SIARV
Società Italiana Attività Regolatorie, Accesso, FarmacoVigilanza

# GIORNATE DI STUDIO E AGGIORNAMENTO DEDICATO ALLE ATTIVITÀ REGOLATORIE, DI ACCESSO E DI FARMACOVIGILANZA

## 19° Corso Didattico SIARV

27 e 28 maggio 2026
STARHOTELS Metropole, Roma

## OLTRE L'ORIZZONTE: INNOVAZIONE FARMACEUTICA TRA TEMPESTE GEOPOLITICHE E NUOVE CURE

RENATO DELLAMANO – VALUEVECTOR S.R.L.

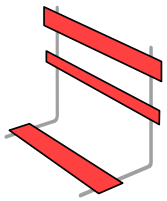
# BEYOND THE HORIZON: PHARMACEUTICAL INNOVATION BETWEEN GEOPOLITICAL STORMS AND NEW CURES

RENATO DELLAMANO – VALUEVECTOR S.R.L.

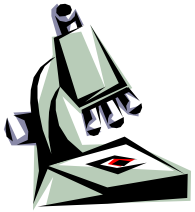
ROME, MAY 27TH 2026

# Old and New Challenges In an Increasingly Complex Context

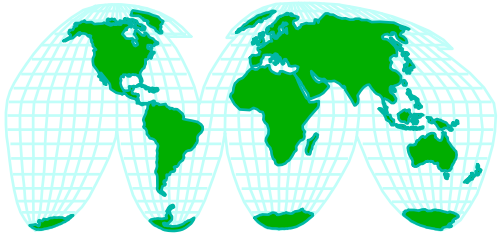
- Inequality in access to innovative therapies



- Evolving context for R&D / clinical research



- Growing international pressures



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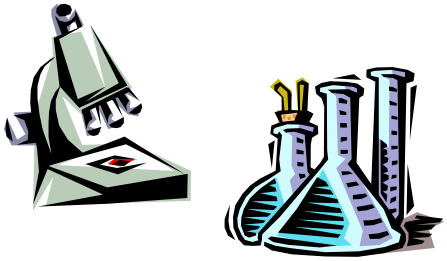

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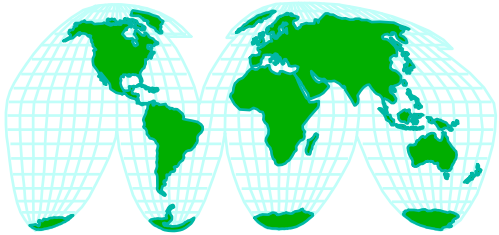

# Inequality in Access to Innovative Therapies – 1 of 3

According to the 2025 update of the EFPIA / IQVIA "W.A.I.T." Indicator, published just few days ago, in the surveyed countries:

- A greater percentage of new centrally approved medicines is not yet available vs historical landscape: 49% (in 2025) vs 46% (in 2019)
- When available, a greater percentage of new centrally approved medicines is only available on a restricted basis: 22% (2025) vs 11% (2019)
- The overall percentage of new centrally approved medicines fully available under the various public reimbursement systems has gone down from 42% (2019) to 28% (2025)

# Inequality in Access to Innovative Therapies – 2 of 3

According to the 2025 update of the EFPIA / IQVIA "W.A.I.T." Indicator…:

- The EU average time to availability in 2025 was 597 days, up by 19 days vs the 2024 survey (578 days) and by 93 days vs 2019 (504 days)
- Access disparity between the European country with the highest availability and the one with the lowest availability was 88%
- Across the largest European countries, considering all forms of availability (full and restricted), Germany was the country with the largest percentage of available products (93% of all centrally approved drugs), followed by Italy (79%), Spain (69%), England (61%), France (60%) and Poland (46%)

# Inequality in Access to Innovative Therapies – 3 of 3

The European Joint Clinical Assessment (JCA) procedure is being introduced with the stated purpose to accelerate time to access; however:

- The JCA procedure is scheduled to complete up to 30 days after EC approval of the drug being assessed
- Some of the countries that have already updated their national HTA procedures to incorporate results of the JCA (e.g., the Netherlands), actually will initiate their assessment only after the availability of the JCA Report
- From January 2028 also Orphan Drugs will become subject to the JCA procedure; what will happen with those countries, e.g., Italy, that allow national P&R submission of Orphan Drug prior to EC approval?

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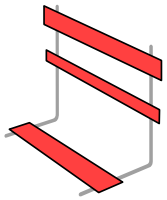

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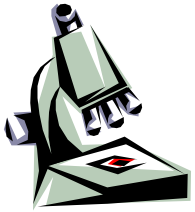

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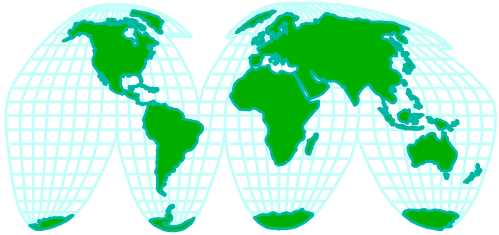

# …In an Evolving Context for R&D – 1 of 2

- According to a recent study*, China experienced rapid growth in clinical trials, surpassing both Japan and the US in total trials and RCTs; in particular, in 2023:
  - China recorded 16,612 total trials (7,798 RCTs) vs 9,100 trials (4,619 RCTs) registered in the US
- According to an analysis published by McKinsey^ in Jan 2026, key factors driving the growth of China as a leader in clinical trials are lower costs and speed to recruitment and execution
  - The size of China's scientific talent pool — in particular the country's investments in science, technology, engineering and mathematics education — is also an important factor

*J Clin Epidemiol, 2025 Jul:183:111791. doi: 10.1016/j.jclinepi.2025.111791. Epub 2025 Apr 17
^https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future#/

# …In an Evolving Context for R&D – 2 of 2

- Besides changes in the geography of R&D activities, three other key trends have been identified as shaping today's and tomorrow's clinical research*:
  1. The Sweeping Influence of AI… What are the risks of an "acritical" use of AI in clinical research and data interpretation and analysis?
  2. The Growing Value of Real-World Evidence studies… How can we ensure the quality and the timeliness of such studies? And how can they influence market access decisions?
  3. Delving Deeper into Patient-Reported Outcomes… How relevant are such outcomes in real-world HTA procedures?

*https://learn.hms.harvard.edu/insights/all-insights/three-trends-shaping-clinical-research

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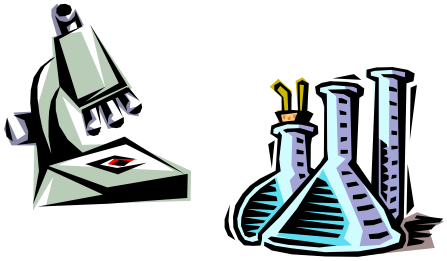

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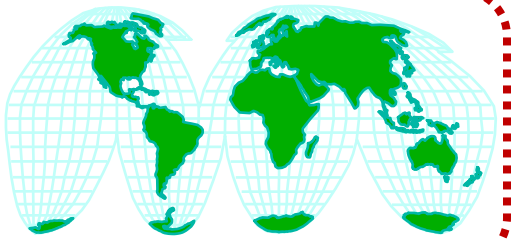

# …And Growing International Pressures

- On April 2 2026, the UK government announced an Arrangement between the US and the UK on pharmaceutical pricing*; among other decisions affecting access, the UK committed to:
  - Doubling its spending on New Medicines as a proportion of the GDP from 0.3% in 2026 to 0.6% by 2036
  - Increasing the net price paid by the NHS for prospective New Medicines by 25%, beginning in April 2026
  - Raising the NICE basic C/E threshold from between £20,000 and £30,000 to between £25,000 and £35,000
  - Ensuring that the benefits of the net price increase for prospective New Medicines are not offset or materially eroded by other mechanisms (e.g., VPAG, Statutory Scheme, etc.)

*https://www.gov.uk/government/publications/uk-us-arrangement-on-pharmaceutical-trade-and-pricing/arrangement-between-the-united-states-of-america-and-the-united-kingdom-on-pharmaceutical-pricing-html

# In Conclusion…

- How can the European (and global…) pharma companies adjust their strategies to the evolving environment and be more cognizant of real unmet needs when making R&D and Business Development investments?
- Can European health systems still pretend to manage healthcare budgets like in the past, without considering a broader perspective?
- How are the epochal changes we are witnessing likely to reshape the way we live our professional lives as people working in the market access field?

# Thank You!