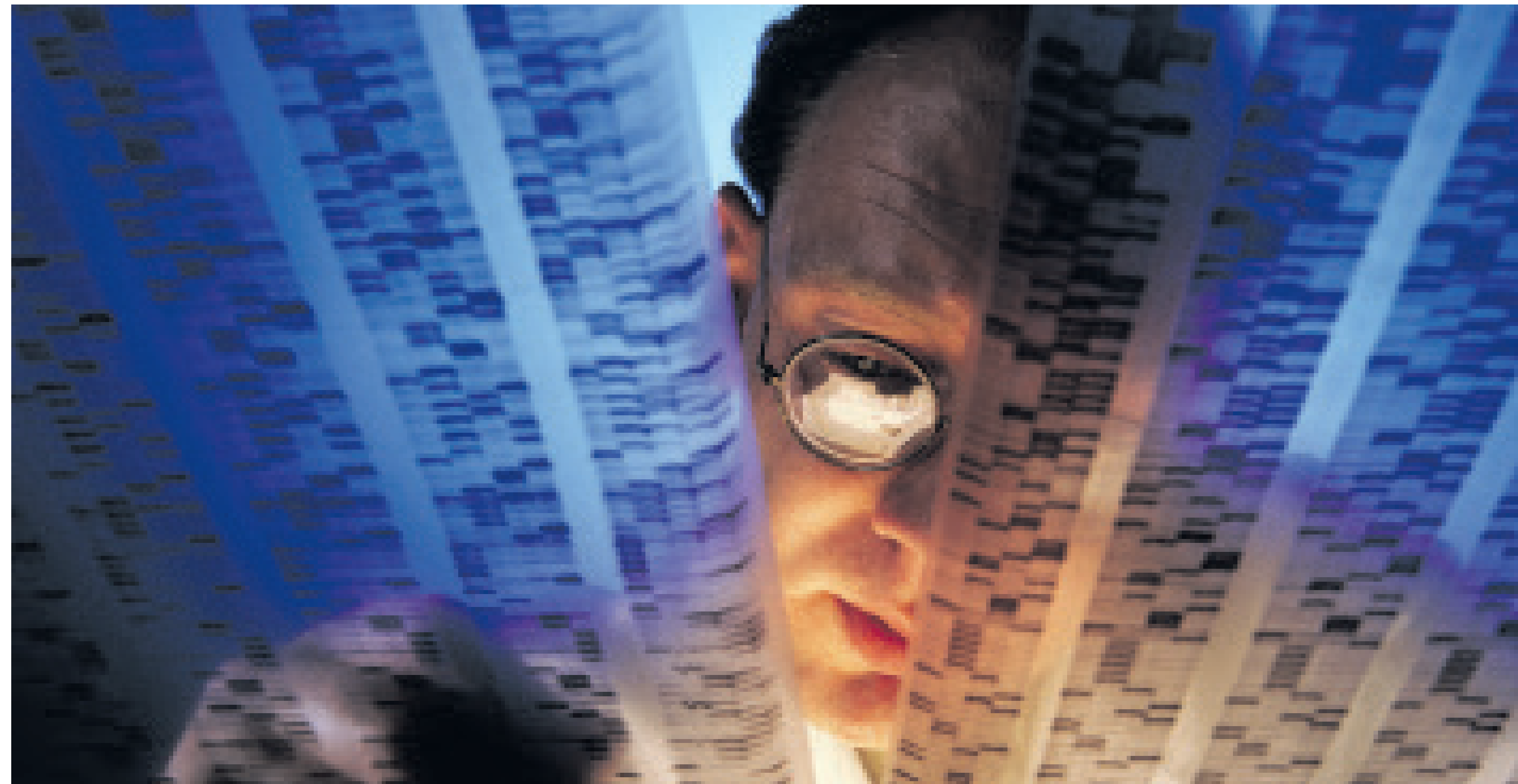
Beaumont, Temple Street and Tallaght Hospitals have received funding in some form from Genuity Science. Beaumont Hospital, which has partnered with the company as part of a brain tumour study, was given €250,000 for genomic scanning equipment.

Genuity Science also provided more than €520,000 to Tallaght Hospital to pay for staff to conduct research. Funds were also given to St Vincent's University Hospital to cover study costs and research nurses for nine projects.

The company has also made significant strides in forming partnerships in academia. Last year, it signed a master research collaboration agreement with University College Dublin (UCD).

A contract is currently being drafted with Trinity College Dublin. That agreement will allow the company and college to collaborate.

UCD declined to comment when asked for details of funding it received from Genuity Science. However, analysis by the investigation team showed that grants have been given to UCD's academic staff. One such grant amounted to €430,000 for asthma research.



The department would have concerns as to the extent to which GMI presents itself as a national project

Other partnerships have also been formed with NUI Galway, University College Cork, the UCD Clinical Research Centre, the UCD Academic Centre on Rare Diseases and Precision Oncology Ireland.

Genuity Science has also formed links with a number of charities and state bodies, including the Asthma Society of Ireland, MS Ireland, the Alzheimer Society of Ireland, Science Foundation Ireland and Teagasc.

Over the past three years, the firm has also built an influential strategic advisory board, which contains senior figures in the Irish health system and tech industry lobby. It includes John O'Brien, who is the chair of the Ireland East Hospital Group; Frank O'Donnell, a lobbyist for Microsoft Ireland; and Sarah O'Connor, the chief executive of Asthma Society of Ireland.

The company's strategic board includes Professor Owen Patrick Smith, who is executive director at the Ireland East Hospital Group, as well as the

professor of paediatric and adolescent medicine at UCD. Smith is also the author of a report from 2016 - known colloquially as the Smith Report - which has heavily informed the state's plans for the creation of a National Genetics and Genomics Medicine Network.

Which means that Blackwood may not have been a million miles off the mark. In building up its network of deals, contracts and partnerships with publicly funded bodies, as well as courting the government for its support and investment, this private company has effectively become the de facto national genomics programme for Ireland.

In its swift accumulation of huge volumes of genetic data, all has not gone smoothly. For starters, as Jones was sitting down to chat amiably with the Business Post in March 2019, she was having far testier conversations with senior officials at the Department of Health.

As far back as the summer of 2018, Genuity's relationship with the department had begun to fray. After one visit, a senior official noted that during a visit to the company's offices he outlined the regulatory background to the new data protection rules. However, he wrote, that it was "fair to say that GMI were not overly concerned with the policy or legal context, but with how the regulations impacted what they are doing".

Genuity would vigorously dispute the contention, but the relationship never recovered. So, by June 2019, according to internal Department of Health documents seen by the Business Post, senior civil servants were describing their engagements with the company as "fractious", and noted serious misgivings about the swiftness with which it was harvesting data.

Worse was to come. In early 2019, it emerged that Crumlin Hospital, one of its partners, had transferred the clinical samples of about 1,500 people to GMI without the appropriate consent.

That was followed by the news that Temple Street Children's Hospital, which is run by Children's Health Ireland, had suspended a project that had run for nearly a year because it wasn't sure it was complying with new data processing laws.

Another problem emerged in relation to a research project with Galway University Hospital as outlined by Simon McGarr, the founder of McGarr Solicitors, which specialises in data protection regulations.

"The concern with the Galway research was that it didn't meet the requirements under the GDPR for informed consent," he said. "Those issues became the subject of a 'widespread compliance and supervision' engagement exercise which continues to this day with the Data Protection Commissioner (DPC)."

At issue, according to the person familiar with the engagement between the DPC and Genuity Science, was the transparency of the firm's research. It appears to have been a robust engagement, because the source said that at the beginning of the engagement, the company did not even agree that genomic data, which is based on a person's genetic code, could even be considered personal data at all.

Genuity found that there was also some resistance within the state's Health Research Declaration Committee (HRDC), which makes rulings on whether medical researchers can proceed with certain projects without seeking explicit consent.

Genuity and its partners have made a number of applications to the HRDC to waive the consent requirement, which they are entitled to do, including on one project with Beaumont Hospital which aimed to use a pre-existing collection of more than 9,000 patients' brain tumour samples.

Initially the HRDC had reservations about the study, based in some measure on Genuity's for-profit nature. The minutes of the committee's meetings show that it was of the view that "the involvement of a 'for-profit' organisation processing personal data introduces a higher risk that data subjects may have a deeper concern for their privacy rights".

It also questioned the direct benefit back to patients whose data was used in the study, considering the high cost of drugs that may be developed. When it announced it was not granting the waiver, Genuity promptly filed an appeal and rolled out the big guns, including Felix McEnroy, a senior barrister who rejected the claim that the presence of a for-profit company necessarily increased the risk. After the appeal, the research was allowed to proceed.

Genuity Science declined to put forward a representative to be interviewed as part of this investigation. A spokesman for the firm said: "Genuity Science has a single primary goal: to improve patients' lives. Our commitment to the lives and quality of life of patients and their families, remains at our core. We seek to better understand the role of genomics in disease to enable pharma and biotech clients to develop new and more targeted therapies for the treatment of life-limiting conditions."

The spokesman said that all research studies undertaken by Genuity Science and its collaborators are re-

viewed and approved by independent research ethics committees prior to commencement. He added Genuity Science does not wish nor proclaim to be the national genomics project.

"All data that is generated and assembled during collaborations is done so in compliance with GDPR and the health research regulations and following strict privacy controls and protections."

The great question hanging over the issue of how Ireland chooses to pursue genomic medicine is simple: should the state take ownership of the entire process, given its sensitivity and potential, or leave it to private industry?

For a time, many experts feared that Ireland would take the latter approach. In an Irish Times opinion piece, two renowned healthcare experts from Trinity College, David McConnell, a fellow emeritus in genetics, and Orla Hardiman, a professor of neurology, argued that Ireland was "putting profit before people with [its] genomic medicine strategy".

In the article they wrote that "an

example of this is the evolution of Genomics Medicine Ireland (GMI), a private company founded in 2015 to mine Irish genetic and medical data, with a clear and unequivocal intention to generate profit".

Hardiman still holds that view, she recently told the Business Post, describing a regulatory vacuum in Ireland in the absence of a nationwide research-oriented collection of genomic data to map the Irish population. That vacuum is not present in other countries, Hardiman said.

"That gap has been filled in other countries by things like the Finnish genomic project [FinGen] where the state has funded those sorts of projects or the British Biobank," she said. "But we don't have anything like that."

It's not just a bad deal for individual donors or patients, according to Hardiman, but for Irish society and the state more generally.

"To me, these are samples collected within the public domain and read by public physicians, who are paid by the state. The samples are from citizens in Ireland. All of the expertise that went into their collection, curation and diagnosis was paid by the state," she said.

A private company coming in and commercialising them "at a knock-down price from the state's point of view" is a concern, she added. "They're getting very good value for money, and the taxpayer is getting very little in return."

A far better system, according to Ricardo Segurado, an associate professor in public health biostatistics in UCD, would be a public-led system.

He cited how the brain tumour research project being run by Beaumont Hospital and Genuity Science could have been turned into a perfect case study for the benefits of a public-led approach.

There is a need for a brain tumour information system, Segurado said, with a database of DNA that could underpin important research. If the state had provided the funding for the project, Segurado added, the sequencing could have still been done by a private company but it would not have retained the data. Instead, the public would have retained the data.



Simon Harris, then Minister for Health: nonplussed

They're getting very good value for money, and the taxpayer is getting very little in return

the water. John Greally, a director at the Center for Epigenomics at Albert Einstein College of Medicine in New York, said there was still time for Ireland to apply the good practices on show in some neighbouring countries, such as Finland.

"There is massive potential for genomics in Ireland, especially in healthcare," he said. "What we have yet to do is to put in place the kinds of structures that our European neighbours assembled before embarking on national genome initiatives."

He agreed with Hardiman that the Finnish model would work quite well in Ireland. Finland has a similar population size to Ireland, for starters. But instead of leaving it to the market, "they convened groups to work on the ethical and legal frameworks to protect the citizens of the country".

"This is sort of a brave new world, but it's not outside the realm of possibility that a private company might at some point in the future go bust."

What happens to the principle of consent then, she asked? "Supposing then Genuity goes bust, or sells the datasets to another company. Supposing that company had a big data repository and supposing Google, Twitter, Amazon or Facebook got into this biomedical domain - and to some extent Google already has done," she said.

It's beyond the realms of possibility with big data, you could then start looking at these huge big data repositories and then start linking them up with other stuff?

"And is there any way of withdrawing it? Once it goes into the commercial domain, you don't know where it goes. Once it becomes commercialised, where does it go after that?"

Advertisement for SMART Health Summit, October 22 Virtual Summit. Includes speaker portraits: Conor Hanley (First Foundry), Eileen Byrne (Clanwilliam Health), Dave O'Shaughnessy (Araya), Robert Quirke (RO QU Group), Brian Thompson (The Health Service Executive), Dave Shanahan (National Oversight Group of Health Innovation Hub Ireland). Ticket price: €125 plus VAT. Business Post LIVE logo.

The different strands that led to Genuity Science

Genuity Science is the product of several mergers and acquisitions between various companies in various countries over the last couple of years. One branch of the company began with WuXi PharmaTech, a company founded by Dr Ge Li in Shanghai in December 2000.

In 2015, WuXi PharmaTech bought NextCODE Health, an Icelandic and American genomic company - which itself had been a spin-out of a previous genomic company called deCode genetics - for \$65 million in cash. This created a new company called WuXi NextCode.

NextCode had been backed by a pair of private equity firms called Arch Venture Partners and Polaris Partners. Those investors had also backed Genomics Medicine Ireland (GMI), which had been founded in 2015 by Paul Thurk, Maurice Treacy, Daniel

Crowley and Sean Ennis. That connection was solidified in 2018 when WuXi NextCode announced it was buying GMI and said it was also raising €350 million from its existing investors Polaris Partners and Arch Venture Partners, as well as some new investors including Temasek, Sequoia Capital, and Yunfeng Capital.

The new company, and with former WuXi NextCode chief executive Rob Brainin named as chief executive of Genuity Science. When contacted by the Business Post, Jones said that "there has been no change in ownership/shareholding of Genuity Science (Ireland) Limited" or in its parent, which she said "includes a range of international funds, including the Ireland Strategic Investment Fund".

She added that "there have been no new investors in our parent company and none have exited as part of this restructuring". This investigation is a collaboration between the Business Post and Noteworthy, the community-led investigative platform from TheJournal.ie.

Noteworthy's story on the failures of government in regulating commercial control of genomic data can be read at noteworthy.ie/selling-our-genes-5219781-Oct2020/



## Health

# 200 brain tumour patients request exclusion from research study

Beaumont Hospital receives requests from patients to opt out of study that aims to harvest genetic data of 9,000 brain tumour patients



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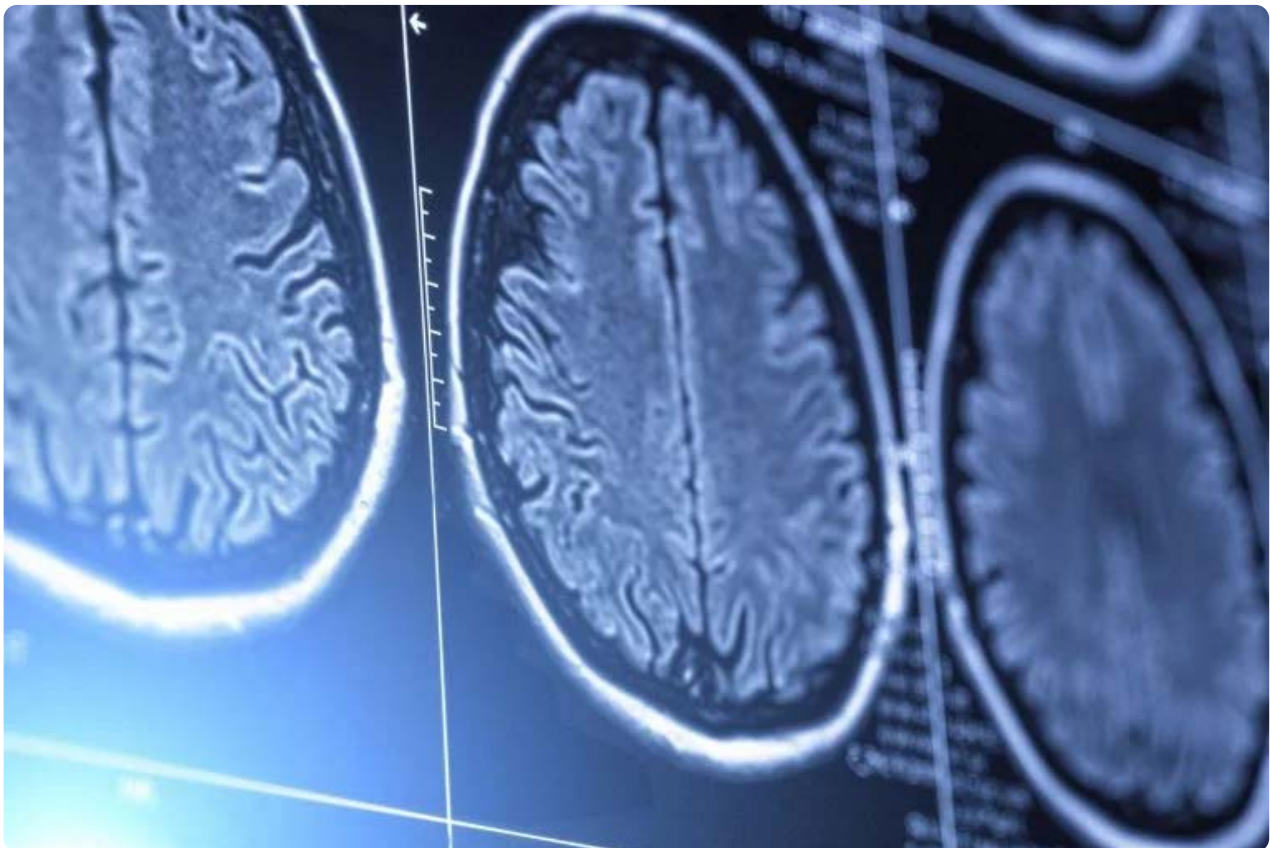


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20th September, 2020

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Nearly 200 requests from patients to opt-out of a research study that aims to harvest the genetic data of 9,000 Irish brain tumour patients

Beaumont Hospital has received nearly 200 requests from patients to opt-out of a research study that aims to harvest the genetic data of 9,000 Irish brain tumour patients, the *Business Post* can reveal.

The study is being run in conjunction with Genuity Ireland, formerly known as Genomics Medicine Ireland (GMI), and was initially refused permission by the state's Health Research Consent Declaration Committee (HRCDC) over concerns about the "low level of transparency" attached to the project.

concerns around the timing and prominence of the original advertisement, which coincided with the beginning of the Covid-19 lockdown restrictions.

A number of patients and experts have said that the campaign might have been missed by people distracted by schools closing and working from home, or by people who simply did not buy physical newspapers.

As a result, the deadline has been twice extended, most recently last week when the deadline was extended again, this time until December 31, 2020.

In April, Beaumont Hospital said it had received just 12 requests to opt-out of the study, of which only eight cases would have been eligible to be included. In new a statement to the Business Post, a spokesman for Beaumont Hospital said that “since the hospital invited questions on the study from the public in March, it has received a total of 295 queries.”

This included 199 requests to opt-out of the study, the spokesman said, of which 163 cases would have been eligible to be included.

The hospital also said that of the 295 original contacts, “60 people have signalled their wish to be involved in the study despite it being an opt-out process”.

In July, GMI split from its Chinese operations in a major corporate restructuring. The company said it had to overhaul its structure after China introduced new national security regulations which make it harder for foreign genetic research companies to share data.

Anne Jones, the former chief executive of GMI, was appointed chief operating officer of Genuity Ireland, which will be run by Rob Brainin, who is based in Boston and was formerly the chief executive of WuXi NextCode.

It’s not clear just how the restructuring affects the shareholders of the company, which include the Irish taxpayer through the Irish Strategic Infrastructure Fund (ISIF).

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