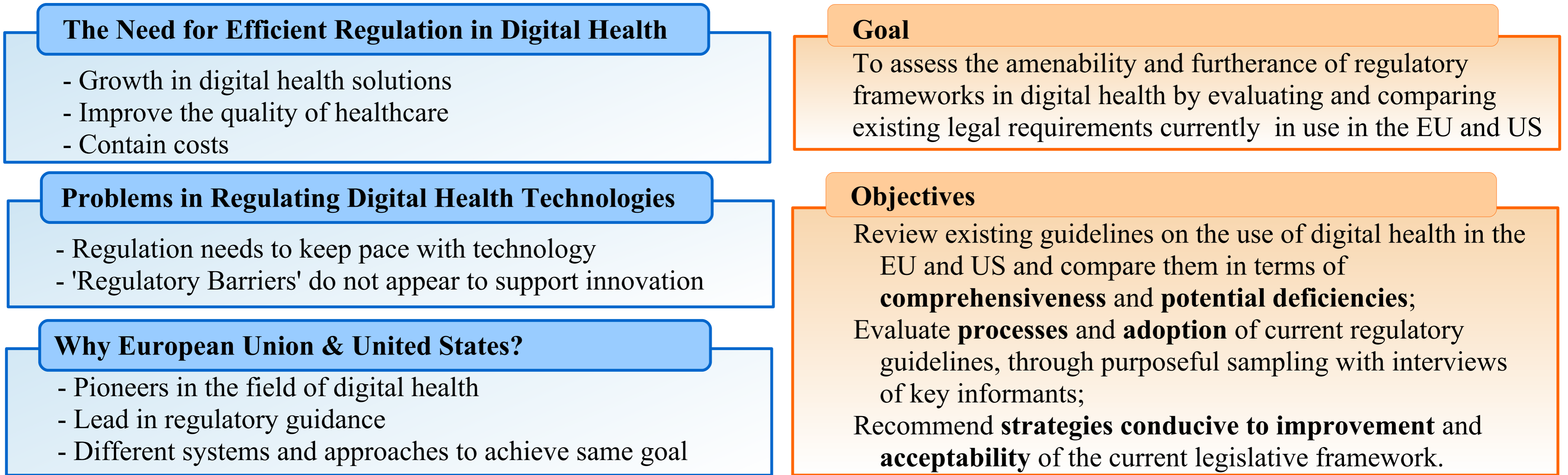
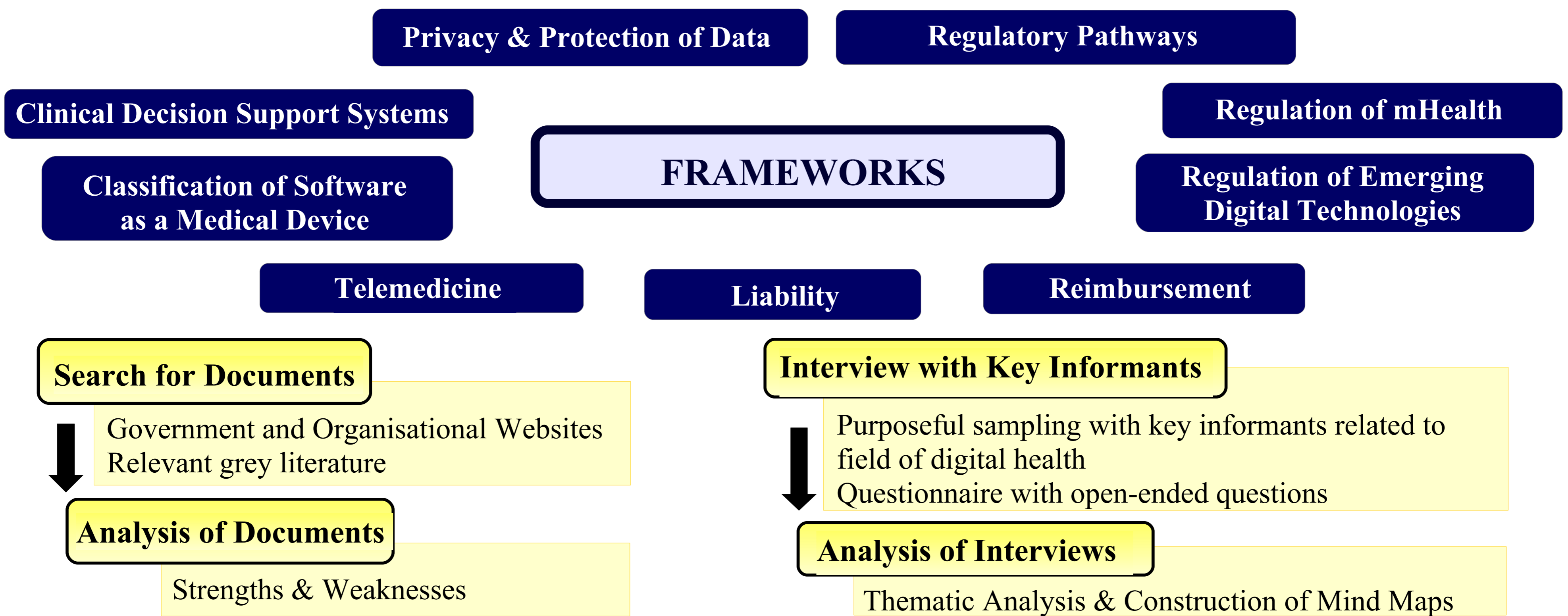


ANALYSIS OF LEGAL AND REGULATORY FRAMEWORKS IN DIGITAL HEALTH

A COMPARISON OF GUIDELINES AND APPROACHES IN THE EUROPEAN UNION AND UNITED STATES



Study Design



Results

EUROPEAN UNION		UNITED STATES		SWOT Analysis	
No separate dedicated body, EC guides all processes	Regulatory Authority	FDA with other departments is the main authority		Strengths	Weaknesses
Single pathway through notified bodies	Regulatory Pathways	Pathways deviate from norm, focusing on speed of approval			
Pan European data protection law	Data Protection	No centralized data protection law		Opportunities	Threats
MDR regulation places SaMD in a higher classification	Classification of SaMD	Enforcement discretion applied to many SaMD categories			
Classification solely risk based	Risk-based Determinants	Classification based on risk, efforts to include effectiveness		Opportunities	Threats
No separate CDSS category, software is called active device	Regulation of CDSS	Detailed classification of CDSS			
Guidelines for use of AI, few directed to healthcare	Regulation of AI-based SaMD	Proposed guidelines for AI-based SaMD		Opportunities	Threats
Part of cross-border healthcare; Licensure covered	Telemedicine	Remote services recognition; Licensure covered			
Efforts directed at new models	Reimbursement	Efforts to extend coverage, coding		Opportunities	Threats
General product liability laws	Liability	General product liability laws			

Efficient + Effective + Flexible + Trustworthy = 'Meaningful Regulation'
 Frameworks to promote use & foster innovation and not to impede