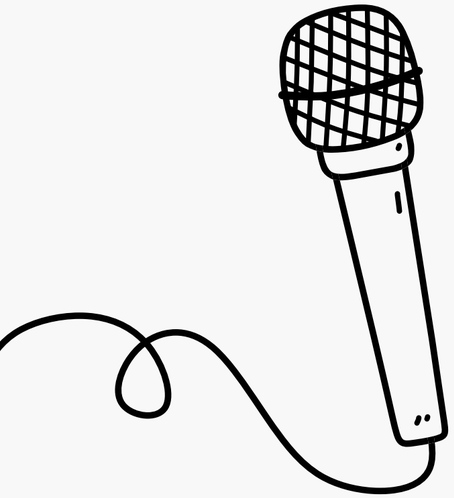
SETTING THE SCENE:



ZISIS KOZLAKIDIS

Head of the Laboratory Services and Biobank Group (LSB), IARC

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VISION EUROPE 2030

DISRUPTIVETECHNOLOGIES,DEMOCRATIZEDTRIALS& NEXT-GEN TREATMENT PARADIGMS

September 2-3, 2025 | Club University Foundation

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Zisis Kozlakidis
International Agency for Research on Cancer (IARC/WHO)

Precision Oncology 2.0

Rewritingtherules:FromRCT-centered models to Innovation-ready systems

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BACKGROUND

Cancerresearch increasingly involves multi-omics data, biomarker-driven therapies, and personalized interventions. The traditional randomized controlled trial (RCT) framework often struggles to adapt to small, heterogeneous patient populations.

Cancer affects diverse populations, yet often RCTs often exclude patients, e.g., with comorbidities or rare cancers.

Thus, infrastructure that supports adaptive trial designs, platform trials, and real-world evidence collection is better suited to evaluate innovation in oncology. For example, building infrastructures (e.g., biobanks, federated data platforms, digital health tools) that capture longitudinal and real-world evidence enables more inclusive, representative insights than narrow RCT models can achieve.

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KEY ISSUES TO BE TACKLED

Enhancing innovation-ready infrastructures(learning healthsystems, longitudinal biobanking, AI-drivenanalytics). Thisensuresthat knowledgegained from one intervention is reinvested into the ‘system’, creating iterative refinement rather than a “one-off” RCT conclusion

Future-proofing cancer research requires regulatory and infrastructural alignment Infrastructures that supports interoperability and cross-border collaborations are key to moving beyond RCT-centricity toward systems designed for continuous innovation and faster patient benefit.

- If we keep excluding “non-ideal” patients in RCTs, how much of cancer’s reality are we actually studying?

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SWOT ANALYSIS

Cancer research is at the forefront of precision medicine, where flexible trial designs, digital monitoring, and global data sharing are essential.

Cancer research is becoming increasingly hybrid, with remote monitoring, wearables, and digital platforms generating streams of patient-reported outcomes and biological data.

Integrate these data in real time, requires networked infrastructures; now often siloed by geography and funding.

Can regulators ever be ready to move as fast as the science—and if not, who should ‘push’ them?

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ONE ACTIONABLE POLICY RECCOMENDATION

Investment in innovation-ready infrastructures, e.g.,adaptivetrialplatforms, interoperable biobanks, and real-world data systems should maintain the momentum of translating discoveries into personalised medicine. Complementing, rather than replacing, RCTs, these infrastructures enable more inclusive and responsive approaches to evidence generation.

As a pro-active policy recommendation, **regulatory sandboxes** should be established to test novel designs safely, aligning infrastructure, regulation, and practice to deliver faster, fairer, and more effective cancer care.

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Healthcare data integration is a bit like dating apps — everyone says they want to connect, but when it's time to share, suddenly nobody's profile is compatible!

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A CALL TO ACTION

Join the movement!

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