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DRIVING DIGITAL IN BIOPHARMA: PODCAST

AUDIO TRANSCRIPT

Episode 1: Synthetic Patient Data for Clinical Trials
Duration: ca. 30 minutes
Interviewer: Sophie Furley
Interviewee: Dr. Boris Bogdan – *Managing Director, Lead-Global precision oncology and PHC, Life Sciences*

JINGLE – 1-2 minutes

((jingle))

((overlayed with snippets of central statements from Boris; e.g. link to covid-19, wasting potential, future and present need of more in-silico / only at the beginning to realizing the potential of leveraging data in healthcare))

Off-voice
You're listening to Driving Digital in Biopharma, a podcast from Accenture.

((fade-out jingle))

INTRO – 1-2 minutes

((Intro-music))

Off-voice
The host of this episode is Sophie Furley – in conversation with experts at Accenture, we will immerse ourselves in the most important topics in life sciences today, including MedTech, Digital Health, medical science, research, primary health care and, above all, patients.

In this episode, our host is speaking to Dr. Boris Bogdan – Managing Director at Accenture and lead of Accenture's' center of excellence for precision oncology and personalized healthcare.

((fade-out intro-music))

TALK – 20-25 minutes

Sophie
Hello Boris, it is a pleasure to have you here!

Boris
((e.g.: "Hello! Thank you for having me! It's nice to be back out and about, fully vaccinated of course ;)"))

Sophie
I agree! This pandemic has, indeed, stirred things around! One thing it has taught us, is that time is a precious resource, right?

((fade-in music to accentuate start of topic))
@Shafi: please check if this is ok like that and aligned with the "Driving Digital in Biopharma series"

Boris
((agrees))

• The Covid-19 pandemic has proved that speed matters when it comes to delivering innovative treatments against serious diseases.

Sophie
So let's make good use of it and jump right into today's *topic*: synthetic patient data in clinical trials!

Boris
(short interaction Boris)
• It's a cutting-edge method for reducing both the time and the costs needed to run a trial without compromising high quality and safety standards

Sophie
There is a long history of transformative methods that have changed medicine. First da Vinci's groundbreaking in-vivo method – the blueprint of modern surgery, so to say – then the innovation of in-vitro-tests during the 19th Century, and now synthetic patient data! This evolution clearly

demonstrates a trend towards effectively speeding up processes…

((fade-out music))

Boris, you name synthetic data as a key accelerator in clinical trials. Can you explain what you mean by the term 'synthetic data' in this context?

Boris
(explains term "synthetic data")

- First of all: Nothing synthetic about this kind of data
- Real patient data taken from previous clinical trials, clinical research and EMRs
- It's called "synthetic" because the data is not being gathered as part of the current clinical trial
- Short explanation of set up of a clinical trial:
  - investigated drug is compared to standard of care; patient cohort getting new investigated drug versus a patient cohort getting standard of care
  - Obviously, there always already exist a lot of data about the "Standard of Care" - from real world setting captured in EMR or from previous clinical research
  - This existing data can be leveraged in clinical trials and replace the need to recruit patients getting the standard of care

Sophie
You recently published a research report on synthetic data called "Better clinical trials: Benefits of synthetic data."

Boris
Yes, that's right. We thought it was an important trend to highlight and drive uptake of this.

Sophie
Why is that? Beyond the lessons of Covid-19, why has synthetic data become such a hot topic right now?

Boris

- The result of two trends that are converging: the growth of data in healthcare and the advancement of technology.
- Growth in patient data
  - Every second, an exponential amount of healthcare data is generated. Today, approximately 30% of the world's data volume is being generated by the healthcare industry. By 2025, the compound annual growth rate of data for healthcare is expected to reach 36%. That's 10% faster than financial services, and 11% faster than media & entertainment (https://www.seagate.com/files/www-content/our-story/trends/files/idc-seagate-dataage-whitepaper.pdf)
  - it takes only 73 days for world oncology data to double (American Journal of Managed Care)

- Advances technology:
  - in Artificial Intelligence, analytics & computing powers
- Bring these two together, and we are now at the point where we can leverage data much better and implement synthetic data
- Which leads to potentially broader adaption of in-silico methods

Sophie
In-silico! A term that has been around for a while – but remains somewhat mysterious… Boris: what exactly is in-silico?
@Jen: please check wording; maybe better word than "in focus" - what we want to say is "why has it just now become a topic"
does this work better?

Boris
(explains term in-silico)

- In-silico methods predict results based on Data without the need for testing in animal models or in human cohorts
- Processes happening with computer simulations, algorithms, programs
- Example: used to find new drugs or combinations in early research
  - Example: one group of researchers investigated the pharmacological profiles of molecules to predict the synergism of cancer drug combinations

- using NCI-ALMANAC data. (https://www.frontiersin.org/articles/10.3389/fchem.2020.00612/full)

- Example: synthetic patient data in clinical trials perhaps add an example? I pulled from this 2020 Frontiers in Chemistry paper: https://www.frontiersin.org/articles/10.3389/fchem.2020.00612/full

Sophie
So, in essence, what is the benefit of the use of synthetic data compared to standard drug development processes?

Boris
(explains key benefits development towards the use of synthetic data versus standard drug development process)

- Minimize control group or even no need to run control arm
  - By simulating an entire control patient population in a trial
- Increases operational success
  - By optimize trial design. By testing feasibility and better defining the target patient population
- Saves time and resources

Sophie
(transition related to time)

Here we are: Time.
Time is a precious resource, one that wasn't or still isn't available during this pandemic. One important benefit you mention is that using synthetic patient data significantly reduces the duration of clinical trials; it shortens timelines, as you said. This surely is beneficial for all involved parties, including patients – But what benefits do you see for patients, specifically?

Boris
(benefits for patients)

- Avoids exposing patients to unnecessary burden and risk / There is an ethical concern with trials
  - Patients are exposed to unnecessary burden but "only" receiving standard of care
  - Some patients do not wish to participate in a trial, when there is the possibility of not receiving the new treatment
  - Speed up the development of new drugs, or new indications for existing drugs Patients benefit directly from new, innovative – and in some cases life-saving therapies – much earlier.

Sophie
(transition with agreement)

What are the benefits for trial sponsors?

Boris
(benefits for trial sponsors)

- Recruiting patients for a trial is a time-consuming and costly process
- With synthetic data, there is a unique opportunity to reduce the number of patients
- And as I mentioned earlier, using historic patient data will optimize trial design and therefore increase operational success.
- Example: In oncology, for example, it is common to conduct single arm trials in the early clinical development phase / Synthetic data can be used to better explain the results from those single arm trials, minimizing the risk of detecting false positive signals.

Sophie
And what are the benefits for health care professionals?

Boris
- HCPs benefit by gaining access to new treatments sooner and having more treatment options for patients.
- Ultimately, it benefits everyone if new innovative therapies reach patients faster.

Sophie
(transition precision oncology)

As global lead for precision oncology, you have a lot of experience with clinical trials, as this is one field with high unmet medical needs…

Can you elaborate on the difficulties within the medical research in this field? And what potential advantages and benefits synthetic data have – in this field, specifically?

Boris
(difficulties in oncology)

- Many new drugs being investigated ->Many ongoing clinical trials competing to recruit patients
- Limited number of patients, as oncology gets more fragmented (refer to precision oncology with more narrow patient populations; oncology indications becoming rare diseases)
- Difficult to recruit patients without delay for clinical trials

Sophie
Boris, how have you observed the covid-19 pandemic affecting drug development?

Boris (increased importance due to high and rapid demand of covid-19 vaccine, e.g. "speed matters")

- rapid development of covid-19 vaccines has set new expectations for drug development
- it's time to leverage advances in technology and data to meet these expectations
- wasting potential on existing patient data in clinical trials
- synthetic data in clinical trials can be a key accelerator

Sophie
How do you propose pharma companies start using synthetic data? What are the key steps they need to take?

Boris

There are four building blocks that are crucial for pharma companies to make strides in the usage of synthetic data tools.

1. Draft your big plan while getting started with pilots
    - Create a bold global vision for leveraging synthetic data in clinical trials; prioritize assets with which to pilot the new approach.

2. take stock of your data & look outside for more
    - Supplement internal data with external data sources to achieve a robust validated data set.

3. Deploy Smart algorithms for 'what-if' analysis
    - Integrate and automate algorithms into analytics platforms to evaluate and predict potential outcomes.

4. Evolve your operating model
    - New governance, skills and processes are needed so that predictive data analytics can inform clinical deployment plans

((Short sci-fi sound to underline where-to-start-plan, fade-in over interviewer))

Sophie
In 2018, you published a book… you write about robots, holograms, and cloned replacement organs… it sounds like science fiction, but it's actually a scientific reference book describing the current era of medicine called *Med Revolution*.

You discuss societal challenges and peruse questions like "What changes for consumers?" and "What changes for the pharma industry?"

Can you briefly summarize what your findings were then and how they may have changed 3 years and a pandemic later?"

Boris

- Technology was already invented then but has become more usable now.
- Different forces leading to a revolutionized form of health care
    - Cloud Computing
    - Internet of Things
    - Artificial Intelligence
    - 3-D print
    - Virtual Reality
    - Nanomedicine

- CRISPR
- Cyborgs

- Pandemic was a catalyst for a change in drug development and health care system over all
- Focus shift from treatment of symptoms to prevention and preservation of health.
- Transparency of data enables consumers to become more emancipated and able to control their health.

Sophie
So, Boris, in your opinion: is the "Med Revolution" over?

Boris
(e.g. "The revolution is only getting started")

- importance of intersection health care and digital transformation
- Increasing amount of Data huge opportunity – but the data first needs to be made usable and technology needs to be rightly applied to extract Value out of the data
- Great example is the use of synthetic data in clinical trials but this is only a small piece of the immense opportunity to leverage data and apply smart analytics in healthcare

Sophie
(e.g. "An exciting time we are living in…" "the revolution is not over…" "let's seize the opportunity" repeats/summarizes Boris strong statement)

Thank you for this insightful conversation, Boris!

Boris
(Thank you etc.)

OUTRO – 1 minute

((fade-in jingle))

Off-voice
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Thank you for listening!

Off-voice
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((fade-out jingle))
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