UNIVERSITÄTS
KLINIKUM
HEIDELBERG

150 iPH
Institute of Pathology Heidelberg

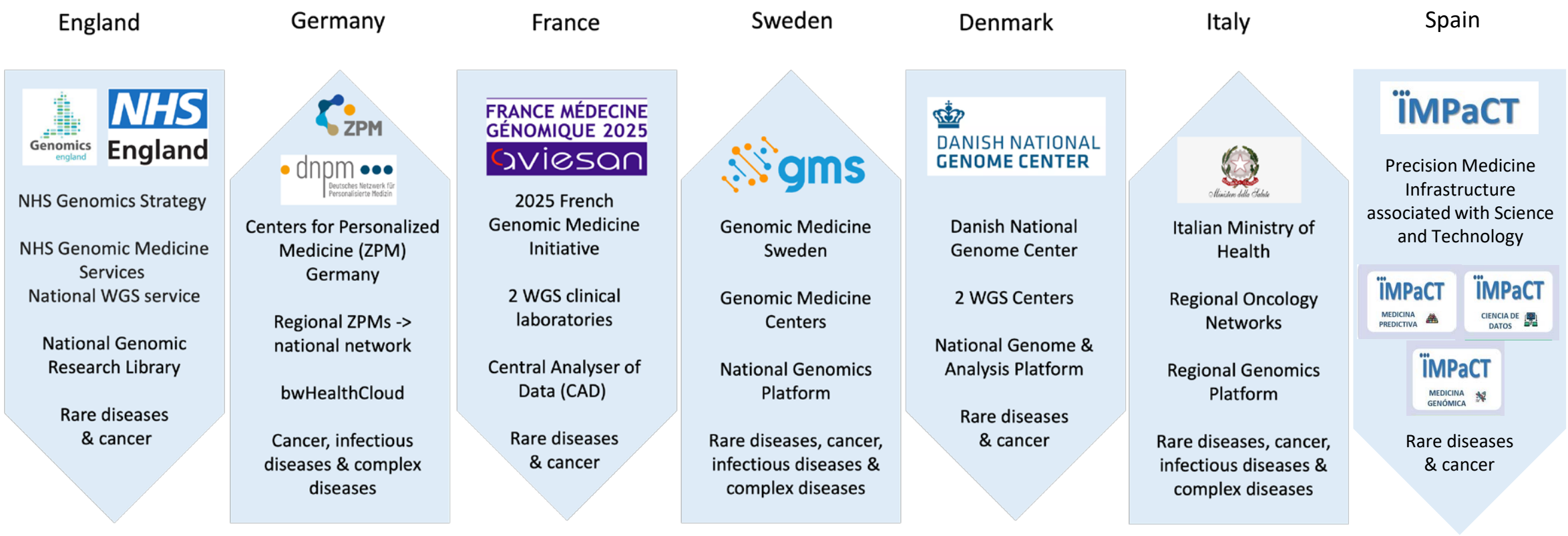
Networks

Albrecht Stenzinger

Institute of Pathology
Center for Molecular Pathology

UK HD

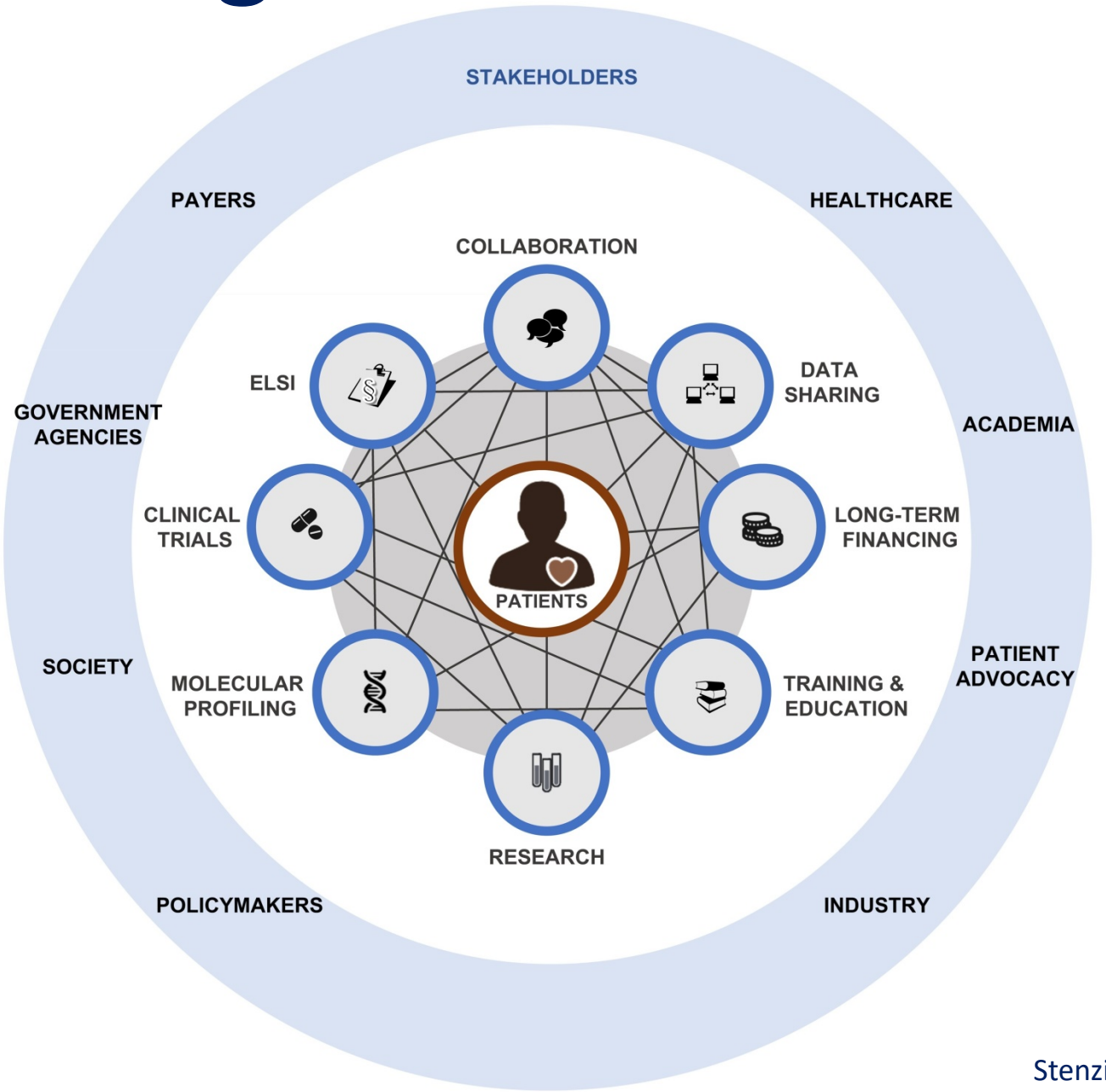
PM Networks in Europe



A. Stenzinger….S. Hill, R. Rosenquist, 2023, in press

Stakeholder Integration

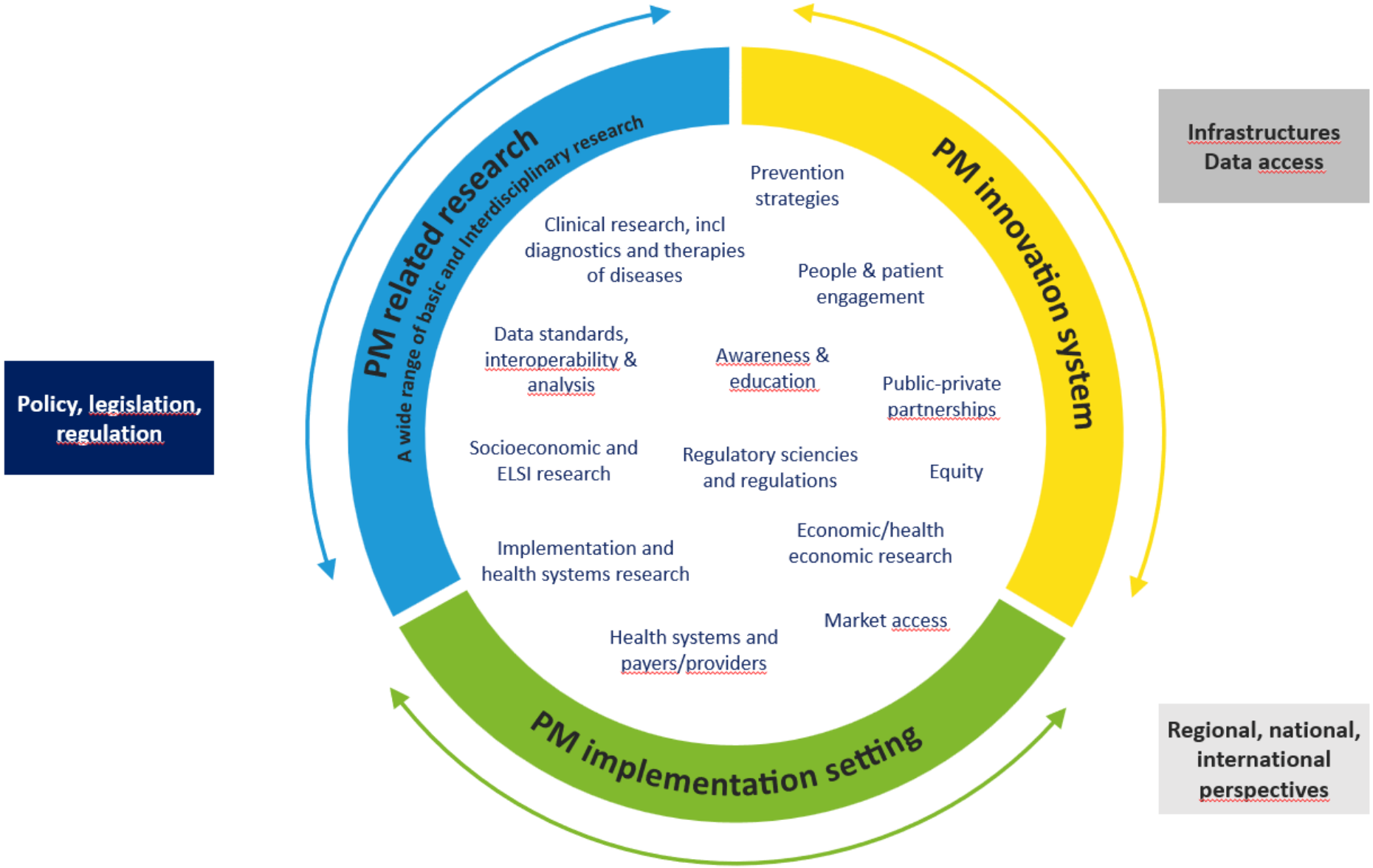
ZPM
Centers for Personalized Medicine



gms
Genomic Medicine Sweden

Stenzinger et al., Semin Cancer Biol, 2022

Unique ecosystems



A. Stenzinger….S. Hill, R. Rosenquist, 2023, in press

Annals of Oncology
Available online 3 July 2023
In Press, Journal Pre-proof What's this?

Original Article

ESMO Study on the Availability and Accessibility of Biomolecular Technologies in Oncology in Europe

A. Bayle [1 2 3 4 5], J. Bonastre [3 4], D. Chaltiel [3 4], N. Latino [5], E. Rouleau [6 7], S. Peters [5 8], M. Galotti [5], G. Bricalli [5], B. Besse [2 9 *], R. Giuliani [5 10 *]

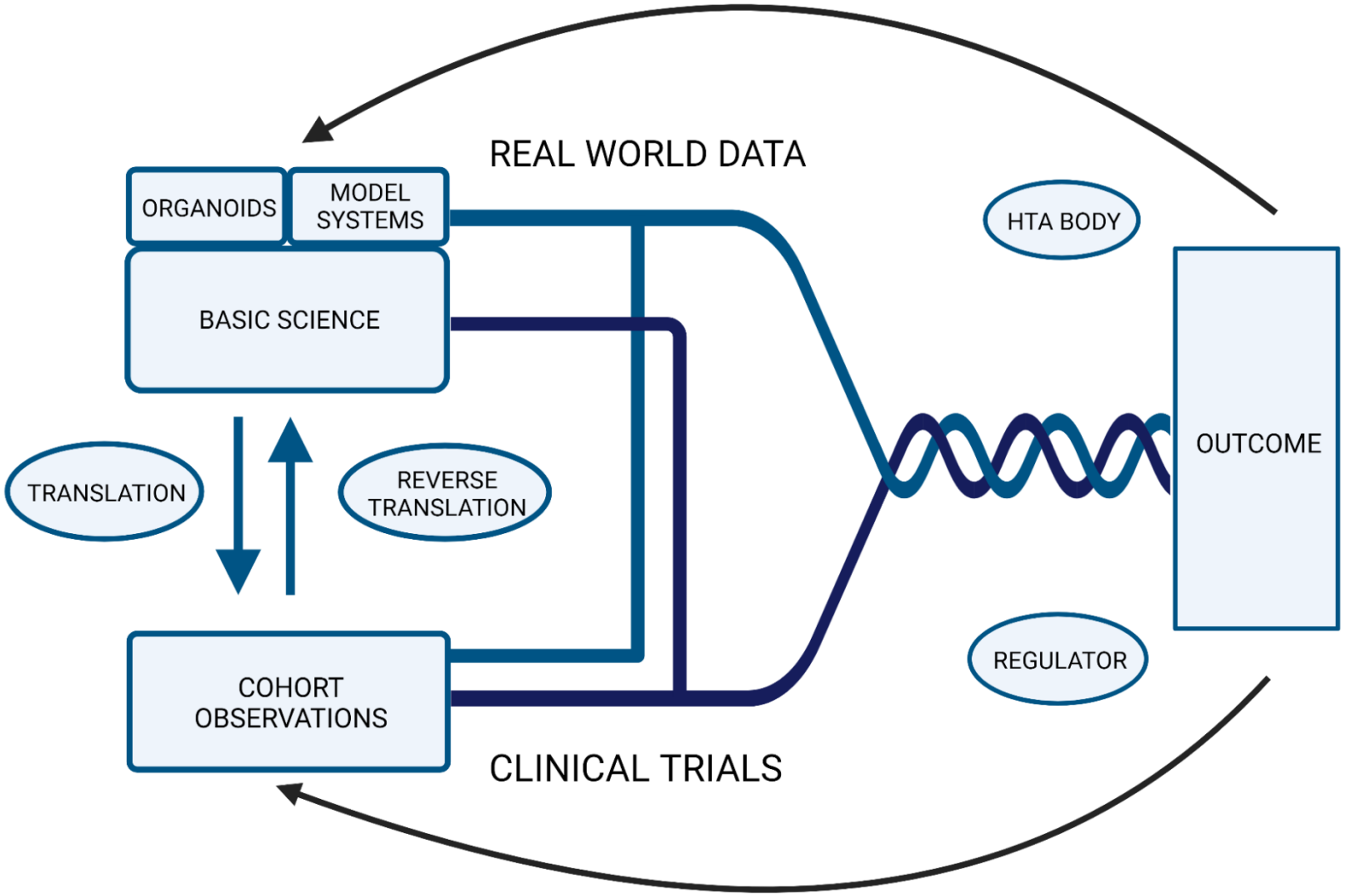
Table 3: Availability of techniques across countries by region

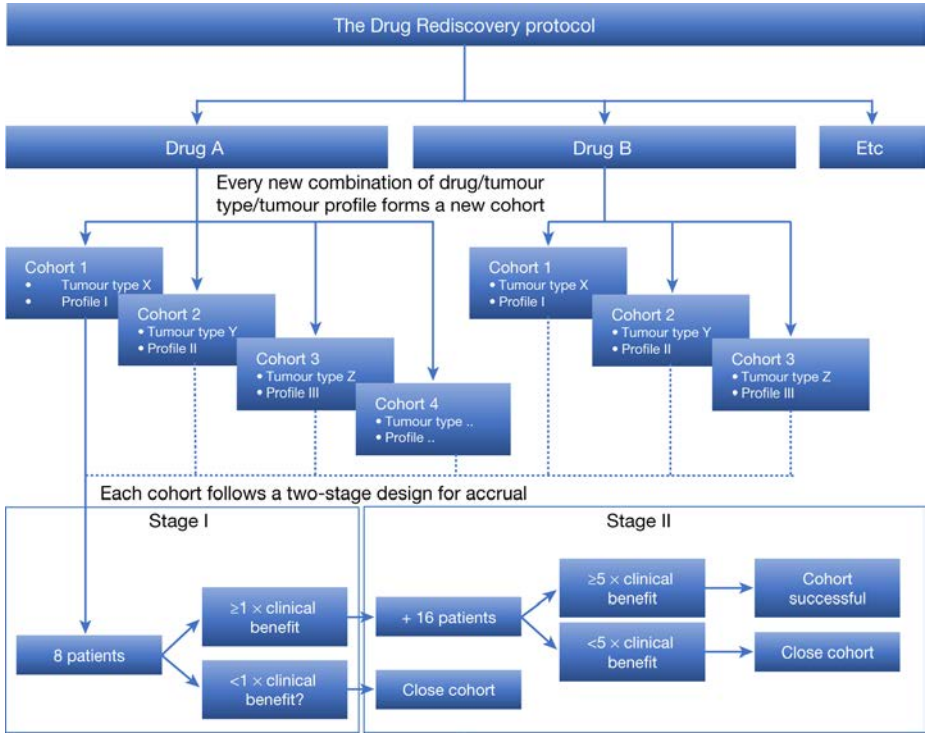
ALWAYS | USUALLY | OCCASIONNALY | RESEARCH | NEVER | NA

	Country*	IHC	FISH Lung_breast_Gastric	FISH Other	PCR	MSI Colon_Gastric	MSI Other	NGS Small	NGS Large	RNA Target	RNA Large	Genomic Assay	TMB	WES	WGS	Liquid Biopsies
Western European countries	**Andorra**															
	Austria															
	Belgium															
	Cyprus															
	Denmark															
	Finland															
	France															
	Germany															
	Greece															
	Iceland															
	Ireland															
	Israel															
	Italy															
	Luxembourg															
	Malta															
	Netherlands															
	Norway															
	Portugal															
	Spain															
	Sweden															
	Switzerland															
	United Kingdom and Northern Ireland															
Eastern European countries	**Albania**															
	Armenia															
	Azerbaijan															
	Belarus															
	Bosnia and Herzegovina															
	Bulgaria															
	Croatia															
	Czech Republic															
	Estonia															
	Georgia															
	Hungary															
	Kazakhstan															
	Kyrgyzstan															
	Latvia															
	Lithuania															
	Poland															
	Republic of North Macedonia															
	Romania															
	Russian Federation															
	Serbia															
	Slovakia															

Bayle et al., 2023

Clinical Trials

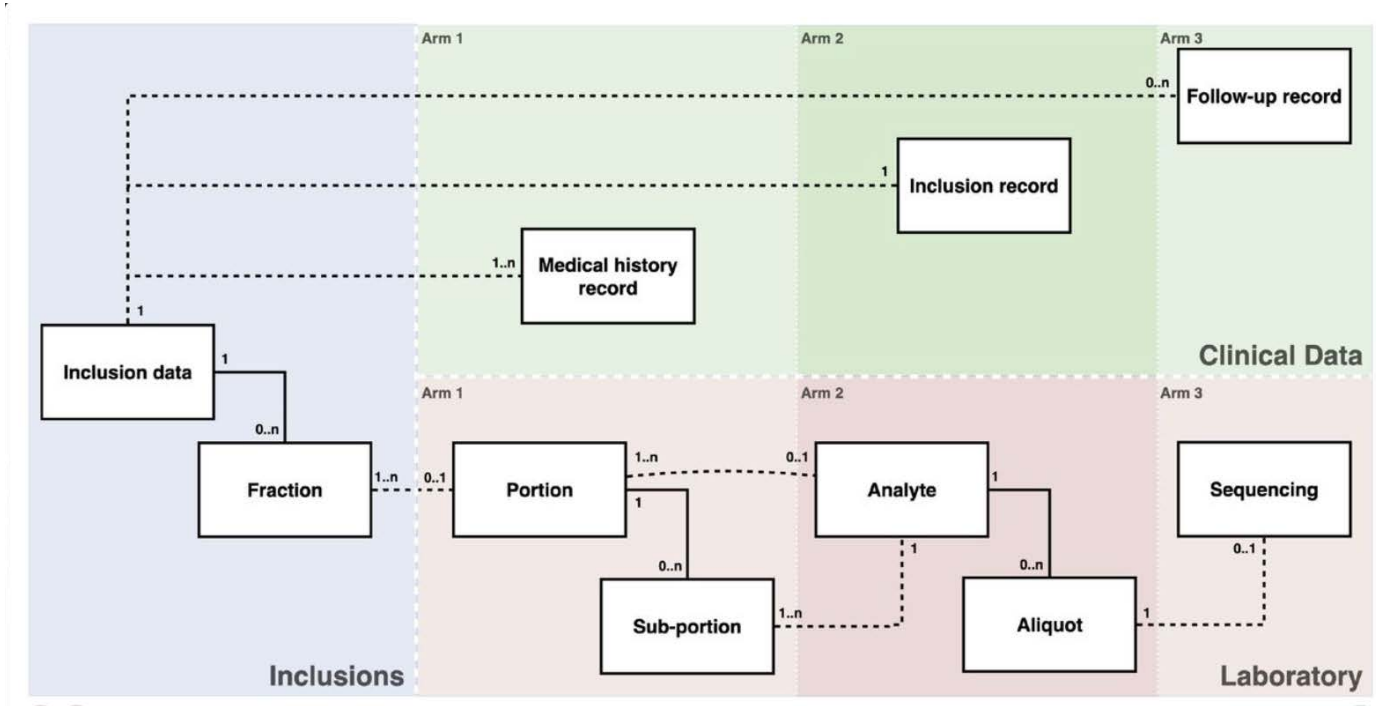


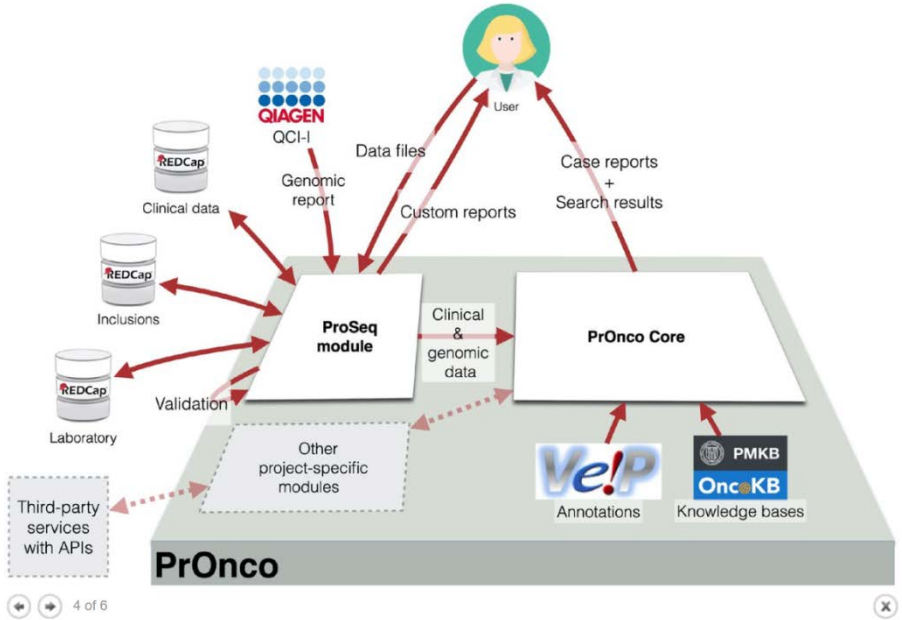


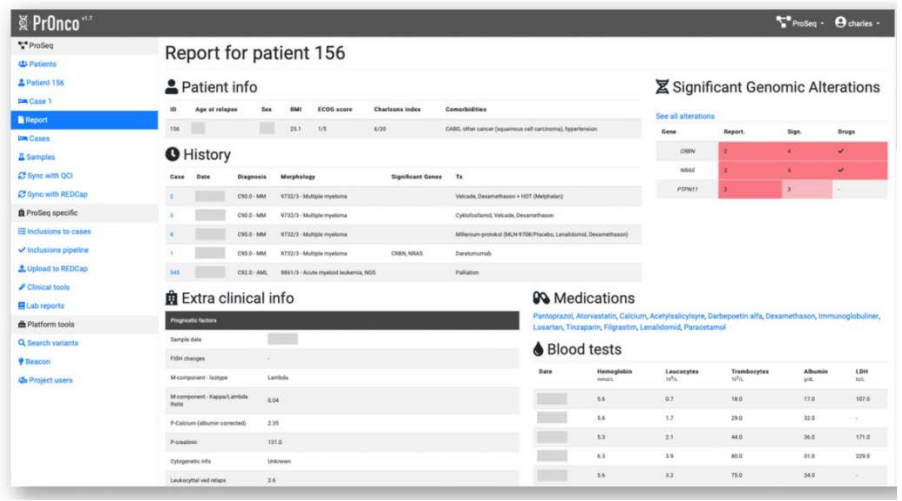
Edsjö….Stenzinger, in revision

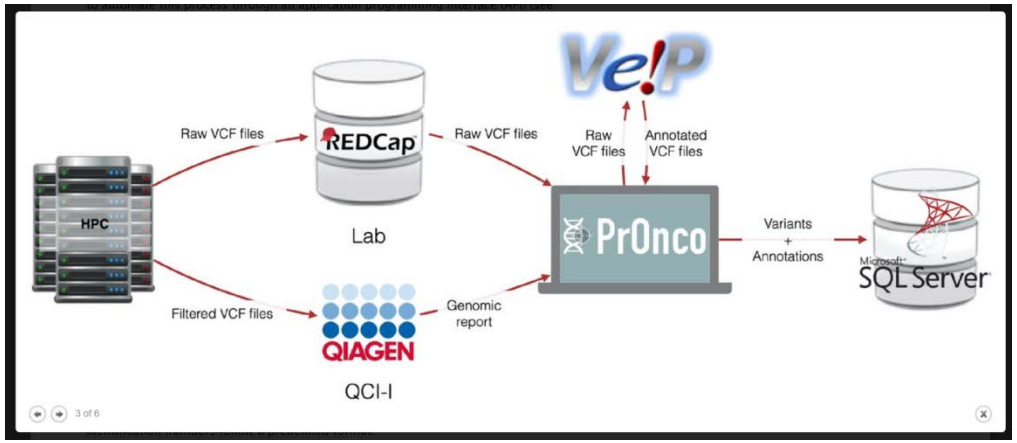
Van der Velden et al., 2019

Sustainable Data Infrastructure









Vesteghem et al., submitted

Personalized Medicine: Regulatory Framework of the EU		
Regulation	**Purpose**	**Challenges**
European Health Data Space (EHDS)	Empowering control and secondary use of personal electronic health data. Fostering a market for electronic health records.	Complexity National resources for implementation Siloed health care systems Orphan diseases Knowledge generating healthcare Ecosystem for innovation
General Data Protection Regulation (GDPR)	Enhancement of control and rights over personal data, simplification of regulatory environment.	
Health Technology Assessment Regulation (HTAR)	Joint clinical assessments, joint scientific consultations, identification of emerging health technologies.	
In Vitro Diagnostic Medical Devices Regulation (IVDR)	Protection of public health, patients and users. Functionality of internal market (SME).	
Clinical Trials Regulation	Favorable environment for clinical research, high standards of public transparency and safety for participants.	

A. Stenzinger….S. Hill, R. Rosenquist, 2023

EU General Data Protection Regulation (GDPR)

- Rights of the data subjects (e.g. right to data erasure, right to data portability)
- Data protection by design and default
- Broad consent under adherence to ethical standards
- Risk assessment and documentation rules
- Additional requirements for data transfer

Meant to enhance and foster

National/regional PM infrastructures & international research networks/consortia
(with ethicolegal governance, consents & standards)

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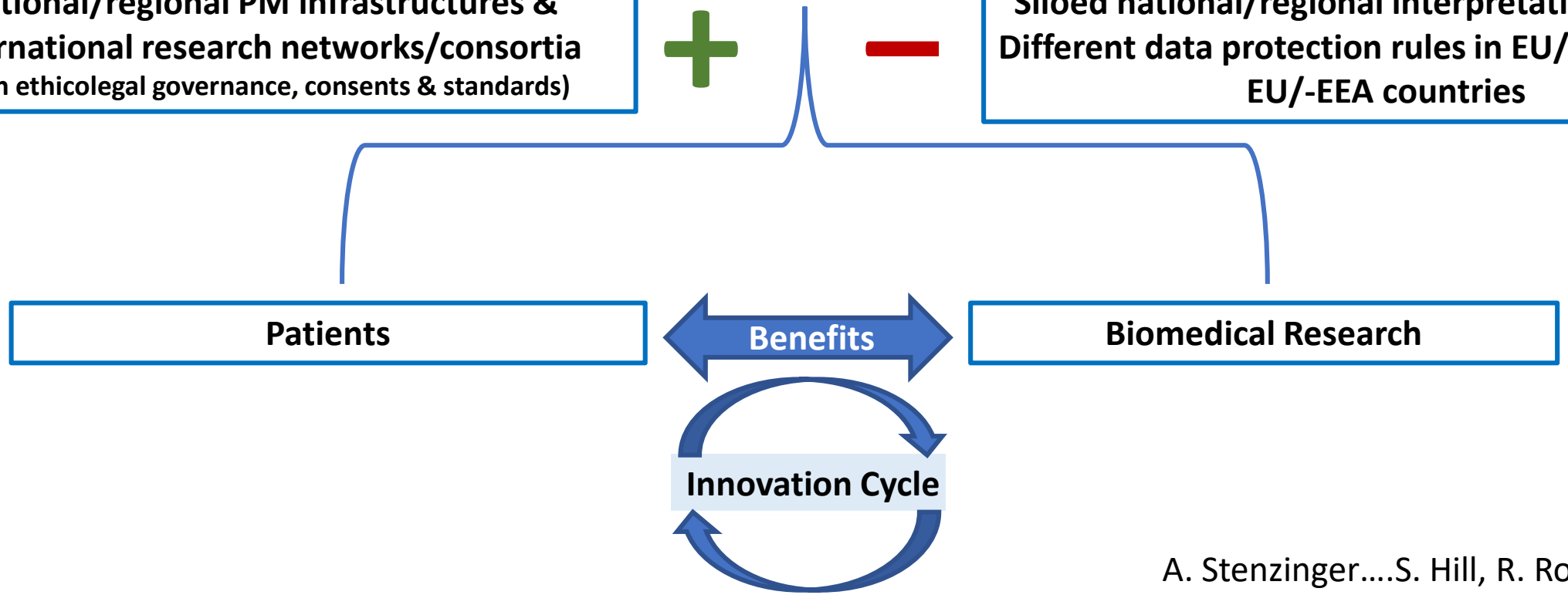
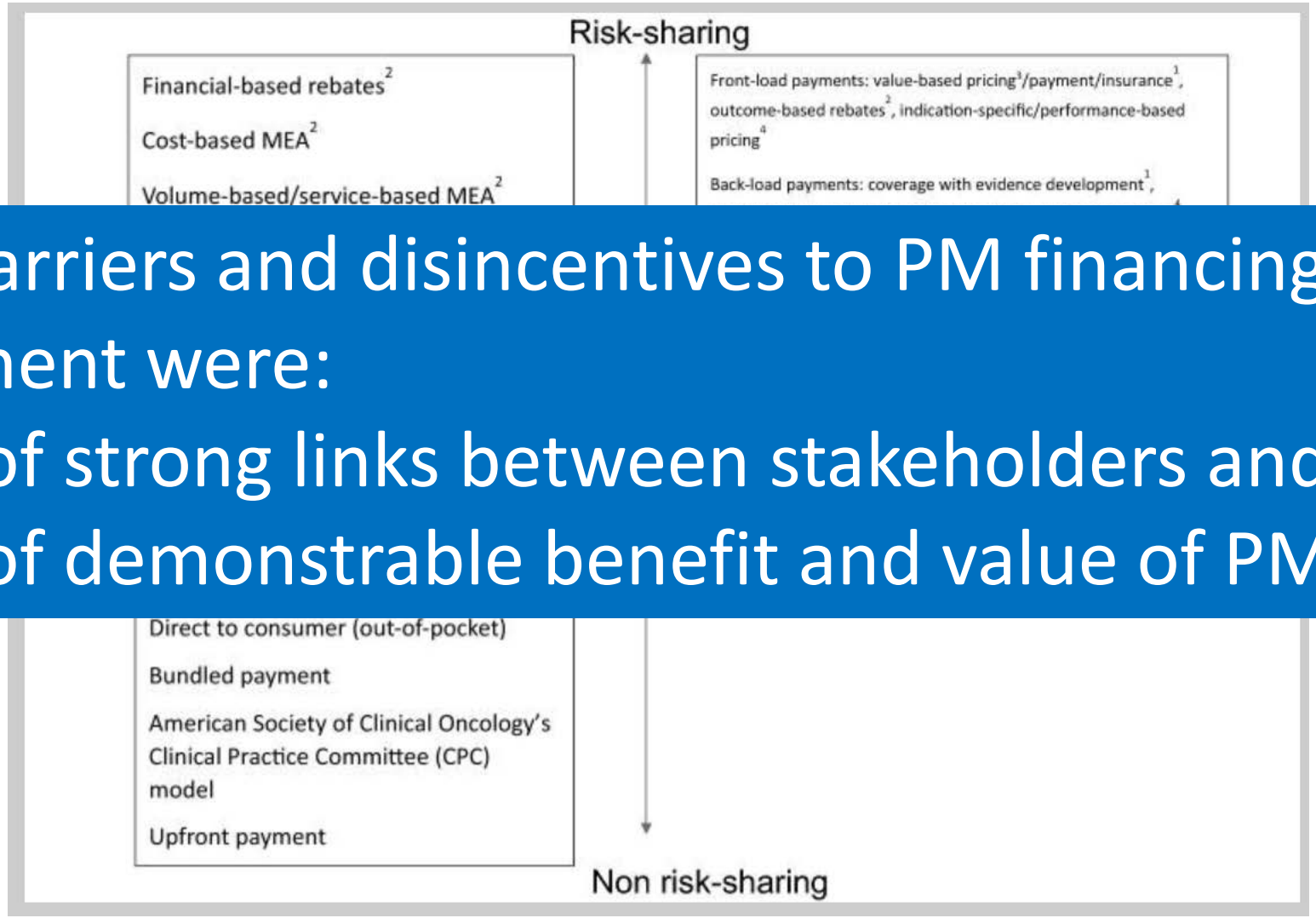
Siloed national/regional interpretations of GDPR
Different data protection rules in EU/EEA and non-EU/-EEA countries



A. Stenzinger….S. Hill, R. Rosenquist, 2023

Sustainable Financing and Reimbursement



The main barriers and disincentives to PM financing and reimbursement were:

1- the lack of strong links between stakeholders and

2- the lack of demonstrable benefit and value of PM

Koleva-Kolarova et al., 2022

Thank you