UseTree Ascenian

COVID-19: AI can help.

Executive summary

1. Introduction

In the last few years the pharmaceutical, diagnostics and medical device industries have been facing a large-scale disruption by AI tech companies, who are challenging established methods in evidence generation by using Real-World Data (RWD) for modeling and predictions. Using a wide variety of data sources for example mobile devices, wearables, biosensors, connected devices, Electronic Health Records (EHRs), trial databases and social media Real-World Evidence (RWE) is playing an increasing role in supporting product value propositions, informing reimbursement decisions, and helping to manage data uncertainty from randomized clinical trials.

Skeptical about the quality of these offerings the uptake of AI by regulatory and payer decision makers was slow. This may be about to change. During the COVID-19 pandemic, evidence for the usefulness of big data and AI is demonstrated daily for example to predict and model patient behavior or the spread of disease whilst delivering beneficial or even live-saving outcomes. This evidence could substantially help to overcome skepticism and further uptake in regulatory and reimbursement decision making.

2. What issues are addressed?

This white paper discusses and investigates, how AI, big data and more specifically RWD, can improve decision making for regulatory approval, pricing of, and access to new treatments and diagnostics.

It discusses challenges for AI adaption across the pharmaceutical, diagnostics and medical device industries, with specific focus on regulatory and reimbursement decision making. It addresses how these challenges may be overcome to ensure that the strict industry standards for quality are met. The paper starts with a set of definitions, followed by an overview of current European and US initiatives in advancing policymaking and to further the acceptance and implementation of AI.

It then considers advantages and hurdles in translating the potential of AI for use in price and reimbursement decision making processes. For

example, it considers uncertainties when payers and health technology agencies are interpreting RWE against evidence requirements, while it shows that AI is allowing a more targeted, better planned demonstration of value, oriented to the real-world health service setting. This discussion is followed by examples how AI tech companies have teamed up with the pharma industry to leverage the power of AI. It further discusses how AI and RWD has helped scientists and others to deal with challenges during the COVID-19 pandemic, for example dealing and making sense of large amounts of data impossible for humans to understand and analyze in short time available.

3. Conclusion

This white paper concludes that AI has the potential to improve drug approval and pricing and reimbursement decisions. It provides guidance and suggestions on how adaption of AI for pricing and reimbursement may be practically translated in a successful endeavour. It identifies three key areas for a successful implementation, namely:

(1) the need for a standardized platform to allow successful integration of RWD,

(2) the need to match regulatory and/or reimbursement requirements for RWE and clinical trials, and finally

(3) to create a perpetual learning and communication system.

The white paper finishes with an offering how the two companies ,who authored the paper, Ascenion and UseTree, will be able to support this transition process by their unique expertise if your company is interested in adapting an AI approach.

4. About Us

UseTree develops products based on a deep understanding of people. The interdisciplinary team of experienced experts advises international companies, as they strive to create products that are as catchy, useful and desirable as possible.

UseTree GmbH
Bismarckstraße 10-12
D-10625 Berlin

Phone: +49 30 8632919 1
info@usetree.com
www.usetree.com

Ascenian focus is on market access strategy for new pharmaceuticals and we have expert teams dedicated to gene and cell therapies, vaccines and medical devices.

United States: Ascenian LLC
New York, USA

Phone: +1 585 787 4566
info@ascenian-consulting.com
www.ascenian-consulting.com

Europe: Ascenian GmbH
Berlin, Germany

Phone: +49 151 176 301 42

UseTree Ascenian