

The background of the slide is a close-up, slightly blurred image of the European Union flag, showing the blue field with yellow stars. A solid blue horizontal band is overlaid on the bottom half of the image, containing the title and speaker information in white text.








# Unlocking Innovation and Streamlining Access: The Impact of EU HTA Regulation


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# PIF innovates for your Health, planning to bring ~90 new innovative medicines to Greece in the next two years

THEN		TODAY		
1960s	Pediatric Cancer 20% of children survived <sup>3</sup>		84% of children survive* <sup>4</sup>	
1960s	Acute Lymphoblastic Leukemia in children 4% of children survived <sup>3</sup>		90% of children survive* <sup>5</sup>	
1970s	Chronic Myeloid Leukemia 22% of patients survived* <sup>6</sup>		70-90% patients survive* largely due to effective treatments <sup>6-8</sup>	
1990-2005	HIV 18.6M people estimated to have died globally due to HIV <sup>9</sup>		Individuals with HIV live almost as long as people without <sup>10,11</sup>	



**> 4,100 εργαζόμενοι**  
σε όλη την Ελλάδα

**PHARMA**  
Innovation Forum  
Greece

Από το 2019  
έως και το 2021,  
συνεισφέραμε **4 δις. ευρώ**  
σε άμεσες εισφορές  
στην ελληνική οικονομία,  
ποσό που αντιστοιχεί  
στο **1,8% του ΑΕΠ**

**PHARMA**  
Innovation Forum  
Greece

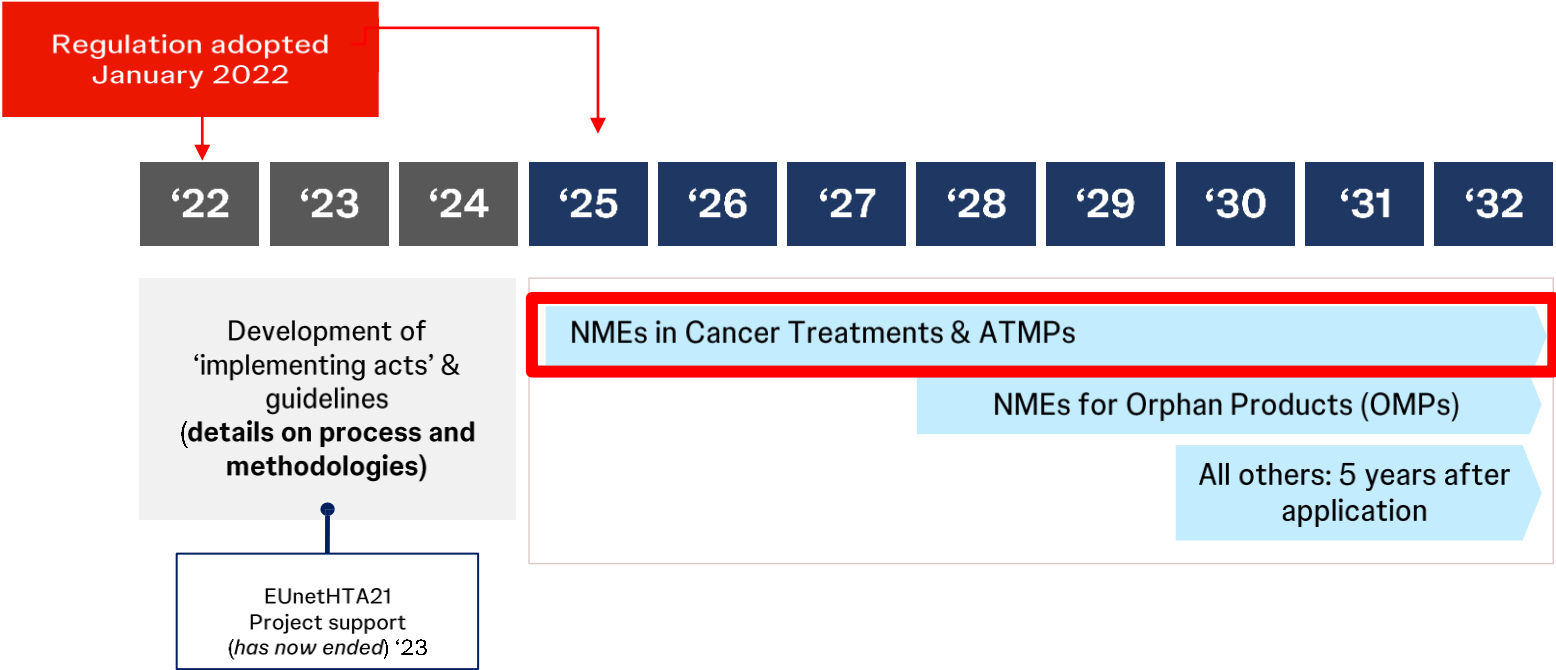
\*2023 KPMG Footprint Report

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Note: Survival is based on 5-year survival rates

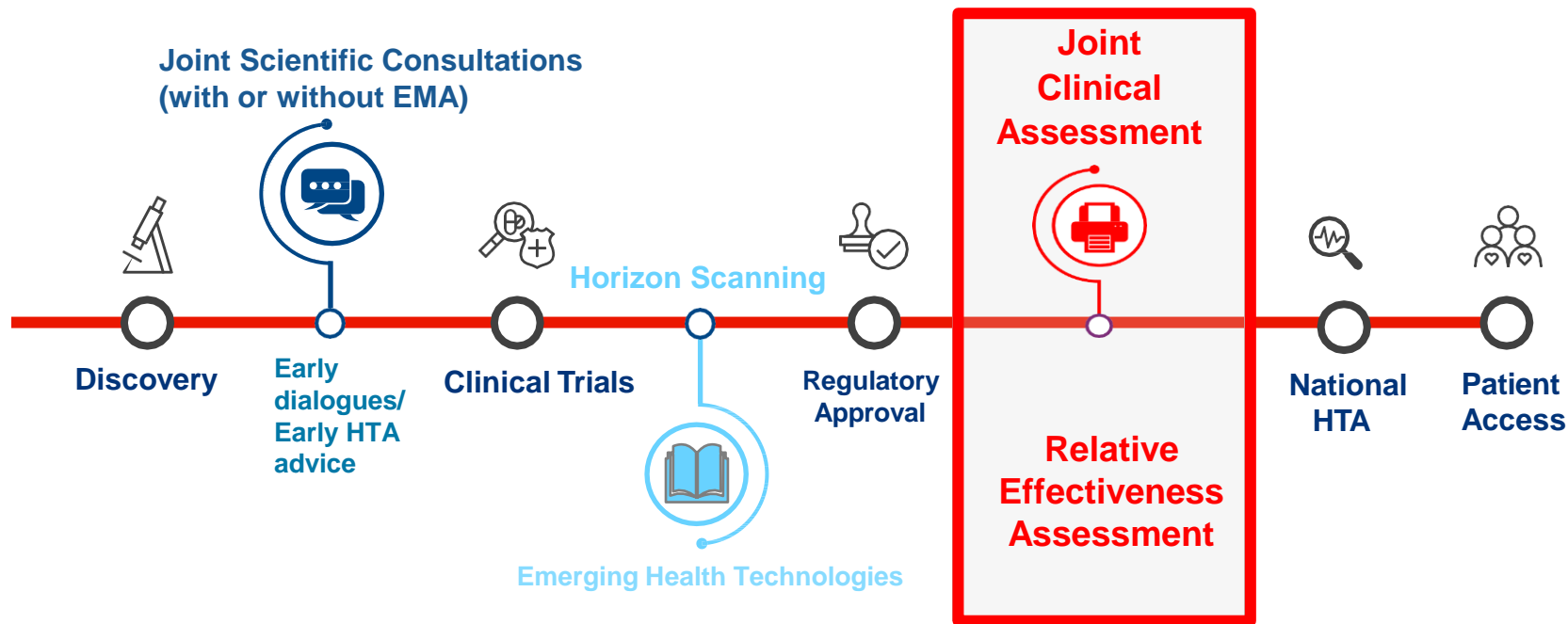
<sup>1</sup>CDC Global Immunization 2021; <sup>2</sup>College of Physicians of Philadelphia History of Vaccines; <sup>3</sup>St. Jude Children's Research Hospital; <sup>4</sup>ASCO Cancer.net 2021; <sup>5</sup>American Cancer Society Survival Rate 2019; <sup>6</sup>American Cancer Society Facts & Figures 2021; <sup>7</sup>Druker et al 2006; <sup>8</sup>Hao et al 2019; <sup>9</sup>WHO GHO data 2021; <sup>10</sup>Marcus et al 2020; <sup>11</sup>Samji et al 2013

# HTA regulation adopted in 2022, implementation from 2025 for Cancer Treatments & ATMPs



\*HTA: Health Technology Assessment, ATMPs: Advanced Therapy Medicinal Products, NMEs: New Molecular Entities, OMPs: Orphan Medicinal Products

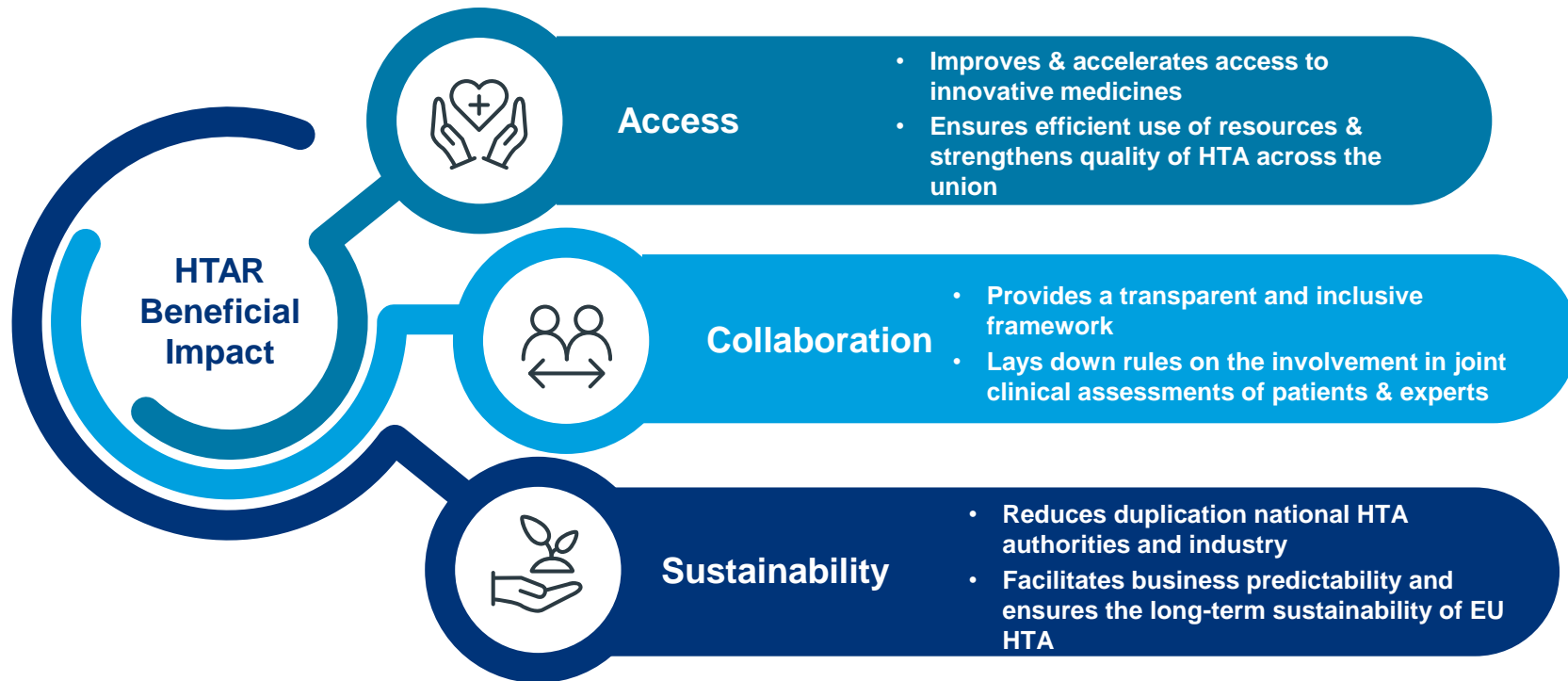
# Joint Clinical Assessment: the main focus & major change of the EU HTA regulation



+ "Voluntary Cooperation": to allow other collaborations between Member States

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# Upcoming legislation transforms the HTA framework into 3 pillars that should benefit patients



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# We are discussing saving time that saves lives



## 3 “pain points” must be addressed to fully realize the benefits of the regulation



# Partnering with stakeholders will secure the implementation of this transformative moment

## PROPOSALS



**Ensure industry is engaged in developing the scope of individuals JCAs as well as the JCA process in general**



**Ensure industry is provided with sufficient time to develop the clinical evidence dossier for JCA**



**Ensure JCA provides a predictable and usable report that can be used by Member-States Decision-Makers without duplication**



# Local readiness can be secured through collaboration, delay avoidance & implementation planning

## Stakeholder Collaboration



Working Group establishment

## Delay Avoidance



Abolish provisions leading to delays  
in reimbursement

## Implementation Planning



Quality submissions speed up  
access



**Ensuring the right patient gets the right treatment at the right time**