ADVANCING 21ST CENTURY REGULATORY SCIENCE THROUGH ARTIFICIAL INTELLIGENCE

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Artificial intelligence has unimaginable potential. Within the next couple of years, it will revolutionize every area of our life, including medicine – and pharmacovigilance.
AI GENERATES “GROSS VALUE ADDED”

- AI can boost the 2035 GVA of the Brazilian economy by $432 Billion USD.
  - $192 Billion USD via labor and capital augmentation
  - $166 Billion USD via “intelligent augmentation”
  - $74 Billion USD via innovation diffusion
  - “AI can improve public services from transportation to disease control.”

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DO YOU HAVE ENOUGH INFORMATION?

• The amount of available digital data is growing by a mind-blowing speed, doubling every two years. In 2013, it encompassed 4.4 zettabytes, by 2020 the digital universe will reach 44 zettabytes, or 44 trillion gigabytes.

• Usually, we make sense of the world around us with the help of rules and processes that build up a system. The world of Big Data is so huge that we will need artificial intelligence to be able to keep track of it.
Artificial intelligence will have a huge impact from genetics to genomics, helping to identify patterns in huge data sets of information and medical records, looking for mutations, linkages to disease and post-marketing pharmacovigilance.

We must view artificial intelligence through the lens of 21st century interoperability: the idea that different systems used by different groups of people can be used for a common purpose because those systems share standards and approaches.
USFDA’S “FRAMEWORK FOR REAL WORLD EVIDENCE PROGRAM”

• A guide to help evaluate the use of RWE to support additional indications for already approved drugs as well as to satisfy drug post-marketing study requirements.

• “The framework is aimed at leveraging information gathered from patients and the medical community to inform and shape the FDA’s decisions across our drug and biologic development efforts.”

• The goal is to develop a path for ensuring that RWE solutions can play a more integral role in both drug development and a drug’s regulatory life cycle.
USFDA AS A MORE ROBUST INTRAMURAL PLAYER

• Work with the medical product centers to develop an FDA curriculum on machine learning and artificial intelligence in partnership with external academic partners.

• The aim of this program is to improve the ability of FDA reviewers and managers to evaluate products that incorporate advanced algorithms and facilitate the FDA’s capacity to develop novel regulatory science tools harnessing these approaches.
More Does Not Always Mean Better

In a world increasingly driven by outcomes reporting and Big Data, more patient-level information from individual consumers is not always synonymous validated data. Despite the frustrating increase in the signals-to-noise ratio, artificial intelligence is becoming an ever-more significant source of potentially valuable electronically generated health care information.
Artificial intelligence will facilitate what the pharmacovigilance ecosystem lacks today – a coordinated and efficient systems for developing actionable evidence on safety and effectiveness.
DATA COLLECTION ISN’T THE GOAL. USING THE DATA IS THE GOAL

• The absence of these capabilities significantly impacts the public health by creating obstacles for patients and clinicians:
  
  • to receive the meaningful information they need to make informed decisions
  
  • perpetuating unnecessarily long delays and gaps in effective and timely safety communications and recall management
  
  • hindering the timely development of new and innovative treatment options
  
  • increasing the overall costs and inefficiency of the healthcare system.
ARE WE THE PROBLEM?

- The fear is not that we will find new information; it’s that we would overwhelm our current systems and capacity with poor quality information.
- These worries beg the question of what staffing levels and training is required to adequately and appropriately handle the 21st century demands for pharmacovigilance data that is usable at a regulatory level.
CONSIDER ICSR VOLUME

• AI can (and must) help us address exponentially increasing amounts of Individual Case Safety Reports (ICSRs)
• Artificial Intelligence will not only operate ICSR processing but also assist in their evaluation – including the direct collection of ICSRs from mobile devices
• What tasks does that allow “us” to do?
WHICH END OF THE HORSE DO YOU WANT TO BE?
THE HIGHLY ITERATIVE, AUTONOMOUS AND ADAPTIVE NATURE OF THESE TOOLS REQUIRES A NEW, TOTAL PRODUCT LIFECYCLE REGULATORY APPROACH THAT FACILITATES A RAPID CYCLE OF PRODUCT IMPROVEMENT AND IMPROVED REGULATORY SAFEGUARDS.
AI IS THE NEW REGULATORY REALITY

“Reality is that which, when you stop believing in it, doesn’t go away.”

-- Philip K. Dick
OBRIGADO BRAZIL