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Opinion:

The life sciences industry urgently needs medical attention!

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A quarter of the 21st century has passed, yet we still don't have widely available and affordable personalised precision medicine. It is high time that we correctly utilise the innovation and progress in medical technology to create new workflows and standards of care.

THE NEED FOR INNOVATION IN R&D PIPELINES

It sounds like a paradox: despite massive efforts and successful innovations, the life sciences industry has moved further away from the medical reality. Current R&D procedures struggle to link patient reality, commercial viability and health-economic impacts. They operate in an increasingly complex industry ecosystem with specific biases that their R&D investment strategy is based on. **These biases may prevent them from seeing the bigger picture of an entire healthcare ecosystem that is direly in need of innovation in a wider variety of therapeutic areas and approaches than are currently available in the R&D pipelines.**

Neglected problems

Major depressive disorder (MDD) is rapidly increasing worldwide. It already affects at least 8% of US adults in any 2-week period, or nearly half the US population aged 18-34 years annually. It is estimated to account for more than 300-billion USD of annual economic burden in the US alone, which is a third higher than the estimated entire annual oncologics sales worldwide.[3]

Antimicrobial resistance (AMR) is even more important, with an estimated 5-million annual deaths associated with AMR, or roughly 7 out of every 100 deaths annually.[4] A conservative prediction by 2030 exceeds a gross domestic product shortfall of more than 1-trillion USD. This can be avoided with a modest 200-billion USD investment as proposed by the world bank.[5]

WHERE DOES THE FOCUS LIE?

Despite the more than 14,000 diagnoses listed in the 10th edition of the international classification of diseases[1], most life science companies focus their innovation on a very limited number of areas, mainly oncology, diabetes, and immunology.[2] These areas are crowded spaces in which the complex patient journeys as well as the high level of competition make for risky investments. Moreover, the contrast to medical need and the actual health economic impact of disease is jarring, considering that for example mental health and antibacterials receive nearly seven-fold less investment despite their massive worldwide impact[2]. A medically-savvy refocus may be the best opportunity to increase the return-of-investment.

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EVIDENCE AND MORE EVIDENCE

The focus on single diseases frequently neglects the fact that real-life disease management nearly always involves comorbidities which add a significant level of complexity.

Unfortunately, data analysis and exploration are missing for the common medical reality of disease-disease and drug-drug interactions. Current trends of evidence generation and acceptance of this evidence for medical guidelines and pre-market authorisations have an additional impact.

Importantly, it appears that current R&D procedures struggle to link patient reality, commercial viability and health-economic impacts. This is further emphasised by the increasing evidence requirements from regulators and payers. This is where a medically informed analysis and linkage of current developments to the wider medical context will play a major role for the market success of innovation.

WHAT WILL YOUR DOCTOR DO?

Even with the right focus and sufficient evidence on the side of life-science innovation, healthcare systems worldwide are generally unable to fully absorb innovation due to a massive investment deficit in staff and infrastructure as well as a large patient backlog that is frequently on the verge of overloading the system.[2] It therefore becomes more important to innovate closer to the live clinical workflows, which themselves need to become more patient-centric.

Complementary to this, it becomes increasingly clear that better use of available information needs to become part of the standard of care. Consider the cases of personalised and precision medicine and how there is still largely unexploited potential of novel

Clinical data generation in need of an overhaul?

Medical evidence generation is exponentially increasing in size, with more than 110,000 primary research papers published in 2020 and a further trend of nearly 10% annual growth, particularly for cross-sectional and cohort studies.[6]

However, this broader evidence is much harder to translate effectively in comparison to only using randomised controlled trials, since much more complexity and uncertainty is involved.

This is reflected by how little of the published literature has an impact on the standard of care, seeing that less than two in 1,000 studies are used as evidence in regional and international medical guidelines.[7]

In response to this, life science companies are increasing efforts to incorporate real-world evidence (RWE) as well as complex clinical trials (CCT) for regulatory pre-marketing authorisation[8] which are in part mirrored by a greater acceptance of RWE and CCT at regulatory agencies. The full potential of RWE and CCT still needs to be achieved.

diagnostic modalities such as next-generation sequencing to improve clinical decisions in cancer[9], infectious disease[10], other non-communicable diseases[11] and personalised pharmacokinetic modelling.[12]

Large, personalised data sets will require a novel form of digital avatars, i.e. complex, patient-specific predictive models that incorporate all available information and enable healthcare professionals and patients to make truly informed decisions.[13] However, these models cannot be built in isolation without a deep understanding of, and in close collaboration with end-users, both medical professionals and patients.

Clinical Workflows

One of the most surprising realisations of research into clinical workflows is the fact that it is mostly conducted within the framework of clinical digitalisation and automation. It is frequently combined with questions on how to increase the quality of care and equally important, the patient-centricity of care[14].

This more than likely signals the need for a novel understanding of the roles of healthcare practitioners and patients within healthcare and urges a rethinking of the patient-provider relationship[15].

THE NEED TO BUILD A DIGITAL INNOVATION PIPELINE

Considering all the above developments and trends, innovation in life sciences clearly cannot remain on the "wet lab" side of healthcare. It must incorporate both hybrid and fully digital products as a vital part of its portfolio. Indeed, life-science innovators appear to be gearing up in exactly that direction[16].
This requires novel organisations, capabilities and the expertise to create medically valuable digital products. Frequently, life science companies can profit from the pre-existing intellectual property that has been collected in the form of large data sets and complex, thoroughly explored biomedical models. Both have been collected and developed in the course of R&D activities over the past few decades, yet they frequently lie shelved.

Another innovation target will be digital therapeutics, which may become a new standard for patients to interact with the healthcare system[17] and will offer the possibility to collect real-world data on a large scale.

In-depth understanding of the current medical reality and the ability to create relevant products on top of existing assets will likely be the biggest differentiating factors in these endeavors.

"It becomes increasingly clear that better use of available information needs to become part of the standard of care."

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About Arcondis

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Our solutions and services include Digitalisation, Data, IT & Infrastructure; Development & Operations; Product Lifecycle Management; Quality, Regulatory & Compliance and People & Culture. As an independent solutions and Managed Service provider, we have the flexibility to prioritise our clients' best interests without being constrained by exclusive partnerships. We follow an outcomes-based approach – from strategy to hands-on delivery and beyond.

With a well-established reputation built over two decades, we have earned the trust of leading companies in Pharma, MedTech, Healthcare and Start-ups. Headquartered in Switzerland, we employ more than 250 specialists and professionals, with offices in North America, Europe and APAC.

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