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INCREASING UNDERSTANDING ABOUT THE ROLE OF REGULATORY INTERMEDIARIES IN REGULATION – A SCOPING REVIEW AND IMPLICATIONS FOR THE EURO-PEAN AI ACT

Research full-length paper

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Abstract

The European Artificial Intelligence (AI) Act has just been adopted, and different kinds of actors and institutions, so-called regulatory intermediaries (RI), will be crucial in its implementation and enforcement. To increase understanding in IS research about the role of RIs in regulation, we conducted a discipline-agnostic scoping review. We identified five roles RIs can take in the agenda-setting and negotiation, seven roles RIs can take in the implementation, and three roles RIs can take in the monitoring and enforcement phase of a regulatory process. We contribute to IS research on the regulation of information technology by (1) providing a conceptualization of the multifaceted roles RIs can play in regulation and (2) identifying numerous RIs that have already emerged or might emerge in the AI Act context. This provides a useful starting point for future research on RIs in the context of the AI Act. As a practical contribution, we inform the providers and deployers of AI systems about actors that will – but also such that might – take important RI roles in the implementation, monitoring and enforcement of the AI Act.

Keywords: Regulatory Intermediary, Artificial Intelligence Act, Scoping Review, Regulation, RITmodel.

1 Introduction

The Information Systems (IS) discipline has recently shown an increased interest in understanding more in-depth the regulation of information technology (IT) in general (Butler et al., 2023) and artificial intelligence (AI) in particular (e.g., Aslan et al., 2022; Burton-Jones et al., 2023; Kahdan et al., 2023; Konttila and Väyrynen, 2022; Lanamäki et al., 2024; Mäntymäki et al., 2023: Vainionpää et al., 2024). Traditionally, IS research has viewed the relation between regulation and the target as quite straightforward: the regulator passes a regulation that sets certain requirements to organizations (i.e., targets), and the organizations or individuals in the organization take measures to comply with the regulation. IS research has, for example, studied in the context of the General Data Protection Regulation (GDPR) organizations' efforts to comply with the regulation (GDPR) organizations (Zhao et al., 2023). IS research has also studied the effect of specific regulations on adoption of IT (e.g., Lin et al., 2023). IS research has also studied the effect of specific regulations and van Offenbeek, 2018).

The regulation of IT and of AI remains an important area of interest also for future IS research: the European Artificial Intelligence Act (AI Act) will be adopted in August 2024. As the world's first

comprehensive regulation of AI, it forbids the use of certain AI systems that are deemed to pose unacceptable risk for fundamental rights and European Union (EU) citizens' well-being (such as social scoring employed by governments), and sets certain obligations for providers and deployers of socalled high-risk AI systems in the EU. Thus, the AI Act is expected to impact both the development and the use of AI systems in the EU (Vainionpää et al., 2023) over years to come, and has been identified as a context of significant importance for IS research on public policy (Burton-Jones et al., 2023).

However, the relation between regulation and its impact on organizations or individuals, as well as diverse outcomes, is not straight-forward (Abbott et al., 2017a). There are numerous other actors apart from the regulator and the targets of the regulation that are key to understanding the impact of regulation and that help the regulator in formulating, implementing, and enforcing regulation. These so-called "regulatory intermediaries" (RI) are actors, often government authorities, that operate between the regulator and the targets of regulation and have a "crucial role in whether and how regulation targets implement and adhere to new regulations" (Vainionpää et al., 2023, p. 11).

There has been a recent call for IS research to pay attention to the role that such RIs play in the context of regulation (Vainionpää et al., 2023). There already are a few recent studies in IS in which RIs – at least implicitly – picture quite strongly. Kokshagina et al. (2023), for example, investigated the regulation of algorithmic control of digital platforms in an Australian context and illustrate the significant role the Australian Consumer and Competition Authority (ACCC) had on the development of an amendment to the Competition and Consumer Act 2010. Butler et al. (2023) identified future research questions in (1) the regulatory domain and in (2) the business domain in their introduction to the Journal of Information Technology special issue on Regulation of and Through IT. Several of these questions, such as "who participated in the social construction of the regulations", "what institutional mechanisms were employed", "are the institutional rules enforceable", and "which industry standards and guidelines were specified for adopting in providing compliance with regulatory principles" are intimately linked to the concept of RIs. In addition, Vainionpää et al. (2023) suggested that future IS research should investigate what the role of RIs is in regulatory compliance (on an industry- or organization-level) and in reducing AI Act -related ambiguity, but also should pay attention to what kind of RIs "will be established, given authority, and when" (Vainionpää et al., 2023, p. 12) during the AI Act policy process.

Against this call for research on RIs generally and also specifically in the context of the AI Act, and the observation that RIs already picture – although mostly implicitly – in IS research, we seek to provide an understanding on the multifaceted roles that RIs can have in the context of regulation. We ask: *"What roles can regulatory intermediaries take, and what implications does this have in the context of the European AI Act*?" To answer this question, we conducted a discipline-agnostic scoping review (Arksey and O'Malley, 2005; Munn et al., 2018) on research that utilizes Abbott et al.'s (2017a) Regulator - Intermediaries. We contribute to IS research on the regulation of IT by (1) providing a conceptualization of the multifaceted roles RIs can play in the creation (i.e., agenda-setting and negotiation), implementation, and monitoring and enforcement of regulation and (2) by pointing IS researchers' attention interested in the AI Act towards certain RIs that have already emerged or might emerge in this context, thus providing a useful starting point for future IS research on RIs in the context of the AI Act which will heavily impact the AI future in Europe.

2 Related research – the AI Act and the RIT model

The AI Act and related IS research. The European Commission (EC) is the "regulator" in the AI Act, the regulatory targets are providers and deployers (i.e., users) of AI systems, but also manufacturers, operators and importers of AI systems (Pathak, 2024). European citizens and society are the beneficiaries. While the AI Act initially sought to only regulate AI systems as products, due to the launch of ChatGPT3 and increased awareness of the public regarding general purpose AI, the soon-to-be

adopted AI Act now also regulates general-purpose AI models that are deemed to potentially hold a systemic risk to fundamental rights and safety (Article 51 in the AI Act).

Although the IS literature is so far very limited regarding the AI Act, IS research is clearly showing an interest in it and addressing it from various angles. Some studies focus on organizations' perception of or responses to the AI Act. For example, Konttila and Väyrynen (2022) investigated healthcare stakeholders' perceptions about the AI Act and found ambiguity and expected slow-down of AI innovation to be a major concern. Kahdan et al. (2023) identified four response strategies that organizations employ in response to the institutional pressures arising from the AI Act, whereas Vainonpää et al. (2024) identified four practices of anticipation about the forthcoming AI Act among Finnish public sector organizations. Some studies focused on compliance-aspects, such as Mäntymäki et al. (2023), who developed meta-requirements for organizational AI governance frameworks that they argue can help organizations to align their operations with the AI Act, and Koenigstorfer et al. (2024), who proposed four design principles for the documentation of AI systems to help organizations comply with the AI Act. Lanamäki et al. (2024) studied the AI Act policy process and illustrated how the arrival of ChatGPT challenged the AI Act's assumption that all AI systems have a pre-defined intended purpose. Also, literature reviews have been conducted. Aslan et al. (2022), for example, identified six ethical AI principles that are visible in the AI Act and conducted a review of extant IS research on these principles. Vainionpää et al. (2023) found that the AI Act's formulation, enforcement, compliance, and anticipated impacts on industry and civil society to be core challenges in the context of the AI Act.

Although RIs are a concept yet foreign to IS research, RIs evolving around the AI Act nevertheless were recently identified as a research gap and as an important topic for future IS research by Vainionpää et al. (2023; 2024). It is this gap we seek to address with the present study.

The Regulator-Intermediary-Target (RIT) model. IS research, but also policy research, has traditionally conceptualized the way regulation guides organizations and individuals in such a way that the regulator influences the target(s) directly. Recently, a more nuanced view on this relationship has emerged and been enthusiastically adopted in policy research. Abbott et al. (2017a) conceptualize "regulatory intermediaries" (RIs) to operate between the regulator and the target of regulation. The RIT model conceptualizes that RIs are needed to fulfil the regulator's lacking operational capacity, expertise, legitimacy, and independence in regulation (Abbott et al., 2017a). RIs perform functions that the regulator cannot perform (Herman, 2020) and thus mediate the influence of the regulator/regulation on the target. RIs can be working in conjunction with regulators, by having an official mandate and a formalized role (Abbott et al., 2017a), or emerge "bottom-up", without the regulator's official mandate, and perform unformalized activities to fill a void in regulation (Brès et al., 2019; Kourula et al., 2019).

In addition to RIs, the RIT model recognizes three main actors that are involved in regulation: the regulator (R) who makes the rules in regulation, and the target of regulation (T) whose behavior is affected by the regulation and who is ultimately responsible for implementing regulation (Abbott et al., 2017a). In addition, as an extension to the original model, the intended beneficiaries (B), who are supposed to benefit from the regulation, have been identified to be actors that can be involved in regulatory processes (Koenig-Archibugi and Macdonald, 2017). The regulator, RI, and targets can be seen to form a "regulatory chain" (shown as $R \rightarrow I \rightarrow T$), and complex regulation can include several different regulators, RIs, targets and intended beneficiaries (Havinga and Verbruggen, 2017; Loconto, 2017).

RIs are important over the whole duration of a regulatory process. The regulatory process consists of five phases: in agenda-setting, the regulation agenda is being set; in negotiation, the regulation is being negotiated, drafted and announced; in implementation, the regulation is implemented by the targets of the regulation; in monitoring, the targets' behavior is being monitored against the regulation; and in enforcement, compliance is being promoted and non-compliance is being responded to (Abbott and Snidal, 2009). RIs are involved in every phase of the regulatory process.

3 Methodology

As we seek to understand the different roles that RIs can take in the context of regulation, we conducted a discipline-agnostic scoping literature review (Arksey and O'Malley, 2005; Munn et al., 2018), which is suitable for identification of the factors or key characteristics of a concept. Scoping review is also suitable to act as a precedent for a systematic literature review (Arksey and O'Malley, 2005; Munn et al., 2018), and the present literature review is intended as such. In this scoping review, we sought to capture the relevant English-language research on RIs that use Abbott et al.'s (2017a) RITmodel. The core criteria for inclusion in the review were that the article (1) is written in English, (2) is a peer-reviewed research paper, (3) utilizes the RIT model (Abbott et al., 2017a), and (4) gives information about who the RI was and what role(s) the RI had.

We conducted the literature search on 14.12.2023 in seven scientific databases: ACM Digital Library, AIS e-Library, EBSCOHost, IEEE Xplore, ProQuest, Scopus, and Web of Science. We used the search term "regulat* intermedia*" (syntax modified accordingly for the different databases) to capture all articles that talk about RIs and limited the search to peer-reviewed articles. 787 articles were imported to Covidence, a software tool that supports conduction of different types of literature reviews, for screening. 413 duplicates were automatically identified by Covidence, and we identified 53 additional articles as duplicates, resulting in 321 articles for title and abstract screening. 191 articles were excluded at this stage, as they did not address RIs in a policy context. The remaining 130 articles underwent full-text screening. Based on our exclusion criteria, we excluded 8 non-English articles, 12 articles that were not accessible by us, 3 non-research articles (introduction, news), and 36 articles that did not specifically mention Abbott et al.'s (2017a) RIT-model. In addition, as we were interested in understanding the roles that RIs can take, we excluded 22 articles that did specify what RI had been studied in the article, or that only mentioned the term RI without providing further information. Thus, 49 articles fulfilled the criteria for inclusion and represent our primary studies (see Table 1).

For the data analysis, one author identified from each article the regulatory context, the actors based on the RIT model (regulator, RI, target, and beneficiaries), the role(s) that a RI had in the investigated context, and the officiality of the RI's role. Initially, the roles extracted from the primary studies were coded and divided into three broad themes based on the regulation process phases in which RIs are expected to have a role in as defined by Abbott et al. (2017a): (1) agenda-setting and negotiation; (2) implementation; and (3) monitoring and enforcement. To further elaborate on the roles in these regulation phases, we took inspiration from Kourula et al.'s (2019) set of 14 roles that RIs can take in four types of transnational governance programs, which are governance initiatives that target "business conduct involving multiple organizations and occurring in more than one country" (Kourula et al., 2019, p. 142). However, as Kourula et al. (2019) mostly only lists, but does not provide detailed descriptions for these roles, we refined understanding of these roles in a data-driven manner based on our primary studies. Ten of the roles proposed by Kourula et al. (2019) were also recognizable in our primary studies: harmonizer, facilitator, bridge, translator, marketer, counselor, expert, creator, enforcer, and disruptor. We did not identify Kourula et al.'s (2019) proposed roles of critic, convenor, commissioner, and consolidator. However, compared to Kourula et al. (2019), we identified three additional roles: second-hand rule maker (as identified by Mehrpouya and Samiolo, 2019), monitor (inspired by Abbott et al., 2017a), and contact point for intended beneficiary, the existence of which was identified in a data driven manner.

4 Findings on the RI's roles in different phases of the regulatory process

In our review, we identified numerous examples of regulators, RIs, targets, and intended beneficiaries. The intermediaries identified (see Table 2) had diverse roles, and one type of intermediary organization could have one specific RI role in one regulatory context, but the same type of organization could

take a very different RI role in another regulatory context. In the remainder of this article, we refer to the primary studies as "Px" (see Table 1).

	Prim. Stud.			Agenda-setting and negotiation			Implementation					Monitoring and enforce- ment					
Authors		Context	A1	A2	A3	A4	A5	I1	I2	I3	I4	15	I 6	I7	M1	M2	M3
Avidan, et al. (2019)	P1	Fracking					Х					Х	Х				
Busch (2020)	P2	House renting														Х	
Carter and Mahallati (2019)	P3	Food certification		Х										Х			
Cheng and Qu (2022)	P4	Policing										Х					
Cho et al. (2017)	P5	Trading										Х					
Ciornei et al. (2022)	P6	Abortion and euthanasia				Х		Х									
Coban (2021)	P7	Banking				Х											
De Silva (2017)	P8	International crime		Х				Х						Х		Х	
Di Porto and Zuppetta (2020)	P9	Algorithmic disclosure						Х		Х							
Erikson and Larsson (2019)	P10	Prostitution			Х			Х	Х	Х		Х		Х	Х		
Euchner (2019)	P11	Prostitution		Х				Х									
Fransen and LeBaron (2018)	P12	Modern slavery		Х				Х							Х		
Giannoumis (2018)	P13	Web accessibility						Х	Х	Х							
Goyal (2020)	P14	Prostitution		Х				Х			Х					Х	
Havinga and Verbruggen, (2017)	P15	Food safety		Х				Х		Х				Х	Х		
Herman (2020)	P16	IFRS	Х				Х	Х		Х							
Holloway and Miller (2022)	P17	Molecular diagnostics						Х		Х	Х						
Jordana (2017)	P18	Banking						Х		Х							
Kalm (2022)	P19	Citizenship			Х			Х							Х		
Kampourakis (2020)	P20	Whistleblowing													Х		
Kellerman (2021)	P21	Trading													Х		
Kingston et al. (2023)	P22	Environment		Х					Х	Х							Х
Koenig-Archibugi and Macdon- ald (2017)	P23	Labor													Х		
Kohler et al. (2021)	P24	IFRS		Х						Х				Х			
Kruck (2017)	P25	Credit rating								Х					Х		
Lacatus and Carraro (2023)	P26	Human rights						Х	Х		Х				Х		
Loconto (2017)	P27	Sustainability		Х				Х							Х		
Lund-Thomsen et al. (2021)	P28	Sustainability						Х								Х	
Maggetti et al. (2017)	P29	Medical device		Х						Х					Х		
Marques (2019)	P30	Retailing	Х														
Medzini (2021a)	P31	GDPR														Х	
Medzini (2021b)	P32	GDPR						Х					Х		Х		
Medzini (2022)	P33	Facebook's self-regulation		Х		Х									Х	Х	
Medzini and Levi-Faur (2023)	P34	Facebook's self-regulation and GDPR			Х			Х		Х					Х	Х	
Mehrpouya and Samiolo (2019)	P35	Pharmaceutic				Х		Х	Х							Х	
Miaz et al. (2024)	P36	Human rights		Х						Х					Х		
Monciardini and Conaldi (2019)	P37	Corporate Social Respon- sibility		Х						Х					Х		
Nouwens et al. (2022)	P38	GDPR														Х	<u> </u>
Owen (2021)	P39	Environment		Х						-		Х					<u> </u>
Paiement (2019)	P40	Labor		X											Х		-
Partiti (2021)	P41	Human rights		-				Х		Х				Х	-		<u> </u>
Pegram (2017)	P42	Human rights								-		Х		_	Х		<u> </u>
Poon (2021)	P43	Finance										-			-	Х	<u> </u>
Qin and Owen (2021)	P44	Recycling							Х							X	<u> </u>
Renckens and Auld (2022)	P45	Sustainability							_						Х		<u> </u>
Silvee and Wu (2023)	P46	Food Safety	l							Х							-
Tziva et al. (2021)	P47	Sustainability		Х					Х	-				Х			
van der Heijden (2017)	P48	Building			Х			Х								Х	
	P49	Prostitution	l –		1							Х				X	
van Wijk and Mascini (2022)	P49	Prostitution										Λ				Λ	

Table 1.RI's roles in different phases of the regulatory process in previous literature.

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Regulator R	Regulatory Intermediary RI	Target T	Intended benefi- ciaries B
E.g., public regula- tors, transnational regulators, interna- tional regulators, general public, standard-setting bodies, multi- stakeholder initia- tives, private regu- lation initiatives, companies perform- ing self-regulation	Organizations: e.g., professional associations, boards, committees, religious organizations, agencies, courts, NGOs, audit firms, police, net- works, working groups, certifiers, contract in- spectors, interest organizations, consultants, whistleblowers, trading venues, beneficiary in- termediaries, auditors, institutions, regulators' partner firms, data protection officers inside or- ganizations, foundations, public regulators, alli- ances, assessors Technology: e.g., digital platforms Individuals: e.g., digital platform users, entrepre- neurs	E.g. businesses, individu- als, public departments, governments, individuals that are performing pro- fession under regulation, victims, national regula- tors implementing inter- national regulation, actors performing prohibited activities, actors involved in specific sector, coun- tries	E.g., workers and their fami- lies, laborers and labor un- ions, general public, patients

Table 2. Actor types and their roles (based on the primary studies in this scoping review).

We identified five RI roles in the agenda-setting and negotiation phase (A1: harmonizer, A2: counselor, A3: creator, A4: second-hand rule-maker, A5: disruptor), seven RI roles in the implementation phase (I1: Expert RI \rightarrow T, I2: Marketer, I3: Translator, I4: Bridge, I5: Facilitator, I6: Contact-point for Intended Beneficiaries, I7: Expert RI \rightarrow RI), and three RI roles in the monitoring and enforcement phase (M1: monitor RI \rightarrow T, M2: enforcer, M3: monitor RI \rightarrow R). In Table 1, we provide an overview of the primary studies, the regulatory context in which the RIs were identified, as well as information about the RI(s) role(s) we identified in the primary study. Due to length restrictions, we only provide a few selected examples for each role in more detail below.

4.1 Agenda-setting and negotiation phase

Originally, the RIT model assumed that the regulator passes the regulation without RIs being a part of this. However, different actors, including RIs, are actively involved during agenda-setting and negotiation, and smart regulators "will anticipate, encourage, and plan for it", because RIs can provide valuable feedback based on their experiences (Abbott et al., 2017a, p. 24). Thus, the acknowledgement of RIs' roles in the agenda-setting and negotiation phase was included as an extension to the original RIT model, but only when regulation is being changed (Abbott et al., 2017a). We identified the RI roles of a harmonizer, counselor, creator, second-hand rule-maker, and disruptor in this phase.

A1 – **Harmonizer.** A harmonizer supports consistency of the regulation: consistent rules, monitoring and enforcement practices using various strategies. For example, the Big-4 international auditing firms have been harmonizing international financial reporting standards (IFRS) over several years via lobbying and through different strategies to influence regulators (e.g., the EC) to adopt IFRS under their legislation (P16). Retail harmonizing RIs in the context of transnational retailing private regulatory initiatives harmonized monitoring and enforcement practices by removing the need for every retailer who participates in the private regulatory initiative to separately audit supplier factories by providing means to do it in a centralized manner with similar requirements and standards (P30).

A2 – Counselor. Counselors provide their knowledge, expertise and experiences to regulators to support the development of new or updating existing regulation. Counselors can be seen as key partners for regulators in policymaking processes as an informant. Auditors in the context of IFRS have participated in the standard drafting phase via due process by, for example, writing a "comment letter" or participating in meetings with the regulator (P24). The input provided by, for example, for-profit consulting companies that take the role of Counselor RIs might be so crucial that regulators might be reluctant to change the regulation without first asking an opinion from these RIs, as illustrated by Owen (P39).

A3 – Creator. This role is an extended counselor role. Instead of just being informants, creators are actively involved in the agenda-setting and negotiation phase to create new or updated regulation together with the regulator. There are differences in how influential the creator role is in regulation. On one hand, in the context of Swedish national regulation on prostitution and human-trafficking, networks consisting of NGOs and public agencies are participating in decision-making with regulators and have extensive influence on the development of the regulators (P10). On the other hand, the RI can be the one who creates the regulation alone, which national regulators can adopt later. For example, the unofficial and informal United States Green Building Council (USGBC), which did not have formal relations to the United States government, developed and offered a voluntary certification system called Leadership in Energy and Environment Design (LEED). Later, several governments and states included the requirement that organizations (i.e., targets) in construction and property industries need to be certified according to the LEED (P48).

A4 – Second-hand rule-maker. This role involves activities where the RI is not part of creating or updating new formal regulation together with the regulator but is creating rules under existing regulation independently, and possibly under the orders, of the regulator. Mehrpouya and Samiolo (P35) call ad-hoc rulemaking RIs "second-order rule-makers". In Belgium, some catholic hospitals' ethical boards, to which religious organizations as RIs provide input on value-loaded ethical questions, are allowed to draw their own ethical guidelines that are compulsory for the medical personnel (P6). Regulators also might force RIs to design and implement specific regulations (P7).

A5 - Disruptor. Disruptors are involved in creating new competitive regulations, or performing tasks that challenge current regulation by acting against them or by providing alternative methods to comply that supports the RIs own goals. One prominent example of this is how a digital information disclosure platform – FracFocus – for chemicals used in fracking managed to sway fracking disclosure regulation and practices. FracFocus allows fracking operators to disclose information about chemicals used in fracking, which these operators took into use voluntarily to relieve pressure coming from external stakeholders. Later, this led states to allow the use of FracFocus to fulfill regulatory requirements on information disclosure about chemicals used in fracking (P1).

4.2 Implementation phase

Ultimately, the regulation's target needs to implement the regulation. RIs can have some role in facilitating the implementation of the regulation. The "direction" of the relationship is mostly from the RI to the target, but RIs can also target their actions towards the regulator, other RIs, or beneficiaries. We identified the following roles that RIs can take in a regulation's implementation phase: expert (RI \rightarrow T), marketer, translator, bridge, facilitator, contact point for intended beneficiaries, and expert (RI \rightarrow RI).

I1 – **Expert (RI**→**T).** There are numerous different ways how RIs use their expertise to help targets to implement the regulation: by providing consultation, training and education, assistance, information, and specialized knowledge that is not being widely available. In some cases, these activities are specified in the regulation, such as the role of Data Protection Officer's (DPO) in the case of the GDPR. DPOs are tasked by regulators to guide organizations in the GDPR implementation, including offering consultation and training, preparing internal guidelines, writing reports, and implementing technological measures (P32). In other cases, RIs can act without an official mandate from the regulator. One example are consultants in the field of molecular diagnostics providing molecular companies paid services, such as guiding through the process of setting up a laboratory, validating assays, doing market research, training laboratory personnel, and providing expertise on regulation (P17).

I2 – **Marketer.** RIs in this role promote a specific regulation. For example, Environmental Nongovernmental Organizations (ENGOs) promote awareness and understanding of EU environmental law and related regulations, such as the Aarhus Convention, which gives third party citizens and ENGOs "legal rights to access environmental information, rights of public participation, and rights of access to justice in environmental matters" (P22, p. 470). The promotion can also be motivational. For example, the Access to Medicine Foundation promotes the Access to Medicine Index, which ranks pharmaceutical companies based on the Access to Medicine Foundation's scoring and performance measurements, by highlighting best practices and "star performers". This can motivate other companies to do better in terms of compliance, to "race to the top" and "look better" than competitors (P35).

I3 – **Translator.** RIs in this role take different tasks that are related to explaining the gap between legal requirements and practical implementation for targets by providing services to assist targets. In the context of United Nations Guiding Principles on Business and Human Rights (UNGP) and Human Rights Due Diligence (HRDD), standardization bodies (e.g., International Organization for Standardization – ISO) give meaning to the general principles of regulation in the form of standards (P41). Consultants without official or formalized mandate from regulators in the field of molecular diagnostics navigate and interpret the regulation that "governs the movement of molecular diagnostics from availability to widespread uptake as insured services" (P17, p. 2). One interesting example is that these consultants can help molecular diagnostics companies to avoid having to send medical tests they developed for approval to the Food and Drugs Administrator's (FDA) by translating and interpreting FDA requirements in a certain way (P17). Interest organizations for people with disabilities (i.e., RIs) co-operate with organizations who develop web pages by providing them with information and by participating in website development. Through this, the RIs help these organizations prevent ending up in court cases due to their incompliance with complex antidiscrimination regulation (P13).

I4 – **Bridge.** Some RIs have a role in multiple regulations at the same time. The bridge role requires the RI to possess expertise on multiple different regulatory programs. For example, consultants with expertise on public regulation and private insurance regulatory requirements in molecular diagnostics help clients bring their medical tests to market efficiently by fulfilling both requirements (P17).

I5 – **Facilitator.** The purpose of RIs in this role is to provide targets with the means to implement a regulation. Digital information disclosure platform FracFocus provides a centralized platform for targets to communicate and relay information on the chemicals used during fracking, which is mandated by regulators (P1). The Technical Barriers of Trade (TBT) committee (i.e., RI) facilitates regulatory dialogue in a transnational setting in World Trade Organization (WTO) members' trade disputes, and that way it assists the WTO members' compliance with the WTO's transnational trade regulation (P5).

I6 – **Contact Point for Intended Beneficiaries.** RIs in this role enable the intended beneficiaries of a regulation to use their rights specified in the regulation. In the context of the GDPR, DPOs act as a contact point for the matters of personal data processing (P32). In the context of fracking, the public can use the digital information disclosure platform FracFocus to find out the chemicals used in fracking in, for example, oil wells, but also to learn more about the topic in general (P1).

I7 – **Expert (RI** \rightarrow **RI).** RIs in this role share information with other RIs. Professional associations facilitate knowledge sharing amongst the members, who are field auditors who act as RIs, about regulation and conducting audits. In addition, mailing list archives hosted by professional associations can be seen as an expert RI, because it contains past interpretations of the regulation and audit procedures that other field auditors can use for their benefit (P3).

4.3 Monitoring and enforcement phase

In the monitoring and enforcement regulatory phase, RIs are usually at the same time evaluating the behavior of targets and enforcing regulation (Abbott et al., 2017a). We identified the monitor ($RI \rightarrow T$), enforcer, and monitor ($RI \rightarrow R$) roles that RIs can take in monitoring and enforcement.

M1 – **Monitor** (**RI** \rightarrow **T**). RIs in this role monitor the target's behavior and regulatory compliance. RIs who are only monitoring do not have legal power or instruments to enforce the regulation, but they inform the regulator when regulatory misconduct happens (Abbott et al., 2017a). Regulators rely on external monitors because they have more direct access to targets. For example, regulators for trading regulation rely on trading venues to monitor and identify criminal actors engaged in market abuse, be-

cause trading venues have the exclusive power to monitor their own markets (P21). Whistleblowers can also be seen as RIs: they take the role of formalized critics when they monitor and report an organization's behavior using their expertise and internal knowledge about its misconducts (P20). Auditors, too, perform a monitoring role (Abbott et al., 2017a), which is based on a given code of conduct or standards. They do not enforce the regulation, but instead report all findings to other authorities. Auditing might also be required by regulators. In the context of the Fair Labor Association's (FLA) private regulation, factories (i.e., targets) involved in FLA are required to let social auditors (i.e., RIs) perform audits in production facilities for assessing whether these factories are compliant (P40).

M2 – Enforcer. RIs in this role combine the monitoring role with the power and capabilities to enforce the regulation. In some cases, the enforcer has the legal power to punish. For example, the police monitors and enforces regulation, and they have the legal power to punish for criminal activity (P14). The enforcement does not have to be punishing in nature. ENGOs enforce regulation by assisting targets of the regulation to comply by communicating and engaging with local communities by, for example, reporting changes in regulation to farmers and acting as their advisers to help them comply with regulation (P22). The enforcement of regulation can also happen in unofficial and unexpected ways. The GDPR regulation requires website owners to provide a way to ask consent from website users about the collection and processing of their personal data. Because of that, browser plugin Consent-O-Matic emerged to provide a way for website users to automatize answering to those consent pop-ups, and the creators of the plugin mentions "we are also aware that we are now acting as a regulatory intermediary and enforcing the GDPR in a particular way" (P38, p. 6).

M3 – **Monitor (RI** \rightarrow **R).** This role is similar to M1, but here it is the regulator who is being monitored. For example, EU Member States acting as regulators might not have the capacity or even willingness to enforce environmental laws, and to overcome that, the EU itself has tasked ENGOs to act as a watchdog against the hierarchically "lower" regulator. In this case, intermediation is reversed, as EN-GOs (i.e., RI) try to stop EU Member States breaking environmental laws, and even EU citizens who normally act as targets can reach out to ENGOs for that matter and report about misconducts (P22).

In summary, our findings show a variety of different RI roles throughout the regulatory process. The identified roles especially show the role of specialized knowledge of the regulation and the regulated field that RIs can use for providing expertise and performing translator activities. These roles influence how a regulation is interpreted and implemented by targets. RIs also have more direct access to targets of the regulation compared to regulators, making them important and powerful actors in activities related to monitoring and enforcement of regulation. We found that RIs can be authorized or tasked by regulators, but that they can also emerge during the regulatory process. The RIs can be organizations, individuals or even digital platforms. Most importantly, our findings show the RIT model to be an excellent lens to map and understand the role of RIs in different regulatory contexts.

5 Discussion

Our contribution is twofold. First, we contribute to IS research, especially to the research stream on the regulation of IT (see Butler et al., 2023) by providing a conceptualization of the multifaceted roles RIs can play, guiding future IS research to the important roles they take in the creation (i.e., agendasetting and negotiation), implementation, and monitoring and enforcement of regulation. As our second contribution, which has also practical implications, we point the attention of IS researchers interested in studying the implementation, impact and outcome of the AI Act towards the many roles RIs will take in this process and provide a starting point by identifying specific RIs in the AI Act context.

5.1 Theoretical contribution: the RI's role(s) in regulation

Our first contribution is to IS research on regulation by providing a conceptualization of the multifaceted roles RIs can play (see Findings). Extant IS research on regulation has mainly focused on the implementation, impact, and outcome of regulation (see Vainionpää et al., 2023). It tries to understand, for example, how regulation affects the development and/or use of technology (e.g., Bernardi et al., 2017, Eaton et al., 2018), how organizations can or attempt to be compliant with regulation (e.g., Dickhaut et al., 2023; Grundstrom et al., 2019; Labadie and Legner, 2023) or engage in malpractices (e.g., Zhao et al., 2023), or how regulation affects organizational processes and practices (e.g., Boonstra and van Offenbeek, 2018). The general assumption in IS research on regulation has often been that "there is some regulation" (e.g., the GDPR), and this regulation has an impact on or results in some outcomes at the level of society, industries, organizations, and/or individuals. However, we argue that this is a (too) simplified view in the light of our literature review. Supported by our scoping review, we point towards the importance of paying attention to RIs, as they have an impact not only on the formulation of a regulation, but also on its implementation, monitoring and enforcement. The RIT model (Abbott et al., 2017a) and its later extensions are useful for identifying the different actors involved in complex regulation environments and for uncovering their roles and relationships to each other. This provides future IS research a conceptual lens to develop a more nuanced understanding of how and on whom regulation has an impact and how it leads to specific outcomes: RIs mediate this relationship.

Butler et al. (2023, p. 98) argued that "regulations and laws are not objective facts but always involve social interpretation". They (Butler et al., 2023, p. 98) called for IS research on the institutional work on and social construction of regulation of IT, arguing that "a complex interplay of coercive mechanisms (lobbying, conflict, and economic pressures from dominant actors), normative (professional assessments, industry standards) and cultural-cognitive/mimetic mechanisms (framing, translation) is at play and constantly shapes the social construction of policies, legislation, regulations etc.". We argue that RIs are important actors who have an integral part in the institutional work on and social construction of regulation of IT. In order to advance conceptual clarity in future IS research on regulation. Our framework of the different roles that RIs can take, and our description of these roles based on what we found in our scoping review, can act as a tool to support a more systematic identification of important actors apart from the regulator and the targets of the regulation and investigation of how exactly they affect the impact and outcomes of a specific regulation.

To understand the regulatory outcome thoroughly and what kind of impact intermediation have on it, "we need to understand from where intermediaries come" (Abbott et al., 2017b, p. 284). We agree and want to emphasize here the importance of distinguishing between RIs that have been tasked by the regulator to act as an RI in a certain role up-front (as conceptualized by Abbott et al., 2017a), such as DPOs in the context of GDPR (P32), and RIs who potentially emerge in a bottom-up fashion for one reason or another (e.g., Brés et al., 2019; Kourula et al., 2019) like was the case in of USGBC which emerged to fill the void in sustainable building regulation by providing a private voluntary building certification program that governments could adopt (P48). Our review thus supports earlier research.

Finally, we want to point out that while most of the RIs identified in our review were different types of organizations – as we would also have expected – a very surprising finding in our review was that also individuals (P3, P14, P20, P24, P32, P33, P34, P40, P45), and even technology such as digital platforms (P1, P2, P9, P38), can act as RIs. With this, we provide an important extension to Kourula et al.'s (2019) intermediary roles, as those did not recognize that also technology can act as a RI.

5.2 The established and emergent RIs in the context of the AI Act

Our second contribution to IS research is in response to a call for IS research to pay attention to and investigate the role of RIs in the context of the AI Act. Vainionpää et al. (2023, p. 12) more specifically called to investigate "what kind of regulatory intermediaries will be established, given authority, and when during the AI Act cycle". Given that IS research on regulation traditionally has focused on the implementation, impact, and outcome of regulation (see Vainionpää et al., 2023), we contribute to

this stream by providing a practical pointer for future IS research on the AI Act regarding what actors at least need to be paid attention to, as these RIs have multifaceted roles and will significantly affect implementation, impact and outcome of the AI Act. At the time of writing this article, the AI Act is just about to enter the implementation phase, having passed the agenda-setting and negotiation phase.

In Table 3, we present several actors we know of that are already officially mandated by the EC to take a role that we argue clearly represent one or more RI roles in the implementation, monitoring and enforcement of the AI Act. In addition, based on the RI roles we identified in the scoping review, we present some actors that are not officially mandated but have the potential to emerge as potent RIs.

Table 3 is compiled based on our own quite intimate knowledge about the AI Act policy process, which we have been following intensively since 2021, and supported by some extant research we refer to in the table. Table 3 is not intended as a finalized list of RIs, as new actors will surely emerge.

Actors	Anticipated RI role		
Actors with official mandate to conduct some task			
<i>European AI Office</i> : coordination and guidance of member states' designated national supervisory authorities (AI Office, 2024; Busuice et al., 2023; Mökander et al., 2021).	I7 – Expert (RI→RI)		
<i>Notified bodies:</i> confirm an AI system's conformity with the AI Act (AI Act, 2024, Article 31; Laux et al., 2024a; Mökander et al., 2021).	M1 – Monitor (RI \rightarrow T)		
Standardization organizations CEN and CENELEC: By complying with certain AI standards – currently being prepared by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), providers of AI systems will presumably conform to the AI Act without having "to interpret the meaning of essential requirements in Title III, Chapter 2" (Commission Implementing Decision, 2023; Laux et al., 2024b, p. 2)	I3 – Translator (RI \rightarrow T)		
<i>EU database for stand-alone high-risk AI systems:</i> going to be set up and maintained by the EC together with Member states to provide information to beneficiaries (i.e., citizens) about the operations of high-risk systems (Busuioc et al., 2023; Mökander et al., 2021) to ensure transparency for the public (AI Act, 2024, Article 60)	I6 – Contact point for intended beneficiaries (RI→B)		
<i>Certain authorities, both on the EU-level and on a national level:</i> will provide more detailed guidelines for interpreting the AI Act and compliance and monitor implementation of the AI Act (see Marano and Li, 2023). E.g., national competition authorities (AI Act 2024, Article 74), national data protection authorities (AI Act, 2024, Article 57) etc.	I1 – Expert ($RI \rightarrow T$) M1 – Monitor ($RI \rightarrow T$) M2 – Enforcer ($RI \rightarrow T$)		
Actors without an official mandate (yet); potentially emerging			
<i>AI Pact</i> : should play a role in supporting organizations for voluntary early compliance, acts as a platform for networking with other organizations implementing the AI Act, and as a regulatory feedback channel towards regulators. (AI Pact, 2024)	I2 – Marketer (RI \rightarrow T) I3 – Translator (RI \rightarrow T) I5 – Facilitator (RI \rightarrow T)		
Providers of AI systems: will play a central role in providing enough transparency regarding the high-risk AI systems they provide to allow AI deployers to interpret the system's outputs appropriately, but also enable them to use the system appropriately (Busuioc et al., 2023).	I3 – Translator (RI \rightarrow T)		
Providers need to provide user instructions for the AI deployers (AI Act, Article 13)	I1 – Expert (RI \rightarrow T)		
<i>AI compute providers</i> such as Microsoft Azure, Amazon Web Services, Apple, Meta, Google Cloud and Alibaba: could take important roles in, e.g., record keeping and enforcement of the AI Act for general-purpose AI models, but this would require them to be given authority by the regulator, i.e., the EC (Heim et al., 2024).	M1 – Monitor (RI→T) M2 – Enforcer (RI→T)		
Might also provide their valuable knowledge from the field and regulation in different forms (e.g., guidelines) to AI companies to support their compliancy efforts.	I1 – Expert (RI→T)		
<i>Auditors for general-purpose AI model provider's training data sets:</i> such actors might be required, but would require assigning then an official auditor role (Hacker et al., 2023)	M1 – Monitor (RI \rightarrow T)		

Table 3.Emerging landscape of RIs in the context of the AI Act.

We would like to still draw the reader's attention to the EU database for stand-alone high-risk systems. We argue that it might take the role of "contact point for intended beneficiaries (I6)", similar to the example of the FracFocus platform (P1). This type of RI will influence how beneficiaries can utilize information found on the digital platform and how it will contribute to the transparency. Avidan et al. (P1) showed how the way FracFocus provides information is opaque, so that the meaning of information is unclear for general users. Similarly, the database for registering high-risk AI systems will be the only official place where citizens can get information about high-risk AI systems deployed in the EU, and therefore its accessibility will have an impact on its usefulness for citizens.

Finally, we emphasize that while most of the actors and roles we have identified are so-called "official" roles authorized by the regulator, based on our review and identification of roles, it is to be expected that diverse actors will take the roles of RIs already before organizations have to be compliant with the AI Act, but also for years and years to come after that. This provides an exciting opportunity for IS research on regulation to investigate how these RIs are "born" while this happens, not only in hindsight, and the potential to inform policy and policymaking (see Burton-Jones et al., 2023).

Table 3 is also a *practical contribution*: it informs the providers and deployers of AI systems (i.e., targets) about actors that will – but also such that might – take important RI roles in the implementation, monitoring and enforcement of the AI Act, and by informing the regulator about the potentially important and impactful RIs that still would have to or could be assigned an official RI role.

6 Conclusions

With our scoping review on the roles of RIs, as well as our discussion on RIs in the recently adopted AI Act, we contribute to IS research on the regulation of IT by (1) providing a conceptualization of the multifaceted roles RIs can play in the creation, implementation, and monitoring and enforcement of regulation; and (2) shedding light for IS researchers interested in the AI Act on the multifaceted roles RIs can take in this process. Our discussion on the established and emerging RIs in the context of the AI Act provides also a practical contribution of our study.

Our study has limitations. Our scoping review focused on research that utilizes Abbott et al.'s (2017a) RIT model. Even if this has proven to be a highly influential model in recent policy research and useful for mapping different actors involved in complex regulation environment and for uncovering their relationships to each other and the roles they play, there are other models and perspectives that could have been utilized for making sense of RIs, using alternative terminology. Including also research addressing the topic before publication of the RIT model would likely have led to the identification of additional RI roles. We leave it to future research to conduct such a more extensive review. In addition, we acknowledge that the multifaceted roles of RIs could be explored further: even if we showed that the direction and the nature of influence of RIs varied, even more variety could likely be identified. The literature could have also been scrutinized even in more detail regarding the different types of RIs – including individuals, technologies, organizations etc. – and their nature in terms of how official vs. unofficial, established vs. emergent they are. Paths for future work include empirical studies in various IT regulation contexts, and particularly in the AI Act context, in which the implementation, and monitoring and enforcement phases certainly will offer exciting opportunities for IS researchers to examine the roles, types and impacts of RIs in the regulation of IT.

In addition, we encourage future IS research to investigate in-depth how exactly different types of RIs moderate the impact and outcomes of regulation, to gain a better understanding of the coercive, normative and cultural-cognitive/mimetic mechanisms that constantly shape regulations' social construction (see Butler et al., 2023) and in which RIs surely have an important role.

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