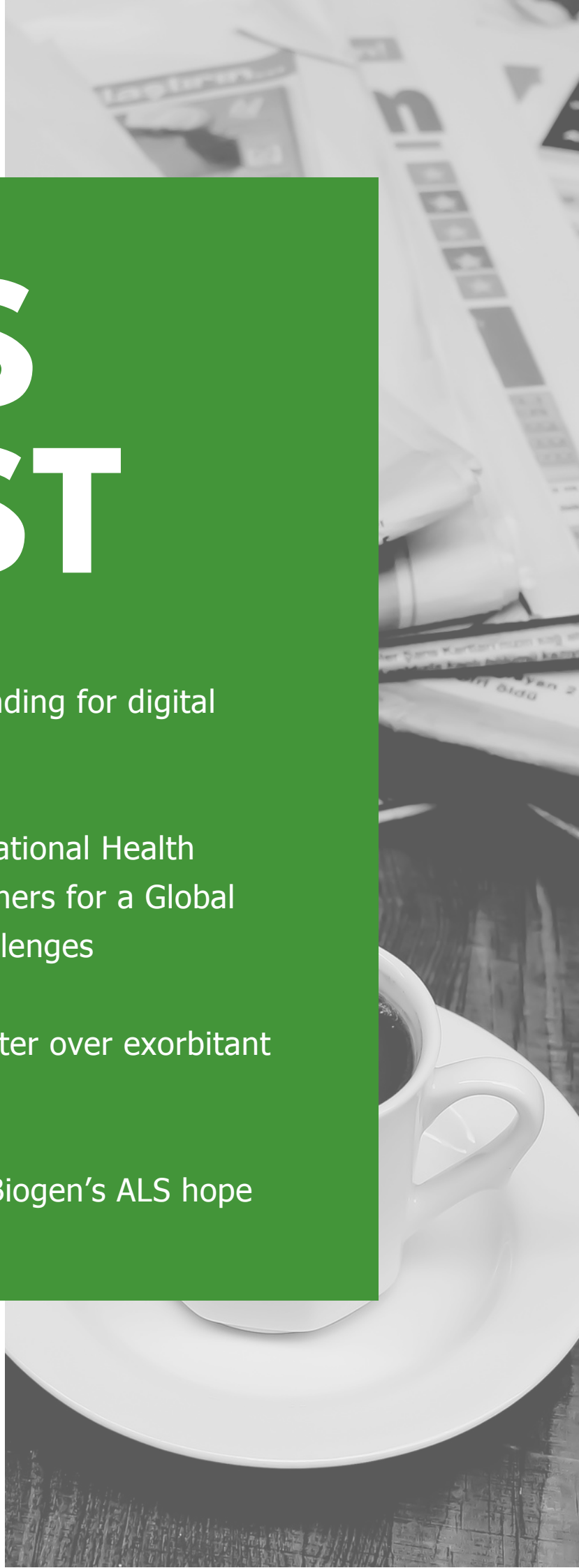
NEWS DIGEST

- NICE and MHRA awarded funding for digital mental health tools
- UK Agencies join with International Health Technology Assessment Partners for a Global Collaboration on Shared Challenges
- US Pharma Amylyx in hot water over exorbitant price of new drug
- US: FDA delays decision on Biogen’s ALS hope tofersen



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NICE and MHRA awarded funding for digital mental health tools

The Wellcome Trust has awarded £1.8 million worth of funding to improve regulations and guidance in the area of digital mental health. The funding has been awarded to the Medicines and Healthcare Products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE).

The MHRA and NICE will use the funding to undertake a project, reviewing key aspects of medical device regulations to produce guidance that will support digital mental health in several significant areas.

Such areas will include:

- Determining what qualifies as a medical device
- Which risk classification digital mental health tools will fall under
- A review of the evidence base for current devices

The agencies will do this by engaging with people with lived experience, subject experts and patients to inform their conclusions. The objective behind this funding is to establish certain mental health software as proportionally regulated medical devices, meaning patients can access effective and safe tools to protect and improve their mental health.

Source > NICE https://www.nice.org.uk/news/article/wellcome-trust-funding-of-1-8m-welcomed-by-nice-and-mhra [Accessed 13th Oct 2022]

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UK Agencies join with International HTA Partners for a Global Collaboration on Shared Challenges

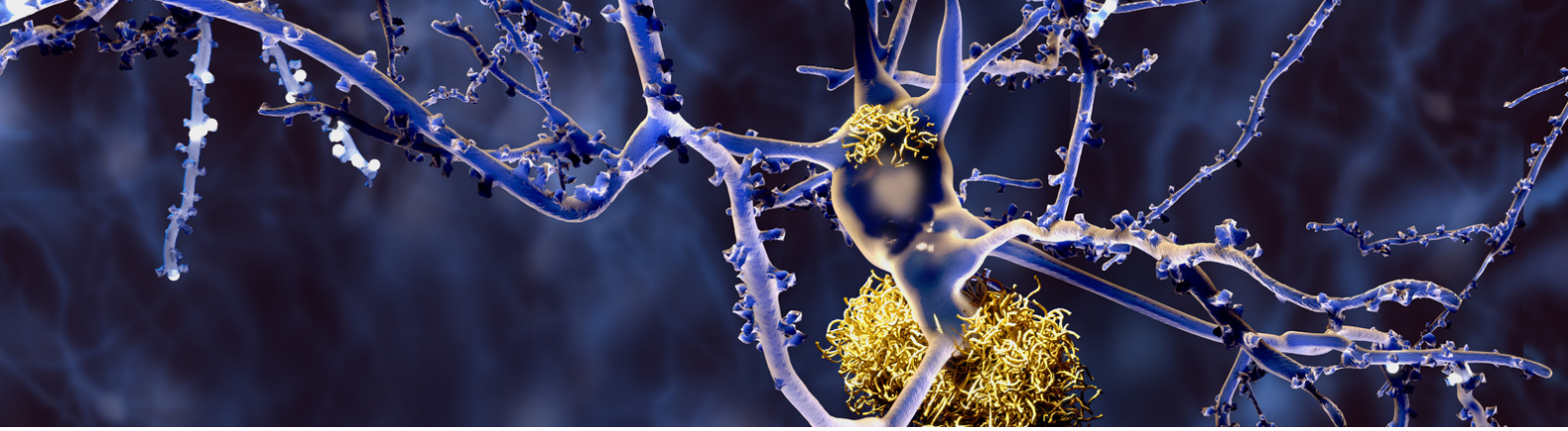
A cross-border alliance of health technology assessment (HTA) agencies has been announced by the Canadian Agency for Drugs and Technologies in Health (CADTH). As well as CADTH, the alliance will include the Australian Government Department of Health and Aged Care (which oversees the Australian HTA agency, the Pharmaceutical Benefits Advisory Committee, PBAC), and four UK-based agencies. UK participants of the alliance will be the National Institute for Health and Care Excellence (NICE), Health Improvement Scotland (which oversees the Scottish Medicines Consortium, the SMC), the All Wales Therapeutics and Toxicology Centre (AWTTC) and Health Technology Wales.

Through the alliance, the above partners will work together on shared priorities, and common challenges. Five priorities areas have been identified:

1. COVID: Including managing medicines with no marketing authorisation, and economic modelling of COVID interventions
2. Futureproofing: Exchanging ideas on how the HTA process can better anticipate technological and methodical challenges
3. Collaboration with Regulators: Exploration of how to implement joint approaches with the regulatory agencies in the UK, Canada and Australia
4. Work-Sharing: Running a pilot for joint clinical assessment between the agencies
5. Digital and Artificial Intelligence (AI): Sharing information on the evaluation of digital health technologies and AI

The alliance will utilise working groups, with annual meetings to review activities and realign on priorities. It has been reported that the alliance may grow, for example the CEO of New Zealand's HTA agency, Pharmac, has expressed interest in the collaboration.

Source > https://remapconsulting.com/hta/uk-agencies-join-with-international-hta-partners-for-a-global-collaboration-on-shared-challenges



US Pharma Amylyx in hot water over exorbitant price of new ALS drug

Amylyx Pharmaceuticals' new amyotrophic lateral sclerosis (ALS) drug Relyvrio (AMX0035) was approved by the US Food and Drug Administration (FDA) last week and has already landed the giant in hot water. Amylyx has set the annual price of the drug to $158,000, a number decried by many as exorbitant. According to the influential Institute for Clinical and Economic Review (ICER), the drug should be priced no higher than $30,000 a year until more evidence comes in regarding the drug's efficacy.

According to Nicole Raleigh, "'Clearer' data isn't expected until 2024, with results from a late-stage phase 3 PHOENIX trial of around 600 patients due at that time.

Back in September, ICER published a final report concluding that Amylyx Pharmaceuticals' AMX0035 oral drug has a role to play in ALS treatment, but offers "low" long-term value for money at current pricing or price estimates. David Rind, Chief medical officer for ICER, stated that "the evidence suggests that AMX0035 extends life, but prices need to be greatly reduced to align with benefits", continuing to add that the recommended price is "much too high a price for the therapy, despite the overwhelming need for treatments for this devastating disease."

Source > https://remapconsulting.com/pricing/us-pharma-amylyx-in-hot-water-over-exorbitant-price-of-new-drug/

US: FDA delays decision on Biogen’s ALS hope tofersen

In similar news regarding innovative new treatments for amyotrophic lateral sclerosis (ALS), the US Food and Drug Administration (FDA) is planning to take an additional three months to review Biogen’s experimental therapy, setting back its decision date from January to April.

Without going into details, Biogen confirmed the extended deadline on Monday 17th October, saying that it has submitted responses to queries raised by the FDA that, according to the regulator, amounted to a “major amendment” to the filing, requiring additional review time.

The FDA started reviewing tofersen in July under its accelerated approval pathway and a priority review based of the results of the VALOR trial, which disappointed at its first readout last year, but has since seen improved data showing it can slow progression of the devastating neurodegenerative disease.

Partnered with Ionis, tofersen is an antisense oligonucleotide, targeting a rare form of ALS caused by mutations in the gene for superoxide dismutase 1 (SOD1). Around 2% of cases of ALS – also known as motor neurone disease (MND) – are linked to mutations in the SOD-1 gene. There are around 31,000 patients with ALS in the United States.

Last month, the FDA ended a five-year drought in new therapies for ALS when it approved Amylyx Pharmaceuticals' Relyvrio (sodium phenylbutyrate and taurursodiol), despite doubts about its efficacy.

Source > https://pharmaphorum.com/news/fda-delays-decision-on-biogens-als-hope-tofersen/

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If you'd like to share anything or hear how we can support you in getting your product to market email Paul and Graham, managing directors, today at: contact@remapconsulting.com.

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