Convergence of Product, Production, and Supply Chain Design Rules: Evidence from Pharmaceutical Pre-Competitive Collaboration Networks

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Abstract

We address a trans-specialist learning and coordination question in pre-competitive manufacturing R&D networks: how do early-stage consortia develop products across 'dissimilar' (where knowledge requirements are different, and not solely based within) specialized networks? A unique aspect of the R&D consortia is that they integrate knowledge across product, production, and supply chain domains. This paper uses network ethnography as the methodology – in combining social network analysis with ethnographic methods – while drawing on a 10-year dataset on the evolution of pre-competitive collaboration networks in pharmaceutical continuous manufacturing deploying digital technologies. Our analysis reveals mechanisms through which design rules for products and processes are developed and converged across product, production, and supply chain domains. Specifically, we show that design rules, which are both 'set-based' and 'trans-specialized', are the key mechanisms that enable heterogeneous specialist stakeholders to exchange knowledge and facilitate the convergence of development efforts. Second, we highlight the roles of boundary spanners and institutional actors (i.e., academia and regulatory bodies) in steering dialogues towards the convergence of design rules in early-stage R&D settings. The theoretical implications of these findings are not only germane to pharmaceutical drug development networks, but to early-stage product and technology development networks at large.

Keywords: Pre-competitive Consortia; Continuous Manufacturing; Digital Technologies; Trans-Specialization; Boundary Spanners**;** Institutional Mechanisms for Design Rules; Network Ethnography; Supply network analysis

1. Introduction and Motivation

Current pharmaceutical supply chains face significant challenges driven by the large-batch production model, which leads to very-high inventory levels - about 200 days of inventory-on-hand for the major Pharmaceuticals, equivalent to several $bn for each Multinational player, of which 4-15% is written-off due to expiry windows (nVentic, 2023), long lead-times of 12-24 months (Srai et al., 2015a), and drug shortages (Rossi, 2022). These limitations, together with recent advances in medicines manufacturing and digital technologies, have led firms to explore continuous manufacturing as an alternative to large batch manufacturing configurations (see the

ISCMP white paper series)[1]. In addition to offering a step change in volume and variety flexibility through multiple production scale and modular scale-out options (Srai et al., 2020), continuous manufacturing technologies may potentially reduce the cycle time for product, production, and supply chain development by addressing the sequential and prolonged nature of pharmaceutical R&D (Brown et al., 2022). Continuous manufacturing-based product, production, and supply chain design also enables novel drug development scenarios involving more decentralized, modular and/or mobile manufacturing, leading to the creation of novel platforms (Joglekar et al., 2022; Srai et al., 2024).

Initial exploration of continuous manufacturing, primarily led by individual firms, had limited success due to the radical nature of the technological and regulatory innovation required, with an emerging consensus that such a transformation is too difficult to undertake alone by an individual firm[2] because of the novelty and complexity of continuous processing regimes deploying digital technologies. Setting manufacturing and design parameters in this environment requires active collaboration and interactions across multiple agencies that create consensus on design rules and standards. Over the last decade, pre-competitive, consortia-based collaborations have become the dominant organizational approach for exploring transformational technologies involving industry-academia-regulator interactions. These pre-competitive networks are not only important within the pharmaceutical industry, but also other evolving arenas such as the National Charging Experience Consortium for Electric Vehicles (Joint Office, 2023), and the 3rd Generation Partnership Project focused on developing standards for mobile telecommunications

[1] 2014 International Symposium on Continuous Manufacturing of Pharmaceuticals (*Implementation, Technology & Regulatory*). Eight white papers here: http://iscmp2014.mit.edu/.

[2] 2018 National Academies of Sciences, Engineering, and Medicine workshop on '*Continuous Manufacturing for the Modernization of Pharmaceutical Production*'. https://www.ncbi.nlm.nih.gov/books/NBK540224/

(3GPP, 2024). In these consortia, there is a high degree of collaboration between industry, academia, and regulatory bodies while setting up standards and design rules.[3]

Whilst there have been approaches within the supply networks, product development, and strategy literature to address these design challenges, and develop design rules, through three-dimensional concurrent engineering (Fine, 1999; *Journal of Operations Management* special issue on three-dimensional concurrent engineering, 2005; Colfer and Baldwin, 2016), these approaches have not explored the role of networks within and across product, production, and supply chain knowledge domains and their interdependencies in developing innovations to derive design rules, in early-stage consortia networks. Knowledge evolves rapidly both within and across these product, production, and supply chain domains, and it is likely that firms with dissimilar know-how may not grasp all aspects of knowledge development in other domains of the consortia network to execute interdependent processes within their domain of the consortia network (Postrel, 2002). Cohesive understanding and sharing of relevant knowledge is a premise central to the follow-on development of modular product and production networks.

Establishing design rules across dissimilar, specialized networks is a non-trivial challenge. This is because exchange of knowledge across different domain networks requires collaborative interactions and negotiations involving stakeholders with diverse expertise (e.g., process analytics and novel equipment suppliers, supply chain designers, universities, and regulators). Such interactions, owing to both technical and agency challenges, may not yield convergence of product and process designs – a critical element for building new products and processes that span knowledge domains. Bridging knowledge gaps to overcome convergence challenges across

[3] While the current study focuses on UK-based research, sister consortia also exist in the US and the EU. All the global pharmaceutical firms participate in the UK consortia, along with UK and US regulatory bodies through the *International Council for Harmonization* (ICH, 2018) and a regular set of joint reviews (e.g., ICAMM, 2023).

dissimilar networks begs the following questions: (i) how can design rules be set up when dependencies across knowledge domains are poorly understood, especially in early-stage pre-competitive R&D efforts? and (ii) how can the convergence of design rules be guaranteed, when various stakeholders across the knowledge domains have differing, and at times competing, goals? Our study addresses these central questions that are critical to our understanding of the product development process in a networked environment – a phenomenon that permeates the development of many advanced technologies.

2. Theoretical Gap and Contribution

During conventional innovation, there are two mechanisms that drive design rule convergence: organizational hierarchy – when various stakeholders work for the same organization, a senior manager in the organization can resolve design rule disputes and drive convergence (Anderson and Joglekar, 2005; Mihm et al., 2010). This is because any value appropriated, because of convergence, results in direct benefit to the organization. Furthermore, it is easier to coordinate and resolve convergence challenges because there is a lesser degree of asymmetric information within the organization. This is consistent with the findings of Mihm et al., (2003; 2010), who suggest that hierarchy improves development by allowing frontline groups to explore solutions and coordinate knowledge exchange across local groups, speeding up convergence towards the achievement of organizational goals.

Alternatively, the marketplace (e.g., supply chain partners with dominant positions) can help resolve differences and set design rules (Veiga and Weyl., 2016). In this case, firms frequently collaborate across modules with "thin crossings", i.e., the degree of interdependency across modules is kept low to set up transactions that create the market. The reduced design interdependency across modules allows for ease of independent development across different specialized systems that put less burden on firms to agree on design rules and set up standards (Baldwin, 2007). Coordination systems in these settings are decentralized and open, where organizations across different specializations rely on pre-established relationships (Narasimhan and Narayanan, 2013).

Early-stage pre-competitive consortia settings do not conform to either hierarchy or market solutions. The knowledge gaps across different communities (e.g., teams working on product synthesis versus teams working on supply chain design) are acute, especially in the development of novel continuous manufacturing regimes deploying digital technologies. This is because technologies and interfaces, and consequently design standards, are not mature and are evolving. In these settings, establishing design standards requires different collaboration approaches since the stakeholders do not have the "relationship" to establish a common baseline. This sets up the theoretical gap in the existing literature that our study seeks to address: *what are the mechanisms that drive design rule convergence in pre-competitive consortia?*

Our study explicates the mechanisms that underpin convergence and contribute to the supply network and new product development literature in fundamental ways. First, it begins with the approach taken to study the mechanisms—network ethnography (Berthod et al., 2017). Second, using network ethnography, our study details not only how specialized "domain-specific" networks exchange knowledge using "set-based design rules" (Ward et al., 1995) but also how such knowledge is exchanged across different "domain networks", detailing the complexity of such development processes across knowledge domains. This complexity also illustrates the specific importance of not only firms but also academia and regulators, an issue that has been under-emphasized in supply networks literature at large.

Third, in examining the roles of stakeholders in detail, this study identifies the role of regulators and academia (as neutral third-party entities, as compared to firms vested in the ideas) as the "secret sauce" in allowing the convergence of design rules. That is, the institutional partners (e.g., regulatory bodies and academia) bridge knowledge gaps, and help resolve trade-offs such that design rule convergence can be reached. This mechanism has not been discussed in the literature (see review by Brusoni et al., 2023).

Finally, we also show visually how boundary objects (i.e., peer reviewed research papers that articulate specific design rules) and boundary spanners (i.e., individuals from multiple organizations) that bridge multiple domain networks, carry knowledge and facilitate the development of trans-specialist knowledge, again the first in the literature to the best of our knowledge. Such a detailed analysis is possible through the use and adaptation of the Multi-Domain Matrix method (Browning, 2015), which demonstrates the specific interaction points drawing on not only 10-year detailed data on networks, but also ethnographic analysis that documents and identifies the interactions among the stakeholders to which some of the authors had unique access to as direct participants in the consortia network. Overall, the contributions of this study answer the call for a deeper understanding of the fundamental approaches and mechanisms that stakeholders in networks use to create and leverage design knowledge.

3. Technology Context

Continuous manufacturing technologies mark a sea change from conventional drug design and batch production. Figure 1 compares batch and continuous regimes by mapping unit operations (from synthesis to storage and distribution) to the three concurrent design domains outlined in the previous section (e.g., Fine et al., 1999). Figure 1 also shows how a continuous process links to a more digitally enabled supply chain using process analytical technologies, and connects tasks carried out in product, production, and supply chain domains. The introduction of process analytical technologies, and active process controls, makes the development inherently *trans-specialized* (a term used in settings where core domain knowledge requires knowledge of other domains in implementing innovations – see Postrel (2002) for a detailed exposition on trans-specialization).

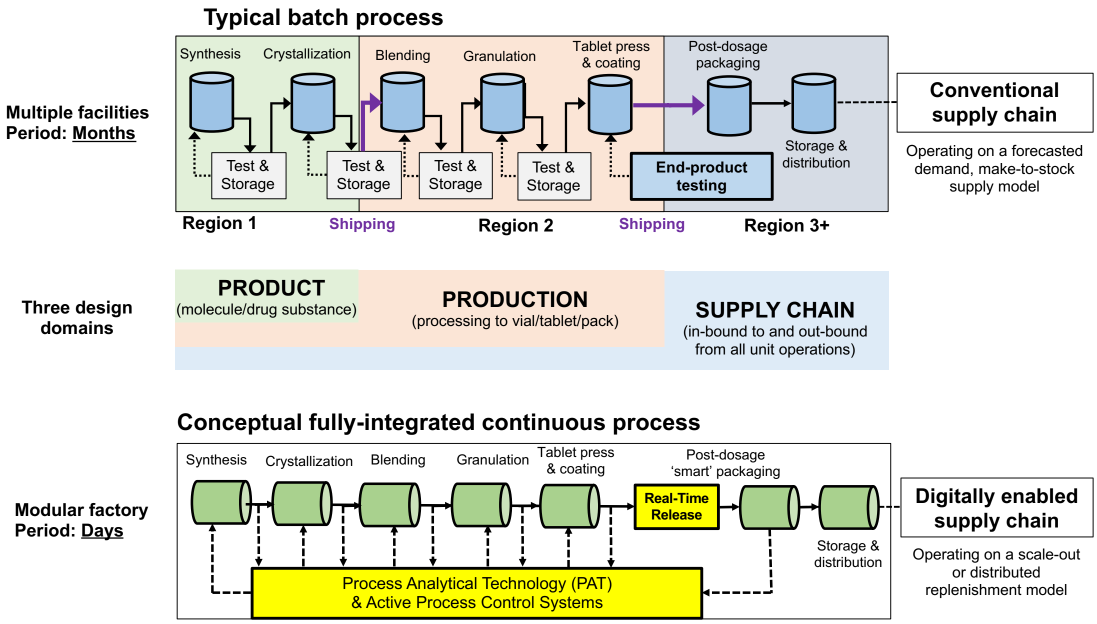

Figure 1: Batch and continuous processing regimes mapped to product, production, and supply chain domains (adapted from Fine et al., 1999; Lee et al., 2015; Harrington et al., 2017)

We organize the data of this paper around Figure 1 referring to the three design domains as (1) *product*; (2) *production*; and (3) *supply chain*. Since this study also uses several technical terms, we provide readers with a glossary of concepts and terminologies in Appendix I.

The basis of scientific discovery in molecule synthesis, process design (in terms of fluid dynamics), and allied controls are fundamentally different for batch and continuous manufacturing technologies. These differences have spawned multiple lines of foundational research in the product domain (see Nagy et al., 2020, for a review). Similar scientific and economic challenges have also emerged in the production domain (see a treatise on reactor design, Johnson et al., 2020), and in the supply chain domain (see Srai et al., 2020, for a chapter on supply chain design). Of note are the data acquisition and integration challenges – involving digital technologies – across these product, production, and supply chain domains, as quality parameters are designed and subsequently controlled to assure quality through process analytical technologies for Real-Time Release Testing (see Su et al., 2020, for a review). Finally, these technologies call for new types of regulatory oversight (Morefield, 2020). Here, the *International Council for Harmonisation for Pharmaceuticals for Human Use* has recognized the fundamental shift, from batch to continuous mode, in setting standards for supporting design and development (ICH, 2018). This standard identifies three novel scientific approaches (control strategy for continuous manufacturing, changes in production output, and continuous process verification) for which new design rules must be established as these three approaches do not apply to batch production.

Design within and across each domain also features emergent and specialized knowledge, beyond the conventional R&D skill sets in pharmaceutical firms. Here, we observed the emergence of 'knowledge communities' (Upham, 2022) in early-stage pre-competitive settings, assessing specialized knowledge from academia, novel equipment developers, and process analytical technology providers, to address technology development gaps. Given the novelty in technologies, regulators must also learn about these underlying developments. They do so by engaging with the R&D effort within pre-competitive consortia. For example, in this study, our discussions with the UK Regulator included developments leveraging digital technologies around predictive process and product design, architectures to support new (micro-factory) processes, and new (digital) supply chains of the future (see Appendix A1: *Consortia-Regulator engagements*). We next review the relevant literature.

4. Literature

This study is at the intersection of two primary literature streams. The first literature stream concerns operations management, specifically supply chains, supply networks, and new product development. The second literature stream is in the strategic management domain that focuses on challenges in knowledge exchange in early and steady-state R&D consortia. These streams underscore the role of hierarchical decision-making (e.g., top-down guidance) and/or market mediation (e.g., supply network input) as mechanisms for achieving design rule convergence.

4.1 Product Development, Three-dimensional Concurrent Engineering, and Supply Networks

The introduction to the idea of modularity and design rules (Baldwin and Clark, 2000), and the proliferation of concurrency practices to enhance clockspeed (Fine, 1999) attracted academic enquiry in the operations management domain, including a special issue on '*Coordinating product design, process design, and supply chain design decisions*' (three-dimensional concurrent engineering) that was published as a two-part special issue in the *Journal of Operations Management* (Rungtusanatham and Forza, 2005; Forza et al., 2005). The special issue sought to examine mechanisms that "*allow product design, manufacturing process design, and supply chain design decisions to be coordinated*." Given the increased importance of networks across knowledge domains, a recent *Journal of Operations Management* special issue on '*Innovation in Supply Networks*' also called for more insight into mechanisms that underpin innovation exchange in supply networks (Kumar et al., 2020). Kumar et al., (2020, p.761) note: "*mechanisms underlying the effects of network characteristics on organizational outcomes remain mostly untested and, in many cases, not explicitly discussed by theory.*" Our study seeks to fill this gap in the literature by examining the key mechanisms that underpin the coordination of innovation knowledge across product, production, and supply chain design in early-stage pre-competitive R&D environments.

While much of prior work here focuses on steady-state settings (e.g., Chesbrough and Prencipe, 2008), our environment is dynamic, and interdependencies are not well understood.

We briefly summarize the literature in Table 1 along two dimensions: maturity of the structure, interfaces, and design rules (either after, or during the emergence of design rules) versus the scope of problem-solving and resulting outcomes (within or across specialized domains). These dimensions yield a four-quadrant framework, which details the literature gap our study addresses.

Table 1: A Framework for Assessing Product, Production, and Supply Chain Concurrency

		Maturity of Structure, Interfaces and/or Design Rules	
		After the Emergence of Network Structure	During the Emergence of Network Structure
Scope of Problem-Solving and Resulting Outcomes[4]	SIMILAR NETWORKS Focused on 'Mirroring' within a Specialized Domain: Product or Production or Supply Chain Innovation and Coordination in Networks	Browning & Eppinger, 2002; Salvador et al., 2002; Sosa et al., 2004; Mihm et al., 2010.	Choi et al., 2001; Yassine et al., 2003; Parraguez et al., 2015.
	DISSIMILAR NETWORKS Focused on 'Partial Mirroring' within and across 2 or 3 Specialized Domains: Product–Production–Supply Chain Innovations	Droge et al., 2004; Fine et al., 2005; Narasimhan and Narayanan, 2013; Bellamy et al., 2014.	Chesbrough and Prencipe, 2008; **Our study**

The two streams of literature presented in Table 1 are interconnected in that technologies that are earlier in their life cycle also result in supply networks that are more likely to evolve more dynamically and result in networks that emerge, rather than being purposefully designed (Choi et al., 2001), because structures and coordination models with respect to technologies continue to develop (Yassine et al., 2003). Even when product structures emerge, uncertainties in development across two distinct domain networks can be resolved by deeper collaborations between firms and their suppliers, or even between suppliers working on their own distinct modules (Narasimhan and

[4] 'Mirroring' refers to the concept that organizational structures often reflect the technical/product architecture they are designed to develop; 'Partial mirroring' refers to when the organizational structure only partially reflects the technical/product architecture (e.g., in consortia settings, Colfer and Baldwin, 2016). See discussion in section 4.2.

Narayanan, 2013; Bellamy et al., 2014). We briefly delve into each of the quadrants and present key gaps, rather than offering a comprehensive review of studies in each quadrant.

In the top left-hand quadrant, Salvador et al., (2002) focus on the impact of product modularity's mitigating effect of the negative implications of product variety; Browning and Eppinger (2002) demonstrate that process architecture mediates the efficiency of product development processes of firms; Sosa et al., (2004) examine misalignments between design interface and teams, and delineate the performance implications due to coordination. A key assumption in each of these papers is that they assume the network structure is given, and the studies explore problem-solving and outcomes in one of the specialized domains. The iterative development of design rules in these settings is handled in a hierarchical setting as products and interfaces are established (Anderson and Joglekar, 2005; Mihm et al., 2010).

The top right-hand quadrant of Table 1 focuses on the emergence of product structure and design rules. Yassine et al., (2003) focus on the difficulty of convergence in the product development process in complex environments, such as automobiles. Organizations in this setting encounter agency issues in exchanging product design information, where designs have a higher rate of churn, which causes performance challenges; Choi et al., (2001) note that the autonomous emergence of networks can result in better innovation efforts across individual entities within the network. Such emergence is more likely when product designs also change; Parraguez et al., (2015) focus on the importance of managing the design process for integrating activities and individuals in a network within a large-scale engineering project. Each paper here takes a dynamic view of the network structure. This stream of literature articulates dynamism in the evolution of product and process innovation within the network, but does not consider innovation *across* networks and the underlying mechanisms.

The bottom left-hand quadrant explores problem-solving across two or three domains. These studies also do not consider the dynamic nature of the networks and assume stability of the network structure (and related design rules). Fine et al., (2005) examine trade-offs across product, process, and supply chain design and their cost implications; Droge et al., (2004) explore the mediating role of supply chain integration in buyer-supplier relationships on the impact of product/process strategy on service performance; Narasimhan and Narayanan (2013) focus on the exchange of specialized knowledge across network entities through collaborative relationships; Bellamy et al., (2014) examine the impact of supply network structure on innovation outcomes. A common theme in this quadrant is that the network is stable, and design rules exist. These studies do not examine the mechanisms that drive knowledge exchange across domain networks.

Finally, the bottom right-hand quadrant addresses the situations where both the networks and design rules evolve in 'partial mirroring' within and across the three specialized domains (product, production, and supply chain). Early-stage networks do not have the benefits of long-term relationships, traditional organizational, or inter-organizational mechanisms of markets or hierarchy to drive innovation convergence. The nature of collaborators in this quadrant include a combination of industry, academia, and regulators, each of whom is interested in developing design rules that can potentially lay a foundation for future product development within the industry. The temporary relationship characterized in this quadrant is also distinctively different from traditional supply network participants that pursue long-term development interactions in relatively established product design settings (Chesbrough and Prencipe, 2008). Further, the extant literature is focused on organizational and inter-organizational arrangements (cf. Chesbrough and Prencipe, 2008), rather than on the mechanisms of interactions across the different stakeholders that facilitate collaboration. The range of evolving relationships among stakeholders, and agency problems, makes convergence of design rules challenging, requiring deeper analysis and study. Overall, our study contributes to this bottom right-hand quadrant – as a research setting.

4.2 Organizational and Inter-organizational Strategies

The second literature stream is related to knowledge management and organizational strategy. Ernst (2005) identifies two propositions underlying the mirroring hypotheses. The first proposition focuses on the convergence of technical and organizational modularity. Ernst argues that the architecture of a complex artefact (i.e., its knowledge map) corresponds with the organizational structure (operational map) of the firm or its partners producing that artefact. The computer industry is often cited as a breeding ground for this new industrial organization model (e.g., Langlois, 1992; Baldwin and Clark, 2000). Modularized product design concepts for mass customization are also emerging in pharmaceuticals (e.g., Govender et al., 2020). A second proposition argues that organizational modularity is made possible by a combination of two developments: the codification of knowledge (Sichel, 1997; Flamm, 1999); and market-led standardization (through technical standards and design rules) of the interfaces between organizationally separate tasks, and underlying knowledge of production. Colfer and Baldwin (2016) conducted a study of 142 articles to find systematic support for such mirroring. Their study also covered alliance and consortia settings, where multiple firms take part in the development of a tightly integrated, technically challenging new product or system. There is also a rich set of literature on the formation of consortia in industries such as semiconductors, consumer electronics, and biotech (Macher et al., 1998; Sakakibara, 2002; Olk and West, 2023). While this literature addresses the evolution of industry structure and the development of standards, it does not investigate the convergence of design rules across dissimilar networks of knowledge.

Thus, our point of departure from this literature, as identified by Colfer and Baldwin (2016), is around the evolution of a set of design rules across all the domains of knowledge (product, production, and supply chain design). Each domain of knowledge, in our context, is fundamentally different in their structure and activity, and thus represent "dissimilar networks" (Piccolo et al., 2022). Evolution of design rules across multiple knowledge domains is a non-sequitur because problem solvers in one knowledge domain may be oblivious either to the structure of the network, or the nature of the problems being solved in other communities and/or knowledge domains. This leaves gaps in the theoretical explanations for the mechanisms that create and develop knowledge across dissimilar network structures. Design rule convergence mechanisms in this literature are shown to be addressed both by organizational hierarchy and market transactions (Colfer and Baldwin, 2016; Brusconi et al., 2023). By taking an integrated view of these two literatures, we argue that design is a process of making trade-offs and negotiations across stakeholders with different expertise. There are two explanations offered for mechanisms that drive design rule convergence: organizational hierarchy (Anderson and Joglekar, 2005; Mihm et al., 2010) and the marketplace (Veiga and Weyl, 2016). However, the convergence of design rules in settings – such as pre-competitive consortia – that feature neither hierarchical nor market mechanisms needs further explication.

5. Research Methodology and Data Analysis

We adopt network ethnography, an approach combining social network analysis and ethnography (Berthod et al., 2017), to explore the mechanisms by which specialist networks are influencing innovation outcomes through design rules. While classical network methods that are well grounded in the operations management literature (e.g., Borgatti and Li, 2009; Kim et al., 2011; Bellamy et al., 2014) can identify organizations that are influential in developing design rules, they do not show the contextual elements of interactions and decisions. By employing well established ethnographic protocols (e.g., Gioia and Chittipeddi, 1991; Gioia, Corley and Hamilton, 2013) – in parallel – we can augment social network analysis with contextual knowledge of these interactions. That is, ethnography identifies the knowledge that is exchanged across the links established through network analysis. The network ethnography process is summarized in Figure 2. Relevant details are then explicated in sections 5.1, 5.2, and 5.3.

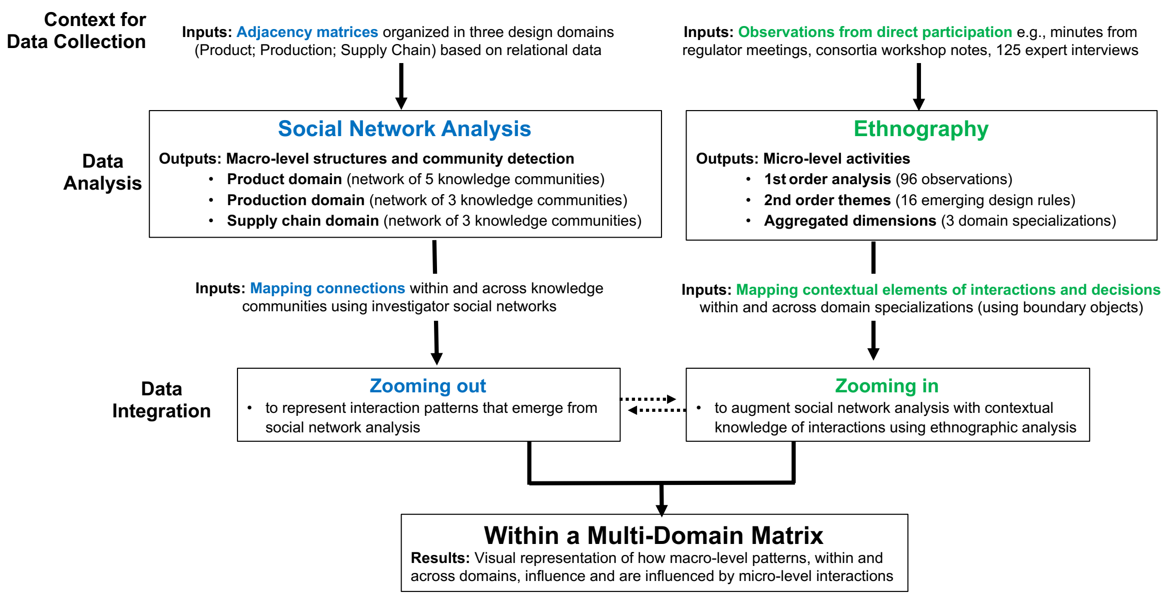

Figure 2. Network ethnography process based on Berthod et al., (2017)

5.1 Social Network Data and Analysis

We accessed publicly available grant applications to iteratively build up a database of consortia organizations and investigators in stages, from 2011 to 2021 (ReMedIES, 2018; UKRI, 2023a-c). Using this relational data, we constructed undirected binary adjacency matrices (Bellamy et al., 2014) to structure the data for social network analysis, in capturing interactions between nodes (organizations). In line with our reference population of pre-competitive collaborations involving different domains, we co-developed three adjacency matrices with academic and industry lead organizations. Matrices were verified for reliability with project partners, and for validity of activities and relationships, over time (see Appendix A2 *Part I: Inputs to social network analysis* and Figures A1-A3).

Gephi software was then used to visualize the adjacency matrices, leading to the three domain networks in their fully evolved form, as shown in Figure 3(a). The nodes represent organizations, and we highlight the hub nodes (i.e., nodes with the highest centrality from social network analysis) and the UK regulator in each domain. We also represent each domain network in reduced form in Figure 3(b), to focus on the top 10 hub nodes and the regulator only (see Appendix A2 *Part II: Outputs from social network analysis* and Tables A1-A2).

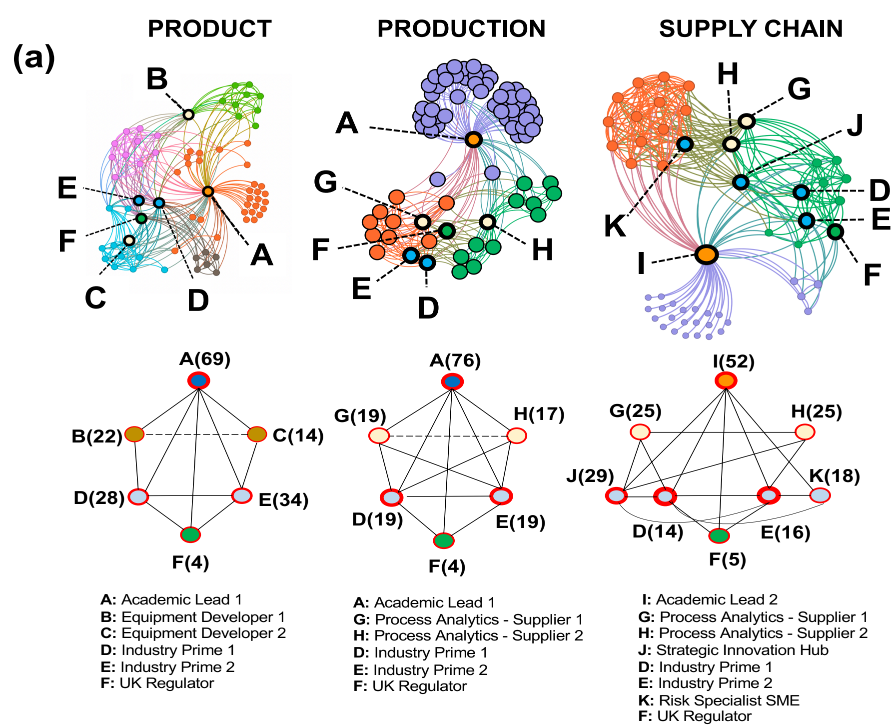

Figure 3: (a) Product, production, and supply chain domain networks (as of 2022); **(b)** Reduced form domain networks showing 10 hub nodes (nodes A-E; G-K) and the regulator (node F). The numbers in brackets, e.g., **A(69)** denote the number of node connections (i.e., edges)

Note that hub nodes span a diverse range of stakeholders, from academia (nodes A and I) to industry primes (nodes D and E), equipment developers and process analytical technology suppliers (nodes B, C, G, and H), a process innovation hub (node J), and a SME specializing in risk (node K). Five of the 10 hub nodes feature in two or more domains, and two nodes (G and H) seen as competing in the production domain (denoted with a dotted line), are collaborating in the supply chain domain (CPI, 2020).

Using Gephi's detection functionality, we identified 11 knowledge communities across the three domains: five product, three production, and three supply chain (see detailed descriptions in Appendix A2 *Part III. Knowledge communities overview*). That is, these communities are 'sub-networks of problem-solvers' within a specific knowledge domain. Each community is shown in a different colour for ease of visualization. We also complement Figure 3 with investigator social network data[5] to track influential individuals within knowledge communities. For example, we mapped collaborations involving investigator A from hub node A, over 10 years, through 11 projects and 64 research outputs (see Appendix A2 *Part IV. Hub node investigators* and Figures A4-A5).

5.2 Ethnographic Data and Analysis

The scope of our ethnographic work over the 10 years involved 250 consortia meetings, 45 workshops, and 125 expert interviews, as summarized in Appendix A3 *Part I: Multiple forums* and Tables A3-A4. We followed a protocol developed for ethnographic analysis by Gioia and Chittipeddi (1991) to process interview and language-based data. This involved a first-order analysis to capture what pre-competitive consortia were doing to solve unique problems specific to product, production, and supply chain domains, based on observations from direct participation e.g., the multiple forums (as above), regulator engagements (see Appendix A1), interviews (see

[5] Investigator social network data is publicly accessible through UK University research portals. For example, the KnowledgeBase Research Information Portal at https://pureportal.strath.ac.uk/

Appendix A3 *Part II*: *Interview protocols),* and investigator progress updates (see Appendix A3 *Part III: Consortia project reporting*). The second author led the analysis, while the first author coded portions independently to ensure a rigorous and bias-free process. At this juncture, we adhered closely to language and terminology in documenting 96 first-order observations.

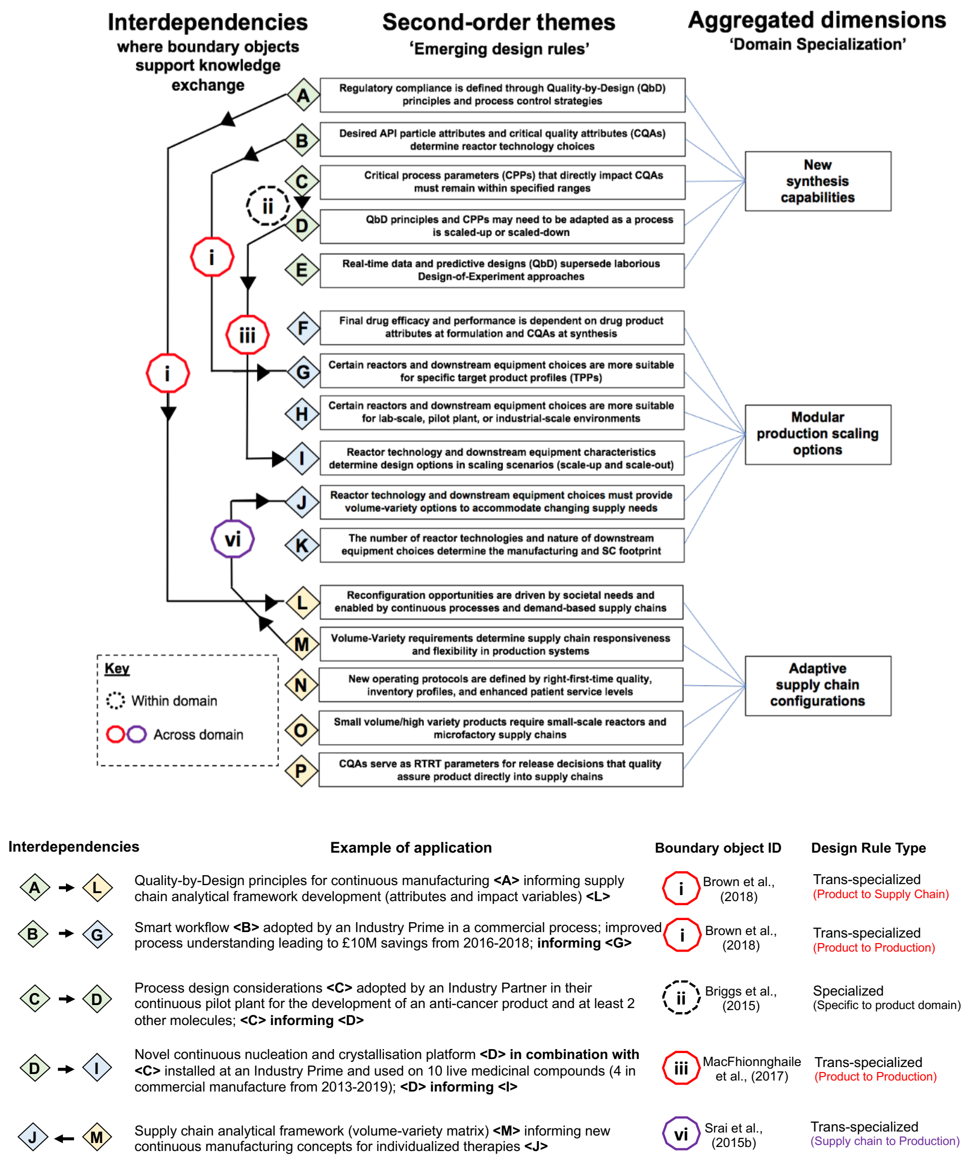

Figure 4. Data structure and emerging design rules (<A> to <P>) from ethnographic analysis; interdependencies example using a subset **(i, ii, iii**, **vi**) of boundary objects

We next iteratively fine-tuned and re-organized this first-order set to reduce the number of key categories by examining similarities and differences across the categories (Gioia, Corley, and Hamilton, 2013). Given the study's longitudinal nature, we integrated new data as consortia activities evolved, over time, and resolved disparities in emerging interpretations by cross-checking their validity with consortia partners and external experts through theme-focused workshops and follow-up discussions. Additional measures to ensure credibility, dependability, and confirmability (as per Selviaridis and Spring, 2022) are summarized in Appendix A3 *Part IV: Methodological measures*. After multiple cycles of engagement and data interpretation, we reached saturation point (Berthod et al., 2017) to arrive at 16 second-order themes (emerging design rules) and three aggregated dimensions (domain specializations). The outcome of this process is the data structure presented in Figure 4, where we label emerging design rules as **<A>** to **<P>**. For a more detailed data structure, see Appendix A3 *Part V. Application of the Gioia methodology.*

5.3 Data Integration using a Multi-Domain Matrix

A Multi-Domain Matrix is an extension of the Dependency Structure Matrix and brings with it the advantages of simplicity and conciseness in representing complex systems (see Browning, 2015, for a comprehensive review). We mapped outputs from sections 5.1-5.2 into a Multi-Domain Matrix to codify patterns involving: (1) **inter-organizational networks** (recall the hub nodes from social network analysis in Figure 3); (2) **knowledge communities** (within-domain communities from social network analysis; see Appendix A2 *Part III);* (3) **hub node investigators** (investigator social networks; see Appendix A2 *Part IV);* and (4) **emerging design rules** (recall Figure 4).

Adopting a Multi-Domain Matrix allows us to 'zoom out' as per Berthod et al., (2017), in stepping back to view broader, macro-level structures and patterns across - as outlined above -

(1),(2),(3), and (4) simultaneously (Browning, 2015). We focused on the hub nodes, and specific hub node investigators, to examine any new relationships that emerged over time. The Multi-Domain Matrix also allows us to 'zoom in'– simultaneously focusing on detailed, micro-level interactions and activities again across (4),(3),(2), and (1). 'Boundary objects' - examples of which we represent using peer reviewed papers **(i)** to **(vii)** in Figure 5 - serve an important function in connecting published and applied design rules not only to the specialist knowledge of hub node investigators (as co-authors of publications), but also to the knowledge communities from where specialist knowledge first emerged, and where the investigators resided. As a result, 'zooming in' enabled us to assign specific labels to specific knowledge communities, e.g., *precision particles*, using the language of investigators in each of the 11 knowledge communities. This 'zooming in'– 'zooming out' activity forms the basis of our analysis of interdependencies using Figure 5, and in answering the research question posed in section 2.

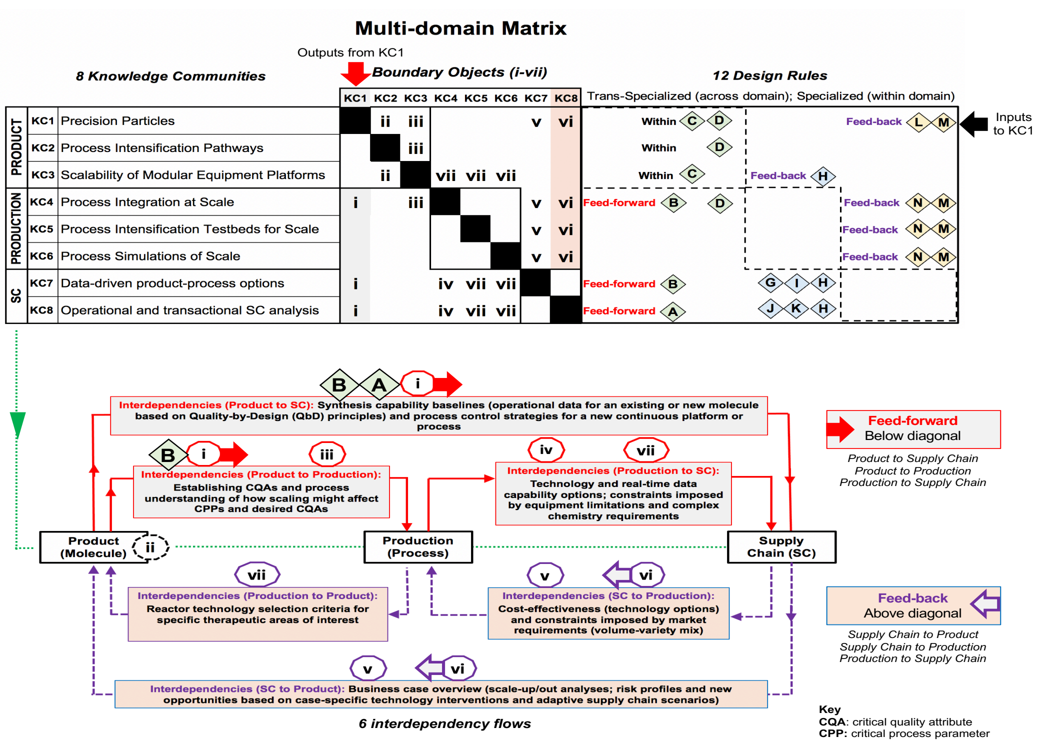

Figure 5. (Top) Multi-Domain Matrix (which highlights 8 knowledge communities and 12 design rules only); (Bottom) information flow diagram (which highlights 6 interdependencies split out above and below the diagonal, as shown in the matrix on the top)

Given space constraints, we show a part of the Multi-Domain Matrix in the top half of Figure 5. For an extended version, and a more detailed overview of 'zooming in'–'zooming out', see Appendix A4: *Multi-Domain Matrix.* To illustrate a representative set of knowledge flows, we feature eight knowledge communities across the product, production, and supply chain domains on the top left-hand side of the matrix. At the centre, the off-diagonal coding represents seven publications (**i-vii**) as 'boundary objects', from which design rules originated. On the top right-hand side, we feature examples of specialist knowledge (12 design rules) which inform different knowledge communities within and across the three domains. The Multi-Domain Matrix enables us to map, for the first time, information on micro-level interactions (i.e., emerging design rules from ethnography, as per Figure 4) to macro-level structures (i.e., knowledge communities that emerged from social network analysis, as per Figure 3).

A Multi-Domain Matrix can contain a variety of labels, codes, and conventions for orientation, as the format lends itself to customizations (Browning, 2015). We now use one knowledge community, *precision particles*, to explain the matrix 'inputs as rows' convention used, and then to describe two interdependency flows. The matrix in Figure 5 should be read as follows:

(a) inputs to *precision particles* (KC1) appear in its matrix row - reading from right to left - across-domain design rules (**<M>** and **<L>**) and within-domain design rules **(<D>** and **<C>)** through boundary objects **(vi)**, **(v)**, **(iii)** and **(ii)**;

(b) outputs from *precision particles* (KC1) appear in its matrix column - reading from top to bottom - boundary object **(i)** informing *process integration at scale* (KC4), *data-driven product-process options* (KC7), and *operational and transactional supply chain analysis* (KC8), through design rules **<B>** and **<A>**.

The bottom half of Figure 5 splits the six observed interdependencies out across the three domains for ease of visualization. Boundary object **(i)** then features design rules **<A>** and **<B>** that are linked to a multidisciplinary system-wide workflow coupling scaled-down experiments, prediction, and multi-scale modelling (Brown et al., 2018). Two of the six interdependencies are represented below the diagonal and denote upstream cascade rules based on workflow and network dependencies: **<B>** informing the production domain on how process scale-up may affect critical quality attributes of a molecule and reactor technology choices downstream for a targeted product profile; **<B>** and **<A>** informing the supply chain domain on how new synthesis capabilities (baseline operational data involving new molecules, continuous processes, and/or platforms) might impact volume-variety profiles, supply chain responsiveness, and flexibility in production systems. These feed-forward interdependencies form the basis of 'trans-specialized' design rules.

6. Empirical Observations

We summarize network ethnography results as three within-domain and three across-domain empirical observations and present a succinct explanation of their contribution to the literature.

6.1 Within-domain

> **Observation 1:** *Specialized knowledge is generated by a diverse ecosystem of knowledge communities, through dynamic problem-solving efforts within product, production, and supply chain domains.*

In a continuous manufacturing context, we observed dynamic 'knowledge communities' looking to address novel problems and develop potential solutions. Within each domain, this required different (specialized) knowledge. We observed different forms of problem-solving 'sub-networks', a.k.a. knowledge communities emerge, over time. For example, in the product domain, social network analysis identified five different knowledge communities, three of which are featured in Figure 5, namely, *precision particles*, *process intensification pathways*, and *scalability of modular equipment platforms*. Gaps identified, which couldn't be addressed by the problem-solving efforts of existing consortia expertise through commissioned projects, would lead to sets of emerging projects being funded, often with new specialist partners for delivery.

While existing studies on open innovation within consortia settings have focused on how firms work with academia and alliance partners in early-stage development (e.g., Chesbrough and Prencipe, 2008), they do not examine specific mechanisms of knowledge exchange across actors. Our study addresses a gap in the literature on how inter-organizational relations come into being, and how they function (Steinmo and Rasmussen, 2018). One unique observation here is how pre-competitive consortia are operating as ecosystems of multiple stakeholders (Jacobides et al., 2018), i.e., knowledge communities – featuring academia, industry primes, first-tier suppliers, second-tier technology specialists, and regulatory bodies – contributing to the body of knowledge in each domain.

Observation 2: *Set-based design rules emerge when problem-solving cycles reveal parameter windows, through domain-specific knowledge exchanges, within each domain.*

Knowledge communities orchestrate very different R&D activities and generate specialized knowledge as the result of their problem-solving efforts (observation 1). In developing solutions based on these cycles of problem-solving, we observed how investigators were exploring multiple design alternatives and developing these concurrently in each domain, i.e., rather than converging on a single solution early in the R&D process, knowledge communities adopted the idea of 'set-based design rules' (Ward et al., 1995).

In a grand departure from the 'end-of-line' testing regime in batch mode (recall Figure 1), with its restricted 'degrees of freedoms,' regulatory compliance in continuous manufacturing can now be defined through 'Quality-by-Design' principles and process control strategies (design rule **<A>** from Figure 4). Set-based rules enable knowledge communities to target ranges of acceptable parameters or 'design spaces', where parameter windows facilitate continuous process improvement as there is now regulatory flexibility to move within these parameter windows (ICH Q8 (R2), in, Yu et al., 2014). Our study contributes to recent calls for a more comprehensive set-based design methodology (e.g., Toche et al., 2020), especially where significant uncertainties exist, and where domain-specific design rules are based on a body of knowledge generated by an ecosystem of partners with different specialized knowledge (what we term as 'domain specialization' in Figure 4 and will define in section 7).

Observation 3: *Academia and regulatory bodies are central to resolving uncertainties in setting standards within each domain.*

We observed knowledge communities emerge to develop specialized knowledge unique to their domain (observation 1) and, where significant uncertainties exist, leave 'room for adaptation' to new developments within their domain, through adopting set-based design choices (observation 2). Our third observation relates to how significant uncertainties in setting new standards are then resolved within domains.

Nuanced network roles have been studied to better understand knowledge integration in the design of products (Parraguez et al., 2016), processes (Roth et al., 2016), and supply chains (Jayaram and Pathak, 2013). We observed new modes of engagement where academic leads were facilitating a move away from customary compliance discussions to up-front agreements and follow-on validations of novel consortium-led initiatives, in turn, resolving within-domain uncertainties and playing a central role in negotiating new design rule-based standards. This is a grand departure as traditional engagements, involving conventional batch rules, have typically seen transitory exchanges and one-off interactions between single firms and the UK regulator.

Our observations also depart from previous descriptions of consortium archetypes (e.g., Pathak et al., 2014: p.263), which are based on homogeneous actors (primary producers, tier-1 supplier, tier-2 supplier). This study is the first to report on engagements involving a range of heterogeneous actors within multiple domains (recall Figure 3 and the diverse sets of actors).

6.2 Across-Domain

> **Observation 4:** *Boundary spanners and boundary objects are the mechanisms for trans-specialised knowledge flows in dissimilar networks.*

While design rules are established, and new design rule-based standards are being employed within domain specializations (observations 1-3), we also observed knowledge communities using design rules developed in other seemingly 'unconnected' knowledge communities to facilitate knowledge development *across* domains. For example, recall Figure 4, where Quality-by-Design principles **<A>** informed supply chain analytical framework development **<L>**; and then an adapted supply chain analytical framework **<M>** informed new continuous manufacturing concepts for individualized therapies **<J>**. This observation confirms partial mirroring, allowing for such exploration, but it also highlights dependencies (some known, others emergent) that are at play across domains.

In this context, we observed the critical role of 'boundary spanners' in early-stage pre-competitive settings, as those individuals who have crossed knowledge communities and possess expertise in multiple domains. For example, hub node investigators A and K working together to translate and integrate specialist knowledge from one domain to another using 'boundary objects' (i.e., artefacts based on **(i)** through to (**vii**), from Figure 5), and in identifying and managing interdependencies between domains (see further details on boundary spanning teams and objects in Appendix A4: *Multi-Domain Matrix*). Supply chain 'integrator' and 'boundary spanner' concepts are well established in the supply chain management literature, having emerged as firms outsourced and off-shored production (e.g., Parker and Anderson, 2002; Anderson et al., 2017). In pre-competitive consortia settings, boundary spanners connect across domains to collect information, identify trans-specialized knowledge gaps, and implement subsequent design rules.

> **Observation 5:** *Cross-domain dependencies can be addressed by creating, evolving, and converging trans-specialized design rules across product, production, and supply chain domains that proactively consider design trade-offs through feedback and feed-forward knowledge flows.*

The application of design rules in downstream domains can require significant adaptations primarily on account of design rule changes upstream and vice versa (observation 4). We refer to such adaptations as *trans-specialized design rules*. When considering the interdependencies between product, production, and supply chain domains, we examine feed-forward and feedback interactions. Development of trans-specialized design rules happens because of feed-forward (downstream adaptations, constraints, and responses to upstream changes) and feedback (upstream adaptations, constraints, and responses to downstream changes) events, which are non-sequential. This information structure is captured by the six interdependency flows in Figure 5 that span product, production, and supply chain knowledge domains. For example, during R&D efforts in the product domain, a knowledge community focused on *precision particles*, requires inputs ('feed-back') from the supply chain domain on the cost-effectiveness of development.

In a departure from earlier consortia findings (Colfer and Baldwin, 2016), our data suggests consortia-based domain networks require an exchange of trans-specialized knowledge to problem solve and converge on necessary specifications that serve the needs of within-domain, and across-domain, stakeholders through an iterative process. We observed 'dissimilarities' that not only occur because the role of each stakeholder is fundamentally different, but also because each stakeholder can operate in a fundamentally different domain (product, production, or supply chain). Ultimately, any product that is developed should speak to specifications within each domain, consider trade-offs, and be portable to specifications across domains.

> **Observation 6:** *Academia and the regulators look to mediate and resolve trans-specialized trade-offs across domains while seeking design rule-based standards, enabling faster convergence.*

The presence of key hub nodes, such as academia and the regulatory body, in each domain, helps resolve trade-offs in terms of design rules and in facilitating the convergence process. For example, achieving convergence for a new design rule may require process understanding of activities happening in the product domain [i.e., feed-forward **(i)** and **(iii)** in Figure 5]; require an understanding of data capability and constraints imposed by production equipment and limitations in handling product chemistry, in the supply chain domain [i.e., feed-forward **(iv)** and **(vii)** in Figure 5]; considerations by production concerning supply chain cost-effectiveness and underlying volume-variety trade-offs in manufacturing and consequent supply chain design [i.e., feedback **(v)** and **(vi)**]; and finally, consideration of reactor technology selection criteria imposed by production on therapeutic areas targeted in the production domain [i.e., feedback **(vii)**].

It is also likely that bridging these constraints in the feed-forward and feedback loops requires additional specialized knowledge from new partners (recall hub nodes J and K in Figure 3b), or even changes to business models (that require different levels of volume-variety trade-offs) and regulatory sign-offs. Academic lead partners play a pivotal role here in aligning network members and activities with the strategic goals of multiple consortia, offering an institutional alternative to the two classic explanations of convergence — hierarchical and market mechanisms — outlined in section 2 (Anderson and Joglekar, 2005; Veiga and Weyl, 2016).

7. Theoretical Generalizations

To generalize the empirical observations from section 6, we outline how our observations address specialized knowledge generation and exchange within and across three different domains. These domains (product, production, and supply chain) are centred on the three-dimensional development concept (Fine, 1999), where existing knowledge structures are typically associated with mirroring hypotheses (Colfer and Baldwin, 2016). However, prior studies have noted that mirroring hypotheses do not translate cleanly into settings that are consortia-based (Colfer and Baldwin, 2016), primarily owing to the dynamics of innovation underlying these settings (Ernst, 2005; Chesbrough and Prencipe, 2008). In this regard, consortia-based collaboration networks are settings where domains are likely to be dissimilar in both the knowledge they specialize in, and the characteristics of network connections between the entities that are part of the domain network (Piccolo et al., 2022; also see online Appendices A2, A3, and A4 for supporting data). Overall, using our six observations as building blocks, the network mechanisms underlying knowledge exchange within and across domains are captured in two propositions detailed below. The first (second) proposition is focused on within (across) domain specialist knowledge exchange.

While focusing on within-domain knowledge exchange, our theorizing captures the idea that each domain is composed of loosely coupled sub-networks or knowledge communities described in our definition of 'domain specialization' (i.e., the "*body of knowledge generated by an ecosystem of partners consisting of multiple stakeholders (academia, industry primes and first-tier companies, regulatory bodies, and process technology specialists) with different specialized knowledge which contribute to the formulation of design rules within a domain*"). For example, in the product domain, there are five different knowledge communities: *precision particles*; *process intensification pathways*; *scalability of modular equipment platforms*; *data characterization for targeted functionality*; and *regulatory alterations*. Each of these knowledge communities orchestrate 'emerging design rules' relating to product design. However, these design rules span multiple aspects of product design as detailed in Figure 4 (i.e., the domain specialization of 'new synthesis capabilities'), ranging from regulatory compliance through process control strategies, to critical process parameters that directly impact the critical quality attributes of a drug product, to real-time data for predictive designs.

Our three within-domain observations characterize the iterative mechanism in developing set-based design rules that cover specific areas relevant to each stakeholder within knowledge communities. This requires the development and evolution of specialized knowledge within specific domains through problem-solving, for example, to explore novel ways of designing, manufacturing, or supplying a drug product. As shown in Figure 3, this can involve hub nodes from (a) academia, (b) industry primes, (c) the regulator, and (d) suppliers of equipment (in the product and production domains); process analytical technologies for real-time monitoring of drug production and scaling (in the production and supply chain domains) and other risk management entities (in the supply chain domain). We draw upon the three within-domain empirical observations, regarding the generation of specialized knowledge by '*domain specialization*' **(observation 1)**, followed by **'***set-based design rules*' based on domain-specific knowledge exchanges **(observation 2)**, and '*the role of academia and regulatory bodies*' in delivering effective collaborations (e.g., in developing new regulatory standards) (**observation 3**), to articulate the first proposition:

> ***Proposition 1***. *The degree to which domain-specific teams in pre-competitive collaboration networks address problems iteratively, through domain specialization, set-based design rules,*

and proactive engagement with academia and regulatory bodies, is positively associated with the effectiveness of within-domain collaboration outcomes.

A key challenge, as described earlier in Figure 5, is coordinating knowledge across different specialized domains. This is shown to be addressed by our three across-domain observations, regarding '*trans-specialized knowledge*' **(observation 4)**, followed by '*addressing across-domain dependencies by converging trans-specialized design rules'* (**observation 5**), and **'***academia and the regulators mediating and resolving trade-offs*' (**observation 6**). Based on these observed mechanisms, we articulate the following proposition:

Proposition 2. *The degree to which boundary-spanning teams in dissimilar, domain-specific, pre-competitive collaboration networks develop trans-specialized knowledge, through negotiations and adjustments mediated by academia and regulatory bodies, is associated with greater (a) probability of convergence of design rules, and (b) effectiveness of development outcomes.*

8. Discussion

We now describe the study's theoretical contributions, and its practical relevance. Convergence of design rules facilitates the rapid development of products across distinct, specialized knowledge domains and also allows for coordination in complex development environments, a hallmark of drug development. A lack of design rules can impede the success of continuous manufacturing initiatives, despite their revolutionary potential. Furthermore, these rules are also a fundamental mechanism, in parallel with boundary spanning agents (individuals), that facilitate technical language to translate across knowledge domains so end products can be developed effectively. In studying the convergence of design rules in this dynamic environment, this study makes the following theoretical and practical contributions.

8.1 Theory Contribution

Despite the practical importance of developing design rules across knowledge domains, in early-stage R&D environments, the (a) diversity of stakeholders engaged in the development of novel process standards, and (b) the specialized nature of knowledge across each of the domain networks make the development and convergence of design rules challenging. In traditional product development efforts where design standards are better established, markets and hierarchies are common forms of mediation mechanisms, while pursuing design convergence, as incentives of different parties must be aligned. Within the same firm (i.e., hierarchy), incentives for the convergence of design rules and standards are higher, especially when module interdependencies are substantially high (Baldwin, 2007). Across firms, especially when standards are established (e.g., automotive) or somewhat uncertain (e.g., semiconductors), firms collaborate on pre-agreed standards and develop technologies across "thin crossings" (i.e., module interdependencies are low) (Baldwin, 2007). However, in the early stages of technology development, high levels of both specialization within the knowledge domain and interdependency across knowledge domains make the convergence of design rules challenging, especially in consortia settings, which are characterized by the involvement of diverse stakeholders that include industry and academia in each knowledge domain (cf. Chesbrough and Prencipe, 2008). According to Baldwin (2007), neither mirroring nor partial mirroring applies in these settings. Our study makes two fundamental contributions, in this regard:

(I) By documenting and proposing that organizations within pre-competitive consortia coordinate their development through set-based design rules, an idea that has not been recognized in the literature. Such set-based design rules, in parallel with boundary-spanning teams, promote adaptation within specific knowledge communities, and facilitate rapid development of products in a complex development environment.

(II) a unique finding is the recognition of the importance of institutional stakeholders, specifically academia and regulators, in facilitating the convergence of design rules.

These contributions stand in sharp contrast to prior literature that argues the importance of hierarchy or market mediation as the mechanisms that enable convergence of product development efforts within and across firms (Mihm et al., 2003, 2010; Baldwin, 2007). Early-stage R&D consortia studies such as Chesbrough and Prencipe (2008), that emphasize the role of academic bodies in the development of novel technologies when the mirroring hypothesis does not hold, do not emphasize the role of institutions in convergence. The issue is non-intuitive because regulatory bodies (i.e., institutions) do not possess direct knowledge of products and processes yet play a central role with academia and industry in facilitating the convergence of design rules. This is because institutions provide a neutral backdrop to validating the R&D efforts stemming from industry-academic interactions. While academic partners furnish tests and results, impartially, without bias or preferential treatment, to large pharma firms, technology providers, and regulators, the latter, on the other hand - by virtue of their monitoring authority - facilitate the narrowing of standards across different entities.

A brief point about allied intellectual property issues is also in order. In such early-stage consortia, parties are working on developing "process standards" recognizing that such processes may apply across many products. Given the primacy of processes, design rules, and interaction standards, product innovation is not necessarily compromised, and firms have a direct incentive to participate in economizing their own R&D efforts. Follow-on development of intellectual property is typically within the confines of the firm. Many process technology patents that are developed get absorbed within the confines of smaller firms (Dahlborg et al., 2017). Dahlborg et al. (2017) also note that many patents that are within academic institutions get transferred to corporate environments. Furthermore, this insight is also consistent with Heinrich et al., (2022), who note that process patents draw more on previous knowledge, are more radical, and pure process patents have lower degrees of protection.

From the standpoint of the product development literature, this study contributes to the ongoing discourse on the seminal mirroring hypothesis, which has been fundamental to our understanding of technology and product development across dissimilar networks. Despite the pre-eminence of the mirroring hypotheses in the literature, as a key mechanism in steady-state development networks, 27 studies out of 129 did not confirm the mirroring hypotheses (Colfer and Baldwin, 2016). Many of these studies are in consortia settings with regard to early-stage R&D efforts (Colfer and Baldwin, 2016). Chesbrough and Prencipe (2008) note that in early-stage innovations, firms need to develop strong ties to start-ups, and other firms that have complementary assets to further the knowledge base. Our study details that these relationships, under partial mirroring, are more successful under the auspices of regulators and academia.

Finally, from a methodological standpoint, this study is among the first in operations management to deploy network ethnography. We tracked hub node investigators across 11 knowledge communities, for over 10 years, through ethnography and investigator social networks to understand the practices underlying knowledge community emergence that shapes the network structure in each knowledge domain (Zilber, 2014). Detailing the mechanisms within social networks requires not only network analysis but also a deep dive into the activities of these networks, deploying embedded experience, using ethnographic analysis. By integrating both quantitative and qualitative data and mapping the resultant Multi-Domain Matrix, this study presents a nuanced analysis that we believe is critical as an approach to undertaking network analysis, and in characterizing knowledge transactions in an emergent network and their resultant outcomes. These transactions may have important implications for studying how networks evolve, and add value over time. Future studies may deploy the approach in this study to examine information exchanges across supply networks in novel ways.

8.2 Policy and Managerial Implications

Consortia were assembled and funded in sequential phases (e.g., CMAC I, then ReMediES, CMAC II, and then DM^2, see Appendix A2 for more details), with new phases getting funded every 2-3 years, while findings from older consortia were either terminated, or commercialized, or the design rules spawned follow-on pre-competitive work. These follow-on projects tackle emergent problems identified by the consortia. The creation of each new program generates emergent challenges; Joglekar et al., (2022) refer to this as a *fly wheel dynamic*. In each phase (e.g., phase "i"), novel problems that are selected in pre-competitive consortia traverse across all three domains to yield either convergent or divergent design rules. *Regulators and academia provide continuity in terms of shaping goals and knowledge consistency through multiple iterations of consortia-based work.* Both domain-specific and cross-domain teams exchange trans-specialized knowledge across different stakeholders, and rely on regulators to facilitate rapid convergence of design rules (Propositions 1 and 2). Failure to leverage propositions 1 and 2, collectively, leads to divergence and disagreements on problems for follow-on phases (i.e., phase "j").

From a practical standpoint, this study also demonstrates that domain specialization is more nuanced in advanced technologies, and technological evolution within "specialization" is driven by an ecosystem of actors with fundamentally different knowledge sets. Both regulators and firms should recognize this diversity - that underlies specialized knowledge - to build effective coordination systems and mechanisms that span different knowledge communities and domain networks. This observation of "*diversity underlying specialization*" also demonstrates the importance of studying mechanisms of knowledge transfer within and across networks using an ethnographic, data-driven, approach to studying what constitutes "domain" specialization.

In terms of public policy, this study implies that funding decisions at the level of product, production, and supply chain R&D for pre-competitive consortia must examine the convergence status of design rules not only to monitor domain progress (in terms of product, production, or supply chain) but also to guide follow-on funding decisions. Such funding decisions can target the objective of design rule convergence within- and across-domain networks. A more nuanced understanding of design rules that recognizes the importance of diverse stakeholders, who produce disciplinary knowledge and exchange cross-disciplinary knowledge through feed-forward and feedback processes across different specialized domains, would be valuable in producing product outcomes from funding investments. This argument is consistent with the operations-public policy nexus (Joglekar et al., 2016; Spring et al., 2017; Helper et al., 2021).

Overall, our findings suggest that funders, regulators, and academic organizations supporting the evolution of fundamentally new technologies may do better in (a) promoting an environment of dialogue across the diverse stakeholders within each domain; and (b) identifying trans-disciplinary collaboration challenges across domains to facilitate successful design convergence. Such interactions need to be mediated by regulatory bodies and academic institutions, as neutral third parties, to enable diverse stakeholders to narrow down standards that can then be adopted in commercial development. The need for mediation, aimed at design rules convergence, by regulatory bodies together with academic interventions is evident in other emergent technologies such as in clean energy, for instance, through the US Department of Energy and National Energy Research Lab (NERL) in the evolution of off-shore wind-generated energy technologies (Hansen et al., 2024; Wilson et al., 2024), or use of real-time process analytics for oversight of autonomous vehicle operations (Chia et al., 2021). The association posited in our twin propositions could be tested in multiple settings to further generalizability.

The second implication goes towards managing network innovation in supply chains, particularly when small suppliers must work with larger OEMs (Selviaridis and Spring, 2022). Recall from Figure 3b that different small technology suppliers (e.g., equipment suppliers in the product domain; process analytical suppliers in the production domain) must work with academic partners and primes in their respective domains to gain regulatory approvals. Arguably, smaller suppliers with limited resources may be particularly vulnerable to trans-specialization knowledge gaps, restricting their Technology Readiness Levels (TRLs) (see Olechowski et al., 2020; Kurpjuweit et al., 2021). This requires ecosystem partners to work with SME suppliers to improve their TRLs by sharing trans-specialized knowledge. Dhalborg et al. (2017) note that small and medium-sized firms are the largest absorbers of academic patents. Promoting such small suppliers may facilitate an innovation eco-system that allows design standards to develop faster where larger companies also benefit through successful commercialization.

9. Conclusions and Limitations

The context for this work is that it is predicated on the novelty of specialized knowledge, which emerges when new types of technologies (e.g., molecule synthesis in continuous mode, and digital technologies for Real Time Release Testing-based quality assurance) are first introduced. This novelty creates problems that beget the structural dissimilarity across product, production, and supply chain domains. Consistent with Carlile (2004), we also argue that design rules are artefacts that not only serve as boundary objects, but also enable boundary spanners to carry their specialist knowledge across domain networks to pose the latest problems and solve them.

We recognize that there have been arguments for the dynamics of modularity (e.g., Chesbrough and Prencipe, 2008) involving networks of innovation between firms, academic partners, and start-up partners. If the novelty wears off because some design rules are formalized, such networks may anticipate trans-specialized dependencies. Then, academic and regulatory partners may not be willing to participate in generating incremental knowledge. This limitation of our work should be controlled for in follow-on empirical studies based on our propositions.

Second, mechanisms for transitioning from pre-competitive to competitive settings are not identified in this current study, especially with regard to IP ownership, talent management, and market creation, particularly around the underlying digital technologies. It is likely that a hybrid combination of pre-competitive and competitive work, and the creation of platforms based on design rules, may prevail (Srai et al., 2024). This is shaping future interdisciplinary and multi-domain programme development, offering opportunities for follow on work.

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APPENDIX I. Glossary of terms

i) Concepts and terminology used across the six observations and two propositions (in alphabetical order)

Concept/term	Definition	Link to observation and proposition; indicative source (if applicable)
Boundary spanning objects	**Boundary-spanning objects** refer to those artefacts, tools, and concepts that can facilitate communication, collaboration, and knowledge sharing both within and across domains. See investigator A and K example in online Appendix A4.	Links to **observation 4** and **propositions 1 and 2**; definition as per this study
Boundary spanning teams	**Boundary-spanning teams** are teams of investigators who actively work across different knowledge communities, both within and across domains, to share information, coordinate activities, and foster collaboration. See investigator A and K example in online Appendix A4.	Links to **observation 4** and **proposition 1 and 2**; definition informed by Parker and Anderson, (2002); Anderson et al., (2017)
Cross-domain dependencies	**Cross-domain dependencies** refer to interdependencies between domains, where actions, decisions, or developments in one domain (e.g., product design) may directly affect or rely on processes and developments in another domain (e.g., supply chain design). See Figure 5.	Links to **observation 5** and **proposition 2**; definition informed by Postrel (2002)
Domain specialization	**'Domain specialization'** refers to the body of specialized knowledge generated by knowledge communities which contribute to the formulation of design rules within a specific domain. In this study, domain specializations span (1) new synthesis capabilities; (2) modular production scaling options, and (3) adaptive supply chain configurations.	Links to **observations 1-3** and **proposition 1**; definition as per this study (see section 7)
Knowledge community	A '**knowledge community**' refers to an ecosystem of partners, which constitute 'a problem solving sub-network' of multiple stakeholders (e.g., academia, first-tier companies, regulatory bodies, and technology specialists) within a knowledge domain.	Links to **observations 1-6** and **propositions 1 and 2**; definition as per this study
Knowledge domain and **domain-specific teams**	A '**knowledge domain'** refers to a specific area of knowledge, activity, or expertise within a broader consortia network. In this study, there are three knowledge domains where **domain-specific teams** are focused on product, production, or supply chain design, respectively, within the broader consortia network.	Links to **observations 1-3** and **proposition 1**; definition as per this study (informed by Postrel, 2002)
Parameter window	A **'parameter window'** refers to the range of values or conditions for specific process parameters or inputs within which a product consistently meets its Critical Quality Attributes (CQAs) and desired quality standards. Parameter windows act as guidelines or boundaries for ensuring the reliability and reproducibility of pharmaceutical products or processes within the 'Quality-by-Design' framework.	Links to **observation 2** and **proposition 1**; definition as per this study (informed by ICH Q8 (R2), in, Yu et al., 2014)
Set-based design rule	A '**set-based design rule**' refers to multiple design alternatives that can be explored concurrently within a defined parameter window to allow for a set of feasible and more flexible solutions. In this study, set-based design rules can refer to both within-domain design rules that are emerging in the early stages of R&D development, and trans-specialized design rules.	Links to **observation 2** and **propositions 1 and 2**; definition informed by Ward et al., (1995)
Specialized knowledge	'**Specialized knowledge**' refers to in-depth, expert understanding or information that is focused on a specific field, subject, or discipline. In this study, investigators (researchers formally named on a consortia grant) use their specialized knowledge to perform tasks, solve problems, and make informed decisions relating to their specialisms.	Links to **observations 1-3** and **proposition 1**; definition as per this study
Trade-offs and convergence	**'Trade-offs'** refer to situations where achieving one goal or outcome may require compromises in (for example) a product or process design; **'Convergence'** refers to the process where multiple options, ideas, or solutions gradually come together toward a single outcome, decision, or solution (e.g., through set-based design rules).	Links to **observations 5 and 6** and **proposition 2**; definition informed by Ulrich and Eppinger (2015).
Trans-specialized design rules	The application of design rules in downstream domains can require significant adaptations primarily on account of design rule changes upstream, and vice versa. We refer to such adaptations as **'Trans-specialized design rules'**. These design rules enable boundary spanners to carry their specialist knowledge across domains to pose the latest problems and solve them.	Links to **observations 5 and 6** and **proposition 2**; definition informed by Carlile (2014)
Trans-specialized knowledge	'**Trans-specialized knowledge**' refers to in-depth, expert understanding or information that traverses a number of fields, subjects, or disciplines (e.g., new synthesis capabilities informing adaptive supply chain configurations, and vice-versa). In this study, trans-specialized knowledge has emerged through boundary-spanning teams and objects.	Links to **observation 4** and **proposition 2**; definition as per this study

ii) Study-specific terminology (in alphabetical order)

Concept/term	Definition	Indicative source (where applicable)
Pre-competitive collaboration network	A **'pre-competitive collaboration network'** refers to a consortium of organizations, typically within the same industry, who come together to collaborate on early-stage R&D projects not directly related to competitive advantage. These consortia focus on solving common challenges, sharing knowledge, and developing technologies or standards that can benefit all partners without impacting their ability to compete in the marketplace. In this study, the UK regulator is central to consortia developments.	Definition as per this study
Three-dimensional (3D) domains of development	'**Three-dimensional (3D) domains of development**' refer to a framework of product development involving the co-evolution of product, process, and supply chain design (i.e., **three design domains** as in Figure 1). The model emphasizes that these three dimensions—product architecture, process architecture, and supply chain architecture—evolve together and should be aligned for successful development and competitive advantage.	Definition informed by Fine (1999)
Mirroring and **Partial Mirroring**	'**Mirroring**' refers to the concept that organizational structures often reflect the technical or product architecture they are designed to develop. In a fully mirrored setup, each subsystem in the product is managed by a distinct organizational unit, leading to a one-to-one correspondence between the organizational structure and the product's technical structure. The concept of '**partial mirroring**' refers to when the organizational structure only partially reflects the product architecture (e.g., in consortia settings). This can happen when multiple subsystems are managed by the same team or when a single subsystem is divided up among multiple teams. In such cases, there is not a strict alignment between the product architecture and the organization, often due to the need for more collaboration across subsystems or to leverage cross-functional expertise.	Definitions informed by Colfer and Baldwin (2016)
Relational data	'**Relational data**' in the context of this study refers to data involving people and organizations. Relational data can be used to represent relationships and interactions involving people (investigators) and nodes (organizations) within a structured framework (such as an adjacency matrix).	Definition as per this study
Stage	A **'stage'** has a temporal connotation within this study. The entire study is focused on pre-competitive consortia between 2011-2021 where there are 'stages' of activity (i.e., ReMedIES programme stage from 2014-2018).	See also online Appendix A2 Part I.
Undirected binary adjacency matrix	An '**adjacency matrix**' is a square matrix used to represent relational data in graph form, where rows and columns can correspond to nodes (e.g., organizations), and the entries indicate whether a direct connection (or relationship) exists between nodes. An adjacency matrix shows how different organizations interact or influence one another, with non-zero values indicating a connection.	Definition informed by Bellamy et al., (2014)
Domain network	A '**domain network**' refers to a network depicting organizations and their relationships within a specific domain (e.g., graphical representations of a product, production, or supply chain domain network in social network analysis). A **domain network** can be organized using adjacency matrices, where organizations are visualized as nodes in the network, and relationships (influences or interactions) are shown as edges connecting the nodes.	Definition as per this study
Dissimilar networks	**'Dissimilar networks'** are networks that not only have different architectures (or internal structures) but also operate within fundamentally different areas of knowledge, meaning their purpose, data, and insights may not be seen to be easily interchangeable or comparable. An inspection of adjacency matrices can provide visual confirmation that networks may exhibit different structures (cf. Piccolo et al., 2022).	Definition informed by Piccolo et al., (2022)
Multi-Domain Matrix	A '**Multi-Domain Matrix**' is a tool used to model and analyze complex interdependencies between different 'domains' within a system. In our study, we refer to domains in this instance as (1) inter-organizational networks, (2) knowledge communities, (3) investigator social networks, and (4) design rules. The **Multi-Domain Matrix** extends the concept of a Dependency Structure Matrix, which focuses on interactions within a single domain, by enabling the mapping of interactions across multiple domains. This allows for a more comprehensive understanding of how changes or decisions in one domain might affect other domains.	Definition informed by Eppinger and Browning (2012)