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“Biggest challenge in running a chronic Hepatitis B trial is often patient recruitment”

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Novotech, the global full-service clinical Contract Research Organization (CRO) that partners with biotech companies to accelerate the development of advanced and novel therapeutics, has released its latest disease report: Hepatitis B - Global Clinical Trial Landscape (2025) in March 2025. The report highlights a 31.95 per cent CAGR in Hepatitis B trials from 2020 to 2024, driven by advances in small molecules, siRNA therapies, and therapeutic vaccines. To know more about the clinical trials landscape of Hepatitis B, particularly the Asia Pacific region, BioSpectrum Asia interacted with Tom Hickey, Director-Therapeutic Strategy at Novotech.

With over 25 years of experience and more than 90 Hepatitis B clinical projects completed, Novotech remains at the frontline of advancing innovative therapies. What key lessons has Novotech learnt from conducting these projects?

From decades of experience in Hepatitis B clinical trials, Novotech has identified key success factors namely- Site & Patient Selection Drives Success: Knowing the right patients for your study, and where to find them. Having a balance of high recruiters with the global Key Opinion Leaders that will guide the trial progress. Regulatory Planning Is Critical: Early engagement with regulatory agencies reduces approval delays and ensures trial designs align with evolving guidelines. Regulators in many of the key regions for chronic Hepatitis B (CHB) are very open to engagement and scientific merit, with many innovations in both therapy class and trial design being first used in this space.

Adaptability to New Science Is Essential: With the rapid emergence of new or improved assays and biomarkers Novotech remains agile and committed to integrating new therapeutic advancements into trial protocols. Retention Strategies Ensure Long-Term Study Viability: Patient adherence is crucial, given the extended duration of many Hepatitis B trials, while it’s

important to recruit patients quickly it is futile if they don't remain on the trial. Novotech employs digital engagement tools and patient support programmes to improve retention rates.

These insights have helped Novotech optimise Hepatitis B trial execution, ensuring higher efficiency, faster approvals, and improved trial outcomes for biotech sponsors.

What are the biggest challenges in running Hepatitis B trials, and how do you address them?

The biggest challenge in running a chronic Hepatitis B trial is often patient recruitment. Something that you wouldn't really expect for a disease with over 250 million people infected worldwide. However, the areas where prevalence of infection is higher are often the areas traditionally least well serviced by clinical research such as West Africa, Asia Pacific, Eastern Europe and Central Asia.

Novotech's origins are in Asia Pacific and Eastern Europe, so through our geographic footprint and close relationships with Key Opinion Leaders in locations like New Zealand, Hong Kong, South Korea, Thailand, Moldova and Ukraine we were uniquely positioned to support companies wishing to work in this space. Since those early days we have expanded our footprint to include CHB sites in Western Europe, the US and Canada, along with places like Pakistan and Uzbekistan in Central Asia, often with our Hepatitis trials allowing us to get an operational foothold in a location.

Another complexity is that often trials in CHB are focused on a particular sub-population; patients with a certain level of disease activity, or at a certain stage of the viral cycle, or specific HBV genotypes, or even HLA matching. Through our past work and knowledge of the space, we know where to go to find the patients that a trial needs. We have a network of over 350 investigators that we have worked in CHB globally that we can tap into.

Coupled with the difficulty in finding patients, CHB studies are often quite long in duration, particularly the later Phase II and Phase III studies we are doing, typically patients are involved for upwards of three years between treatment and then follow-up periods. For a condition that doesn't often have any tangible health impacts at the stage many of these patients are at, it can be difficult to keep them engaged and involved in the study as they don't feel that sick. We work to ensure that patients feel a sense of community around their study, that they understand the benefits of the treatment and what the potential risks are for them without treatment. Our Patient Engagement teams have different tools that can be deployed to assist with this from newsletters to AI.

The vast majority of endpoints in CHB research are related to changes in laboratory measurements, with a lot of innovation happening recently in developing assays targeted specifically to measure biomarkers to understand viral replication activity and viral levels. Given that we were supporting so many trials in this space we felt it imperative to have a reliable laboratory to do this analysis, so our team at Novotech Laboratories set out to ensure they had one of the most comprehensive sets of CHB and CHD assays in industry, acquiring numerous instruments specifically to run these assays.

How does Novotech navigate regulatory and operational challenges across global trial sites?

Novotech's deep expertise in global regulatory frameworks allows for efficient trial approvals across different regions. The company offers local regulatory expertise. Dedicated teams with in-depth knowledge of FDA, EMA, PMDA, and NMPA requirements, ensuring compliance across trial sites. This has been particularly important in navigating regulatory requirements for what are often first-in-class therapy types.

Novotech optimises approval timelines through strong relationships with ethics committees and regulatory agencies. With established trial infrastructure in Asia-Pacific, the US, and Europe, Novotech ensures seamless coordination between multi-regional sites. This expertise enables Novotech to overcome site activation delays, align trial execution with global standards, and accelerate study timelines.

Which emerging therapies in Hepatitis B show the most promise in clinical trials?

Since the arrival of the game changing nucleos(t)ide analogues, Entecavir and Tenofovir, in the mid-2000s, there hasn't really been any new weapons added to the arsenal. We are hopefully close to the approval of the first of those with GSK's Bepirovirsen and there are many other promising therapies coming hot on its heels like Arbutus' Imdusiran and AusperBio's AHB-137 along with other therapies targeting Hepatitis B patients co-infected with Hepatitis D like Bluejay Therapeutics' Brelovitug.

Looking earlier in development, there are some really interesting studies which have just entered the clinic using both gene therapy and epigenomic approaches from Precision Biosciences, Tune Therapeutics and Epigenic Therapeutics.

How is Novotech adapting to the rise of personalised medicine in Hepatitis B research?

The rise of personalised medicine in Hepatitis B treatment is transforming clinical trial designs, requiring precision-based patient selection and biomarker-driven approaches. As more knowledge becomes available on the Hepatitis B virus biology and as we better understand the human immune system, we are better understanding what treatments will work best for which patients and when. Novotech is adapting by incorporating the most modern Biomarkers, Genomic Screening and Analyses available- Supporting trials that utilise HBV activity profiling and immune response biomarkers to tailor treatments.

Leveraging Real-World Data (RWD) – Enhancing patient stratification and endpoint measurement through longitudinal patient data analysis. Flexible Trial Designs – Implementing adaptive clinical trial models that adjust protocols based on interim safety and efficacy results. Novotech's approach ensures personalised Hepatitis B therapies can be tested efficiently and brought to market faster.

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