



MICHALOPOULOU  
& ASSOCIATES

Law under the microscope

# Legal aspects regarding the use of Innovative medicines in a Digitizing world

Cancer & Personalized Conference • *Thursday October 17<sup>th</sup> 2019* •  
*Divani Caravel*

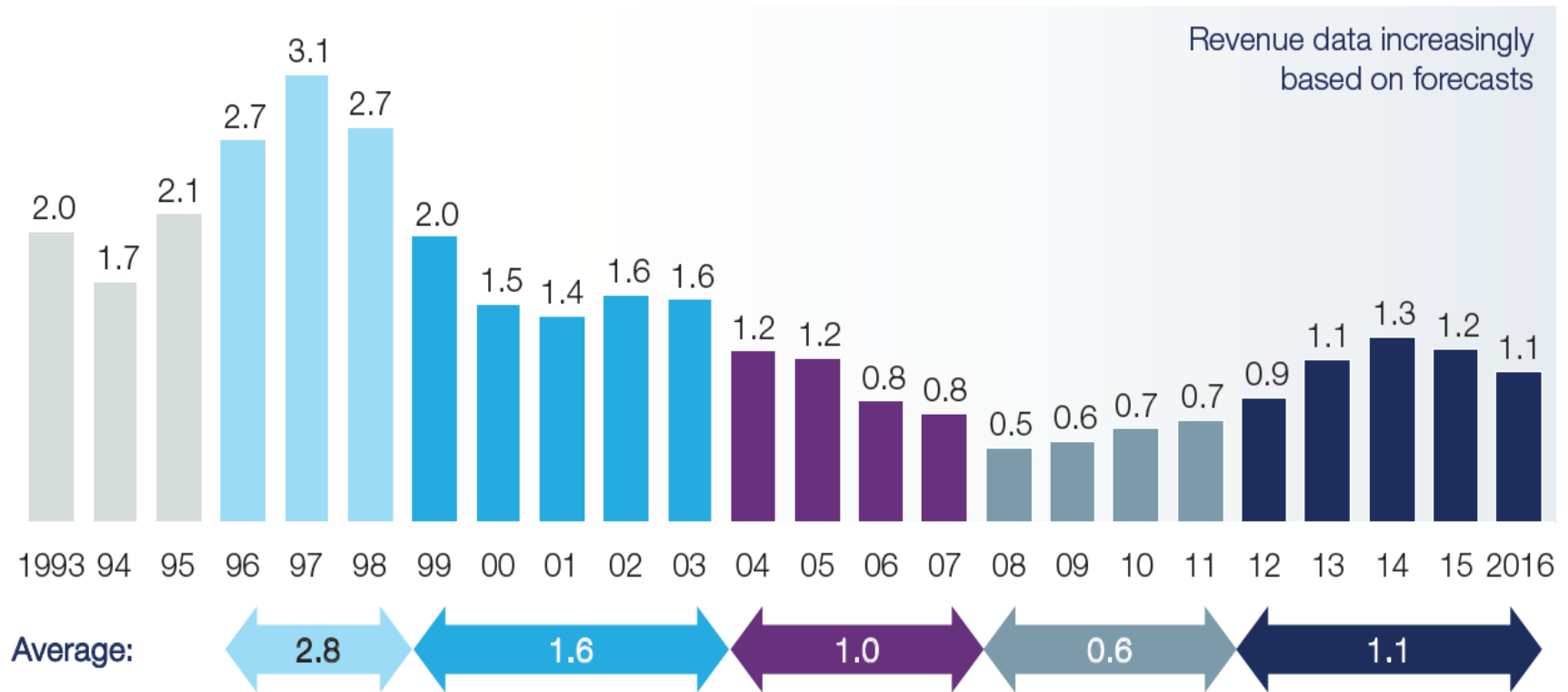
# Healthcare challenges & Innovation in R & D: the 100 billion \$ opportunity

- **Agging Populations**
- **Chronic diseases burden**
- **Middle class growth in Asia**



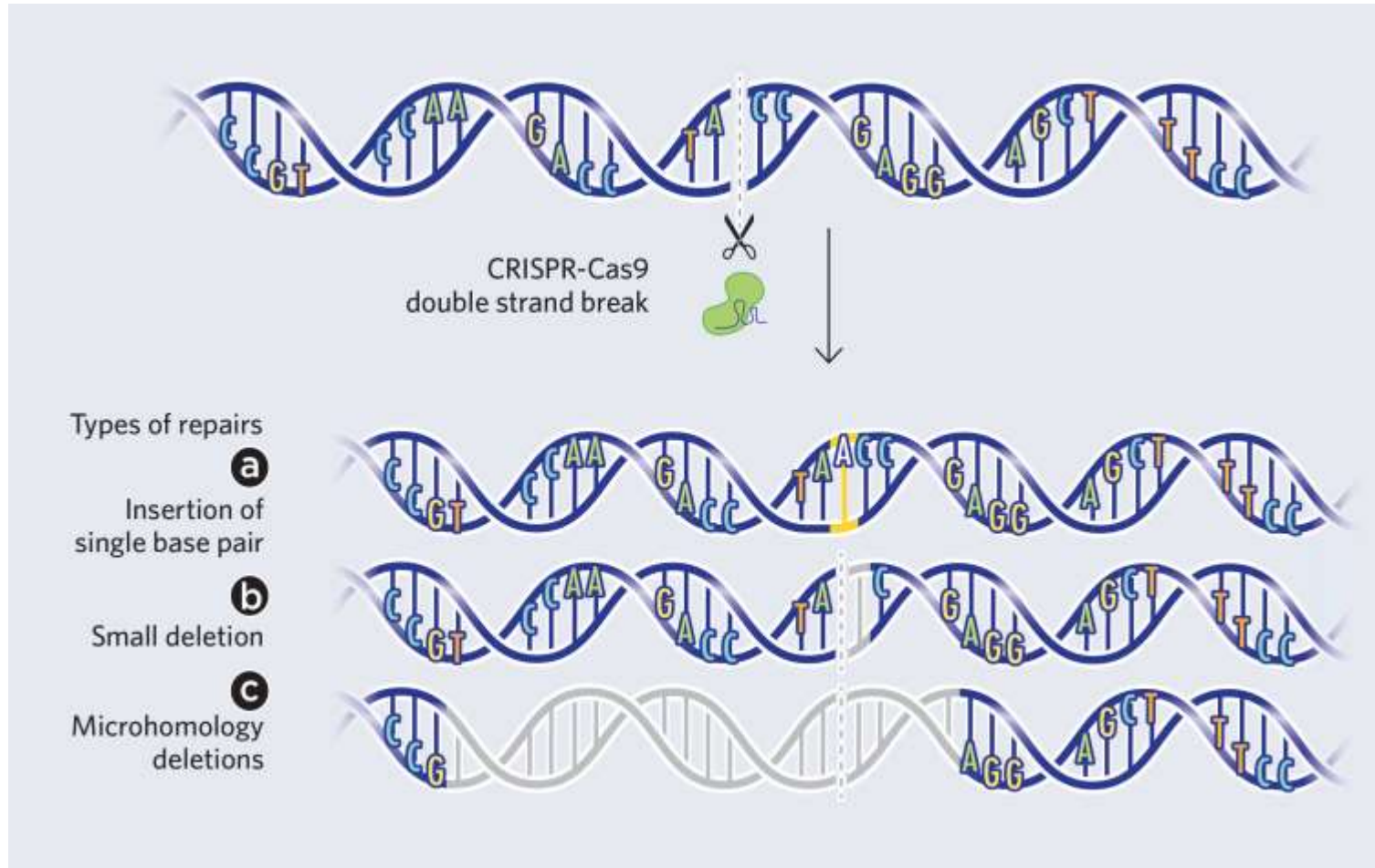
*Source: Qualcomm Previewing 5G's effect on the health care industry*

# Productivity is improving but there is an uncertainty going forward



Source: EvaluatePharma May 2017; PhRMA 2016; McKinsey analysis

# Precision & Personalized Medicine



Source: Could AI make gene editing more accurate, The Scientist Magazine, May 2019

# ***“Scientists Designed a Drug for Just One Patient. Her Name Is Mila”***



Source: The New York Times, Oct. 9<sup>th</sup> 2019

# Patient Involvement in CR “Nothing about me without me”

- Γιατί
- Πότε
- Πώς
- → Patient Reported Outcomes (PROs)
- → Διακήρυξη του Ελσίνκι (τροπ. 2013)

# Clinical Trials & Artificial Intelligence

*“So much of this money is spent on humans checking other humans work in person. Half of the money is spent with clinical monitors at clinical sites. It’s a regulatory requirement. It’s not efficient and it’s not effective. It doesn’t necessarily pick out the problems. Getting rid of that piece of it cuts clinical trials cost by more than half and we’re ready to do that right now”*

**Stephen D Wiviott**  
Associate Professor  
Brigham and Women's Hospital, Boston, US



# World completely Digital not simply Digitized: a Complete Rethink

## Real World Evidence

- Patients matched to clinical trials using diverse data sources
- Trials 'Live' monitoring
- Data Collection through non-interventional means



# Ethical & Legal Concerns of Gene Editing

- Clinical Trials Regulation
- EU Genome Declaration on Cross-border Access to Genomic Database
- GDPR rights (information, access, rectification, erasure, restriction, data portability, object)
- & Privacy rights



*Source: UNESCO panel of experts calls for ban on "editing" of human DNA to avoid unethical tampering with hereditary traits*



- **Identify AI capabilities to competitive digital differentiation**
  - **Invest in technology**
  - **Draft Transparent & Compliant Processes & Procedures**
    - **Align with EU and national legislation**
    - **Define your Legal Strategy**  
(Data Privacy, Security, Accessibility)
    - **HCP education**
    - **Train and render “Expert Patients”**
- &**
- **Contribute in AI- based regulation: the Time is Now!**

# Thank you



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