Inter-organizational relationships in temporary organizations

Interactions in an R&D consortium

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Abstract

This paper presents our preliminary findings of an investigation of how *temporality*, manifested in the time-bounded nature of a large inter-organizational project, relates with *inter-organizational interactions*. We rely on theoretical concepts from the IMP (Industrial Marketing and Purchasing) perspective, project management and temporary organizations. We apply such concepts to a single case study featuring a complex inter-organizational project called ENABLE, which started in 2014 with the aim to support the development of new antibiotics. We find that entrainment-based pacing has a more prominent role as a temporal marker in this project, compared to event-based and chronological pacing. Moreover, we find no evidence that temporality hinders inter-organizational interactions or specifically weakens activity links, actor bonds and resource ties, except possibly for ties involving the resource type products.

1 Introduction

The importance of long-term relationships is well grounded in industrial marketing and purchasing (IMP) research (Håkansson, 1982; Håkansson & Snehota, 1989). For instance established relationships have been shown to be a major source and support of innovation for buyers and sellers (Håkansson, 1987; Håkansson & Waluszewski, 2002a; Holmen et al., 2005; Johnsen & Ford, 2007; Håkansson et al. 2009). For the development of business relationships, time plays a central part in the IMP literature (Medlin, 2012). In particular, activities evolve over time in a process of specialization (Dubois, 1994; Baraldi et al. 2014), the development of resources is often path dependent (Håkansson & Waluszewski, 2002b), and the evolution of each actor is a multidimensional co-evolution that takes place within two or more actors in parallel (Håkansson et al., 2009).

However, it has been argued that the IMP literature would benefit from a "deeper treatment of time and space" (Halinen et al. 2012). Adopting a time perspective on interaction in business relationships, Medlin (2004) discusses that a sense of time is used to give meaning to business interactions (ibid.). In particular, an actor's attitude towards interaction is influenced by the perceived importance of the counterpart in the future (Håkansson et al. 2009), which means that without a perceived future there is no need to interact (Medlin 2004).

Despite the importance of continuity and of a perceived future together to support relationships and hence innovation, innovation efforts are increasingly coordinated in temporary inter-organizational projects (Jones & Lichtenstein 2008), and new organizational forms are often temporary (Malone & Laubacher 1998). The emergence, importance and prevalence of relationships in temporary organizations, such as projects, depend on the duration of the project (Jones & Lichtenstein 2008; Saunders & Ahuja 2006). Saunders and Ahuja (2006) argue that temporary virtual teams are more focused on short-term project-specific tasks than on building relationships, compared to continuous inter-organizational virtual teams. At the very least, these authors recognize that the relationships involving long-term virtual teams are more complex than in short-term teams.

The importance of the time scale clearly emerges also from Sydow et al. (2004), who propose that "long-term" projects with duration of 10-15 years should develop knowledge and learning processes similar to permanent organizations. However, there is no agreement in the literature as to the time boundaries between the short-term and the long-term. Sydow et al. (2004) talk about short-term projects of one to two years, while Saunders and Ahuja (2006) mentions short-term projects of four to five weeks. But even more important than the formal duration of the temporary organization is that the view of time is different in temporary organizations compared to on-going organizations (Bakker 2010). Time in organizations is often thought of as either linear or cyclical (Burrell 1992). In temporary organizations, time is perceived as "a linear foreseeable sequence" (Lundin & Söderholm 1995, p.440), whereby the organization has a beginning, a middle point and an end. This linearity makes time predictable and easier to plan compared to on-going organizations where time is often viewed as cyclical, or as a spiral (Burrell 1992). At last, the most important demarcation between temporary and on-going organizations when it comes to time is that, in temporary organizations, time is limited, i.e., there is a point in the future when the temporary organization is decided a priori to cease to exist.

Linking to these issues surfacing in the project and temporary organization literature, there is a need also in the IMP literature to better understand business interactions and networks as processes occurring within a specific timeframe (Halinen et al. 2012). A more sophisticated conceptualization of time helps us to better understand business processes including B2B interactions; whereas process research deals with how events "come in to being and unfold over time" (ibid, p. 215). Time can be seen as the life of process (Hernes 2014), and represents, together with temporality, a "conundrum" in social science (ibid. p. 31). Halinen et al.'s (2012) article is an introduction to a special issue focusing on time and process in business networks. It mentions several different concepts of time (event-time, clock-time, human time etc.), and talks about temporality and the "temporal", stressing that inter-organizational interaction processes are situated in time.

However, the notion of temporality as a limitation or constraint imposed by time on inter-organizational interactions is not elaborated on in the IMP literature. And also looking more broadly at the management literature, one of the most underdeveloped area under the time theme in the field of temporary organizations is the effects of temporariness (Bakker 2010), i.e. the impact on organizing and organizations caused by the fact that time is limited. As mentioned above, the actual duration of projects influences the emergence, importance and prevalence of relationships occurring within temporary organizations. Moreover, the increased use of temporary organizations, especially for managing innovation (Jones & Lichtenstein 2008), should influence the networks that embed the temporary organization as well as the participating organizations on several dimensions, namely their activity links, resource ties and actor bonds (Håkansson & Snehota, 1995).

Against this background, the aim of this paper is to understand how inter-organizational interactions, including the formation and development of business relationships, relates to temporality, that is, the imposition of a time limit for such interactions which occurs during a project. More specifically, the paper investigates how relationships are formed, maintained and possibly terminated, by focussing on a focal relationship within an inter-organizational project called ENABLE. ENABLE is tasked with conducting early development of new antibiotics, with the goal to make at least one molecule go through clinical phase 1 trials[1],[2]. The project includes over 40 collaborating partners, and adopts a "failing fast and cheap" strategy. In other words, if a program is not likely to be successful (the likelihood of deliver a new medicine), then the development should be stopped sooner than later. Funding can then be applied to programs more likely to deliver new medicines. Following this principle, funding for a given program can be stopped by a funding committee (PMC, see below) decision, generally made every third month. The project started in 2014 and is planned to span 6 years. This paper is organized as follows. First, we introduce theoretical concepts about business relationships and temporary organizations, which we merge then into our analytical frame. After describing our method, we present the case of ENABLE, on which we subsequently apply our analytical frame to reach our conclusions.

[1] http://nd4bb-enable.eu/

[2] https://www.imi.europa.eu/projects-results/project-factsheets/enable

2 Business relationships

A relationship can be defined as a "mutually oriented interaction between two reciprocally committed parties" (Håkansson & Snehota 1995, p.25). Business relationships have been viewed as "quasi-organizations" (Blois 1972), with the logic that the whole is greater than the sum of its parts. Business relationships have been studied extensively within the IMP perspective, covering many different topics (Ford et al., 2003; Ford & Håkansson, 2006) ranging from purchasing (Araujo et al. 1999; Gadde & Snehota, 2000), to product development (Holmen et al., 2005) and to strategy development (Gadde et al. 2003).

The IMP view stresses that "interaction is the essential analytical concept at the heart of the relationship and network perspective of business markets" (Medlin 2004, p.185), and consist of two elements: the dynamics of exchange and adaptation (Johanson & Mattsson 1987). Analyzing business relationships thus means analyzing business interaction. The Activity-Resource-Actor (ARA) model was developed to analyze business interaction by focusing on activity links, resource ties and actor bonds (Håkansson & Snehota 1995). However, not all business interactions lead to the creation of business relationships. As seen in the definition of a relationship above, mutual orientation and commitment is needed. Further, adaptations leading to interdependencies between actors (Hallén et al., 1991; Brennan & Turnbull, 1999) are an important condition and consequence of business relationships, as well as trust (Andersen & Kumar, 2006).

Considering the dynamics of exchange – one of the elements mentioned above – relationships are formed and maintained through episodes of interaction between the actors. Time is a central concept for business interaction in the IMP view (Håkansson et al. 2009), which especially stresses the long-term nature of business relationships as emerging from continuous interactions (Håkansson & Snehota, 1995). Relationships are created over time because it takes time for the parties to learn to know each other and achieve the mutual orientation, trust and commitment which are necessary to develop and reinforce a business relationship (Ibid). This often leads to adaptions (Hallén et al., 1991), the second element of business relationships mentioned above.

Adaptations, mutual orientations as well as interdependencies are in turn visible across the three layers of the ARA model. Activity links emerge when two organizations change their activities, such as manufacturing or testing, to make them fit better into each other or more coordinated, typically in search of improved efficiency (Dubois, 1994; Håkansson & Snehota, 1995). Resource ties emerge when two organizations combine their resources, such as products, machinery and competences, in unique ways to make them better address the specific needs of one or both parties (Ibid; Baraldi & Strömsten, 2008; Baraldi et al., 2012). Finally, actor bonds concern the mutual orientation and understanding, including shared perceptions and goals, that connect either single individuals or subunits in the two organizations (Håkansson & Snehota, 1995; Munkgsgaard, 2010),

3 Temporary organizations

Projects, in the sense of a unique undertaking with a limited time and scope, have existed for millennia (Packendorff 1995). However, the scholarly interest in temporary

organizations emerged quite recently (see Bakker 2010, p.468). In an initial attempt to outline a theory of the temporary organization, Lundin and Söderholm (1995) introduced four basic concepts that would let us differentiate a temporary organization from its context and other types of organizations. These four concepts are (1) time, (2) task, (3) team and (4) transition. Time is fundamental in understanding temporary organizations. Even if there is no single definition of a temporary organization, there seems to be agreement that some kind of limitation in time is needed for temporary organizations. This is often an ex ante defined limited time period in which interactions are to occur.

However, there can also be other ex ante defined criteria defining a temporal organization, e.g. the completion of a specific task. The task is what legitimizes the temporary organization (Lundin & Söderholm 1995). Organizational tasks can be divided into two types: unique and repetitive. Temporary organizations are created to deal with unique tasks, while permanent organizations are better suited for the repetitive one (ibid). However, the duration of the temporary organization seems to influence the degree to which participants focus on tasks (Jones & Lichtenstein 2008; Saunders & Ahuja 2006; Sydow et al. 2004).

Temporary organizations consist of individuals and are thus also dependent on the team(s) holding them together. Members are often chosen based on their skills and should complement each other in order to deal with the task at hand. The transition concept is included in Lundin and Söderholms (1995) theory of temporary organizations to highlight their progression and accomplishment. The theory has an action approach, which implies that something has to be transformed or changed "as a consequence of the existence of the temporary organization" (ibid, p. 442). The idea of transition, or change, is particularly important for temporary organizations, as accomplishing a specific, well-defined task is what legitimizes the creation of the temporary organization.

3.1 Relationships in temporary organizations

Palisi (1970) asks whether "there are differences in the types of social behavior found in transitory versus permanent groups" (p. 202). Bakker (2010) argues that the duration of a temporary organization probably affects trust and social relations among project participants.

The literature provides conflicting views about relational processes and the importance of relationships in temporary organizations. Looking at if leaders in temporary organizations are relationship-oriented or task-oriented, Bryman et al. (1987) found that site managers in the construction industry (mean project length 24,7 months) seems to have stronger task emphasis compared to other leaders in other industries (see table 1 in Bryman et al. 1987). However, they also found that the more relationship-oriented project leaders were, the more effective they seemed to be. This correlation is stronger for project of longer duration, suggesting that temporary organizations of longer duration benefit more from relationship-focused leaders.

Arguing for an action oriented theory of the temporary organization, Lundin and Söderholm (1995) consider the relationship issue when they discuss the relation

between individuals and teams in temporary organizations. They argue that each individual carries their own expectations and experiences into the team, and, gathered together in the team, these expectations and experiences provide the basis for commitment, motivation, communication and leadership. Looking at learning in temporary systems, Grabher (2004) found relationship- and task-oriented focuses in teams in the software industry. The focus was relationship-oriented when the basis of the ties connecting project members was a common history, and task-oriented when the basis of the ties was common interest. Saunders and Ahuja (2006) argue that there are two main differences between continuous and temporary teams: members of continuous, stable teams anticipate future interactions, and are therefore concerned with the long-term efficiency of the interaction process. Temporary teams' members, on the other hand, are not concerned with long-term efficiency, as there is no anticipation of future interaction with the same group of people. This leads to a greater focus on finishing the task at hand.

Looking at coordination issues in the particular type of temporary organization focused in this paper, namely inter-organizational projects, Jones and Lichtenstein (2008) show how two different kinds of embeddedness enhance coordination and help the parties handle uncertainty, namely temporal and social embeddedness. Temporal embeddedness relates to time-oriented markers and managerial tools and entails in turn three different kinds of pacing: chronological pacing, based on the passage of time (such as deadlines and timelines); event-based pacing, based on milestones (corresponding to the completing of particular project tasks, see above); and entrainment-based pacing, whereby the activities of various actors are synchronized through calendar or environmental influences (such as Christmas, vacations etc.). Social embeddedness as a mechanism that supports project coordination entails two levels: relational and structural embeddedness (Ibid). Relational embeddedness focuses on the dyad, that is, two parties interacting within the project; while structural embeddedness focuses on the extent to which the various dyads in a project are connected to each other. These forms of embeddedness within a project recall clearly two of the functions of inter-organizational relationships, the dyadic and the network function, suggested within the IMP view by Håkansson and Snehota (1995, p. 27)

4 Theoretical and analytical framework

The previous section about temporary organizations identified a series of relevant features of projects, intended both as particular organizations which can connect other organizations (e.g., firms and universities) and as managerial tools to achieve particular goals. Summing up, these features include: starting from the very project leader (Bryman, 1987, a,b), there is a stronger focus on the specific tasks to be achieved (Bakker, 2010) than on the relationships among members (Grabhner 2004; Miles 1964; Saunders 2006); projects also display a reduced concern with the long-term efficiency of project-specific processes, including likely interaction processes (Ibid); temporality and time-related markers are essential tools for coordinating project activities. Whereas these features seem to obstruct inter-organizational relationships within projects, Jones and Lichtenstein (2008) stress that such relationships are instead themselves helpful for coordinating project activities and, we may add, for achieving a project's goal.

In order to investigate how the temporary nature of projects interplays with inter-organizational interactions, our framework departs from the IMP view that such

interactions between two counterparts can lead to changes and transform aspects of the resources and activities of the organizations involved (Håkansson et al. 2009). These interactions, if they are repeated over time and entail mutual adaptations, become a business relationship which can span over many years (ibid). However, these interactions happen also as discrete episodes, which can occur irregularly and can be far apart from each other, that is, they can give rise to so called "interimistic" relations (Lambe et al. 2000).

No matter how continuous or intermittent the interactions in an inter-organizational relationship are, within a project the rhythm of interaction is accelerated. Further, these interactions can happen between organizations that already have an on-going business relationship, as well as organizations that are completely new to each other. Especially in very large inter-organizational projects chances are high that parties are exposed to new actors. Being exposed to time pressures, members in large inter-organizational projects are likely to try to make the most out of the situation during the limited time available. As seen in the previous section, a short as opposed to a long duration of a project orients its members to focus more on task completion than relational processes.

Our analytical scheme will first extract from the ENABLE case specific manifestations of temporality, as expressed by various time-oriented markers focussing on the three types of pacing proposed by Jones and Lichtenstein (2008), namely *chronological*, *event-based* and *entrainment-based*. Then, these forms of temporality will be related to the nature of interactions in a key relationship and a few related others, with particular focus on the development and changes in their activity links, resource ties and actor bonds (Håkansson & Snehota, 1995).

5 A note on methodology

This study is part of an on-going research project for a PhD thesis. The aim of the larger research project is to expand current understanding in the fields of IMP and temporary organizations on how interaction is coordinated in large inter-organizational projects and how temporality influences these interactions, which is in line with this paper. As the phenomenon investigated is complex and previous knowledge of inter-organizational interactions within time-bound projects is limited, the method chosen is a single in-depth qualitative case study (Yin, 2014) of the ENABLE project. The empirical material has been collected mainly through interviews: between 2015 and 2018, a total of 44 semi-structured interviews have been conducted with ENABLE's project manager, members of its central steering teams, companies as well as academic laboratories participating in current activities. Almost all interviews have been transcribed and then analyzed by first writing comprehensive narratives, followed by a more systematic search for particular evidence of how interactions between selected project members unfolded and how particular manifestations of temporality and time pressures relate with the emergence and development of selected relationships inside ENABLE.

The interviews were complemented by documents produced in and for ENABLE by its members and initiators. This kind of data contributed to understanding the context, goals and rules affecting how specific interactions and processes unfolded within the project. In particular, some management tools and temporal pacing instruments were expressed into flowcharts and schemes that we could consult and subsequently ask

interviewees about. The use of different sources of data for this research was based on the argument of Dubois and Gadde (2002) and their *systematic combining* approach, according to which multiple sources of data contribute to the revelation of unknown and surprising aspects of a phenomenon, rather than checking the accuracy of the data (which is the triangulation argument used by Yin, 2014). Systematic combining is an iterative process where the empirical world, the framework of the research, theory and the case are developed together and in which each part directs and redirects the other parts (Dubois & Gadde 2002). Following this abductive or retroductive logic (Alvesson & Sköldberg 2000), the theoretical frame proposed above is accordingly more a result of this study, rather than an analytical frame created a priori and then simply applied to our case.

6 The study context – antibiotic drug development

Drugs under development often fail for one of two reasons: they do not work as good as expected, or they are not safe to use. In order to ensure that drugs are both safe and efficient, the drug development process is highly regulated. It is also, perhaps for the same reasons, a very complex process, which can take 12-15 years and may incur costs exceeding $1 billion (Hughes et al. 2011). This process has been refined, and now follows a somewhat generic path (see e.g. descriptions of drug development process by Nwaka & Ridley 2003; Payne et al. 2007; Paul et al. 2010; So et al. 2011). This R&D path is often divided in to different stages. On the most rudimental level drug development can be divided into three stages: (1) discovery, (2) development and (3) launch/commercialization (Blau et al. 2004). However, it is common to divide drug R&D into even more detailed stages:: (1) discovery, (2) pre-clinical development, (3) phase 1 clinical trials, (4) phase 2 clinical trials, (5) phase 3 clinical trials, (6) approval and (7) launch/commercialization (see eg. Okhravi et al. 2017).

Where to draw the line between discovery and development is not always clear (compare e.g. figure 1 in Nwaka & Ridley 2003 with figure 2 in Paul et al. 2010). However, usually drugs in development go through the following detailed stages once a target has been identified and validated (the target is what the drug will "attack" in order to kill or in any other way incapacitate, in the case of antibiotics, the bacteria causing the infection.): (1) high throughput screening (HTS) to hit (also called target-to-hit or hit identification), (2) hit-to-lead (also called lead identification), (3) lead optimization, (4) candidate selection and (5) pre-clinical development (Nwaka & Ridley 2003; Payne et al. 2007; Paul et al. 2010; So et al. 2011). The ENABLE project accepts drug development programs that are in the "hit to lead" stage or in the "lead to candidate" stage, and supports these programs until completion of phase 1 clinical trials.

When a target has been identified different screening strategies are used to find hit molecules. What a hit actually mean can differ between scientists, but is defined by Hughes et al. (2011, p.1242) as "being a compound which has the desired activity in a compound screen and whose activity is confirmed upon retesting". During the hit-to-lead and lead-to-candidate stages analogues of the hit, molecule(s) are prepared and tested in different assays. Analysis of the results allows the design of the next-generation analogues that are in turn prepared and tested, in an iterative process. This is also called lead optimization and the aim is to find the most promising molecule(s) to enter clinical phase 1 testing. An assay is an experimental setting that allows assessment or measurement of biological activities or other properties of the molecule(s). Flowcharts

that show planned assays are often used in drug development. Figure 5 shows a generic flowchart suggested to be used in ENABLE programs. Each drug development program also has more specific assays done depending on the program and on the molecule(s) it works with.

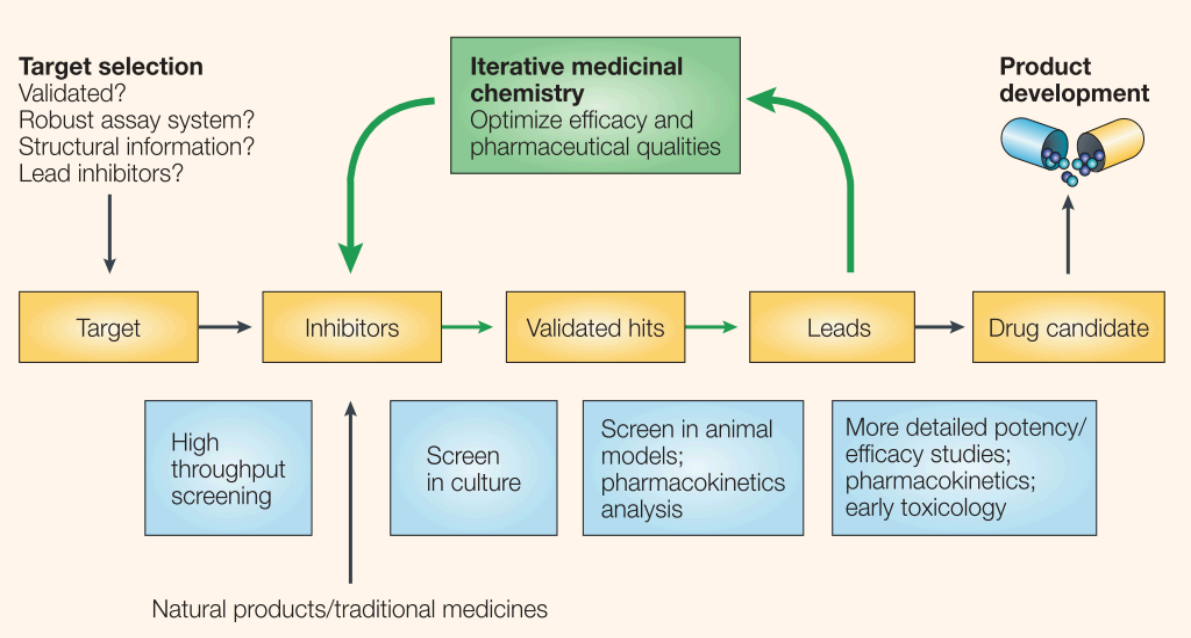

Figure 1: Overview of the iterative drug discovery process. Source: Nwaka and Ridley (2003, p.923)

7 The case of ENABLE

ENABLE is one of several projects included in the New Drugs 4 Bad Bugs[3] (ND4BB) program. ND4BB was initiated after a EU action plan on antimicrobial resistance[4] (AMR) was published in 2011. The ND4BB program consists of 7 projects[5] that focus on addressing the scientific, regulatory and business challenges that are obstructing the development of new antibiotics and was initiated by IMI (Innovative Medicine Initiative), a partnership between the European Commission (EC) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). In the IMI model EFPIA partners, SMEs and academics come together to address each project's objectives collaboratively.

The pharmaceutical company GlaxoSmithKline (GSK) was the lead EFPIA partner in the creation of ENABLE. They established collaboration with another large pharmaceutical company, Sanofi, with the objective to build under the IMI umbrella a public-private consortium aiming at developing new antibiotics active against the severe hospital

[3] http://www.imi.europa.eu/content/nd4bb

[4] https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

[5] http://www.imi.europa.eu/sites/default/files/uploads/documents/projects/ND4BBoverview.pdf

infections caused by Gram-negative bacteria[6]. In addition, Basilea and AstraZeneca were part of the EFPIA consortium. The EFPIA consortium jointly wrote a call that was launched by IMI in December 2012[7] looking for the recruitment of two consortia to join with the EFPIA consortium to form the full project. One consortium was to be a drug discovery and development platform, where scientist and experts in drug development would create a fully functional drug development unit. This unit should be able to help progress several drug development programs in both hit-to-lead and lead-to-candidate stages in parallel until phase 1 of clinical trials. The second consortium was to include academics and SMEs who had hit-to-lead (or later stage) programs that could be developed in collaboration and with the support of the drug discovery hub, the first consortium.

The rationale for the call was that "one of the major challenges in antibiotic discovery is not the identification of new targets, but the generation and optimization of novel molecular starting points (Hits and Leads) with a novel mode of action" (European Union 2012, p. 28). Optimization of a Lead is a highly collaborative and iterative process, but historically academics, SMEs and industry partners have competed with each other instead of collaborating. The call for ENABLE was aimed to "break down these barriers" (European Union 2012, p.29), which would be done by establishing a vibrant drug discovery hub across Europe with the resources, skills and expertise to generate a pipeline of 'Leads' and 'Development Candidates' originating from private or public partners targeting the systemic treatment of infections due to resistant Gram-negative bacterial pathogens.

The two consortia that were selected by IMI from this call were then merged with the EFPIA consortium and together they created the ENABLE project in the end of 2013. At this time ENABLE consisted of 32 different organizational partners, including EFPIA partners, universities, SMEs, non-profit research centers and CROs (see table 1 for a list of the 32 partners). ENABLE started in February 2014, with a timeframe planned to span 6 years, until 2020. The overarching goals of the ENABLE project are to (1) create a drug discovery platform with the expertise and resource base to conduct multiple antibacterial programs in parallel; and (2) increase the overall pipeline in the antibacterial area by applying this platform to optimize a variety of antibacterial programs. More specifically, reflecting the various R&D stages reviewed above, the objective of the consortium is to identify (A) three antibacterial leads, (B) two antibacterial candidates and (C) bring at least one compound into preclinical and Phase 1 clinical studies, all of which should have the potential to treat serious systemic resistant Gram-negative infections.

As in all IMI projects, a project agreement was signed by all ENABLE members that governs the members' collaboration in relation to ENABLE. New members can join ENABLE continuously and in February 2018 ENABLE had 44 different member organizations.

[6] Bacteria can be divided into Gram-positive and Gram-negative, with the latter type being generally more difficult to kill by antibiotics because they have two difficult-to-penetrate successive membranes that limit influx and multiple "pumps" which are capable of effluxing out substances meant to kill them.

[7] https://www.imi.europa.eu/apply-funding/closed-calls/imi1-call-8

Table 1: List of original ENABLE members and role at project start

Participant name	HUB	Hit-owner
Agencia Estatal Consejo Superior de Investigacione Cientificas (CSIC)		X
Asclepia	X	
Aston University (Aston)	X	
AstraZeneca AB (AstraZeneca)	X	
Basilea	X	
Beactica AB (Beactica)	X	
Biomol-Informatics (BIOMOL)	X	
Cardiff University (CU)	X	
European Biotechnology Network (EBN)	X	
Fundación Medina (MEDINA)		X
GlaxoSmithKline (GSK)	X	X
Inspiralis Ltd	X	
John Innes Centre (JIC)	X	
KeytoLead AB (K2L)	X	
Latvian Institute of Organic Synthesis (LIOS)	X	
Molecular Discovery Ltd (MD)	X	
MPS Hamburg GmbH (bankrupt before project started)	X	
National Medicines Institute (NMI)	X	
Northern Antibiotics (NAB)		X
OT Chemistry (OT)	X	
Redx Pharma (REDX)		X
Region Hovedstaden (REGH)	X	
Sanofi-Aventis Recherche & Développment (SARD)	X	X
Servicio Madrileno De Salud (SERMAS)	X	
SP Process Development (SP) (Have changed name to RISE)	X	
University of Barcelona (UB)		X
University of Copenhagen (UCPH)	X	X
University of Helsinki (UH)	X	
University of Liège (Ulg)	X	
University of Oxford (UOXF)		X
Uppsala University (UU)	X	
VU University Amsterdam (VUA)	X	

7.1 ENABLE's organization

ENABLE's organization can be divided in to three broad parts (see Figure 2 below): (1) the management organization, (2) the drug discovery hub and (3) the owners of the hits/leads. ENABLE's management consists of a General Assembly (GA) made up of a representative of each partner, a Consortium Management Office (CMO), responsible for the day-to-day running of the project, and a Portfolio Management Committee (PMC), responsible for funding decisions for the ENABLE portfolio. The drug discovery hub is divided into different platform representing the different skills and expertise needed in drug discovery. These are for instance chemistry, modeling, microbiology, in vivo

pharmacology and pharmaceutical development. Overall, there are currently six different platforms in the project. Each platform can include several organizations and partners in ENABLE.

The portfolio of ENABLE consists of programs created around compounds brought to the Consortium by the so-called "hit-owners". Mostly companies, but also occasionally some academic labs. Due to the scientific challenges inherent to antibacterial drug development, resulting with most compounds failing at various stages, this portfolio has to be continuously fueled and updated. This is done in an open call process where both current and potentially new partners can submit their program to be included into ENABLE's portfolio[8]. In addition, the PMC can choose to terminate the IMI funding of programs that for different reasons are not progressing in a satisfactory manner in terms of speed, probability of success or quality of the science.

Similar to other IMI projects, the responsibility for ENABLE's overall scientific progress is on the Project Coordinator (PC). This role is held by GSK, while Sanofi holds the role of Project Co-coordinator (PCC). The PCC's responsibility is to deputize and support the PC. Collaborating closely with the PC, there is the Leader of the Managing Entity (LME), a person from Uppsala University, the organization that plays the role of "managing entity". The managing entity is amongst other things responsible for the distribution of all financial resources from IMI to all project members.

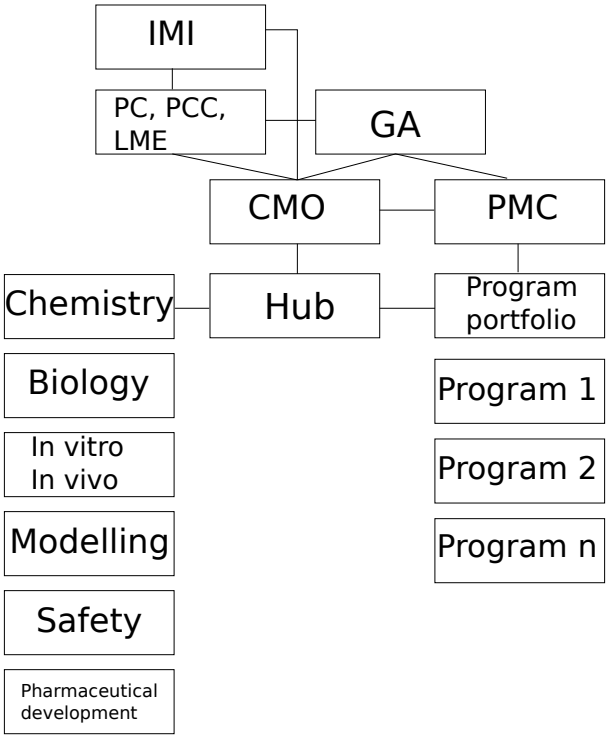

Figure 2: Organizational overview of ENABLE project

7.2 ENABLE's processes

ENABLE's development and evaluation activities revolve around a roughly three-month cycle. Every third month (except in 2018 when it will be every fourth month) each

[8] http://nd4bb-enable.eu/open-calls-1-1

program in the ENABLE portfolio is evaluated by the PMC. Based on this evaluation the program will either (1) continue to be supported within ENABLE or (2) be terminated. If terminated, the program will no longer receive IMI funding, but the corresponding hit-owner organization may remain a member of ENABLE. In practice most hit-owners affected by this decision have stopped their active involvement in ENABLE, although the majority remain project partners.

The PMC has three responsibilities. First, they evaluate new expressions of interest and accept or deny funding of the corresponding program with the ENABLE portfolio.

Second, deciding on the continuation or termination of IMI funding of active programs. Third, the PMC decides key program transitions, such as lead nomination or candidate selection. In the PMC meeting, each hit-owner's program leader (see below for more details about program leaders) presents their progress of their program since the last PMC meeting, relative to objectives set in previous meetings. The PMC requests that the program proposes plans for the next quarter and objectives that should be met within the following year. After the presentation and a round of questions-answers, the PMC takes their decision in a closed session without program leaders present. This is to allow discussion of the portfolio as a whole, as ENABLE only has fixed amount of resources that can be applied to the portfolio.

Each program is led by two program leaders (PLs), who interact with several teams attached to the program, such as the specialized groups from the six platforms shown on figure 2. One of the program leaders comes from the hit-owner organization and one from an organization belonging to the drug discovery hub (typically a public or private specialized lab). However, GSK and Sanofi are running a joint program, which has no PL from the drug discovery hub, instead the two PLs are from GSK and from Sanofi. There are different teams around each program. First, there is a *core team* consisting of around 5 – 15 people, both from the hit-owner organization and the drug discovery hub. Then there is a *program team*, which is a fluid group expanding the core team to include also a wide range of experts from the whole consortium. This group is often the largest of the teams, but as the level of engagement of any specific group or member is fluid it is hard to say how many there actually are in this group for a program at any one time. It depends on the agenda for the program team meetings at each time. In addition to these two teams there are teams formed around different platforms, such as chemistry or microbiology teams. This depends on which stage the program is currently in. The core teams generally meet in webinars one to two times each month. The program teams meet in a webinar generally once a month, and the additional teams (chemistry, microbiology) often meet following the core and program team meetings.

7.3 Inter-organizational interactions involving GSK and Sanofi

In 2012 GSK approached Sanofi with a proposition to build a consortium within the ND4BB initiative that eventually led to the ENABLE project. It was seen as a great opportunity by both partners to work with another big pharma company in an enriching way. This was viewed as a new way of conducting antibiotic development, and was seen almost as an experiment (interview with GSK employee). The goal envisioned by GSK and Sanofi was two-fold: to find new antibiotics against Gram-negative bacteria and to establish a new semi-open innovation concept in the antibacterial space.

In the views of the two companies this potential consortium was also a way to establish a stronger network of academics by establishing new links to several academic institutions in the field. GSK and Sanofi signed an initial collaboration agreement in the end of 2012. This was done as a pre-requisite for the aforementioned call from IMI. The rationale was that there was a need to have a robust contract regulating the collaboration between GSK and Sanofi in place before the wider consortium was created. GSK and Sanofi, in addition to the other EFPIA partners Basilea and AstraZeneca, were both involved in writing the call and providing feedback to IMI on the different application consortia. Independent experts nominated by IMI then selected the winning consortia. The call for ENABLE came out in December 2012, and the winning consortia were selected in 2013. A project agreement that governs the ENABLE partners' collaboration was signed in January 2014 by 32 partners (see table 1). ENABLE officially started in February 2014.

GSK and Sanofi interact with each other and the wider consortium on several levels in ENABLE. As mentioned above, GSK has the role of project coordinator and Sanofi of project co-coordinator. This means that they have the scientific responsibility for ENABLE. They also have several positions in two of the most influential management bodies, the Consortium Management Office (CMO) and the Portfolio Management Committee (PMC) where they both hold one voting seat, similar to the other EFPIA partners and in addition to public partners and independent experts. GSK and Sanofi are also part of ENABLE as a single hit-owner, running joint R&D programs in collaboration with a part of the discovery hub partners. Of note, Sanofi and GSK do not take part in the PMC discussion and votes regarding their common program.

More precisely, when ENABLE started GSK and Sanofi entered the project with a first program at lead stage. Figure 3 shows the key actors and organizations involved in this program. However, this program was terminated at the March 2015 PMC. The decision to terminate the program was proposed by the program team to the PMC. This decision had been agreed upon between GSK and Sanofi at a joint steering committee (JSC) meeting in early March 2015. The joint steering committee (JSC) is a non-ENABLE committee which is the governance body of the GSK-Sanofi collaboration, and consists of equal representation from both organizations.

The key ENABLE partners in the GSK-Sanofi program that helped progress the program are the following. LIOS, a state research institute, provided their chemistry competences and resources. They prepared new analogues of the lead compound. A drug analogue is a molecule that shares chemical and therapeutical similarities with the original molecule. JIC, a specialized research center in the UK, contributed with in vitro activities and studying mechanisms of action, which is the way the antibiotic act on its molecular target. At Uppsala University they did microbiology studies, measuring frequency of resistance as well as checking for cross-resistance. SSI (Statens Serum Institut, third party member of Region Hovedstaden, REGH) ran in vivo pharmacology, testing tolerability and efficacy. OT Chemistry, another SME specialized in chemistry, handles all logistics in ENABLE in respect to compound handling. When a new analogue has been prepared at LIOS it is sent to OT that is then responsible for distribution among the various actors that will test the molecule. Compounds created at either GSK or Sanofi were instead screened at their own facilities, and handled by their logistics internally in order to save time and conserve ENABLE resources.

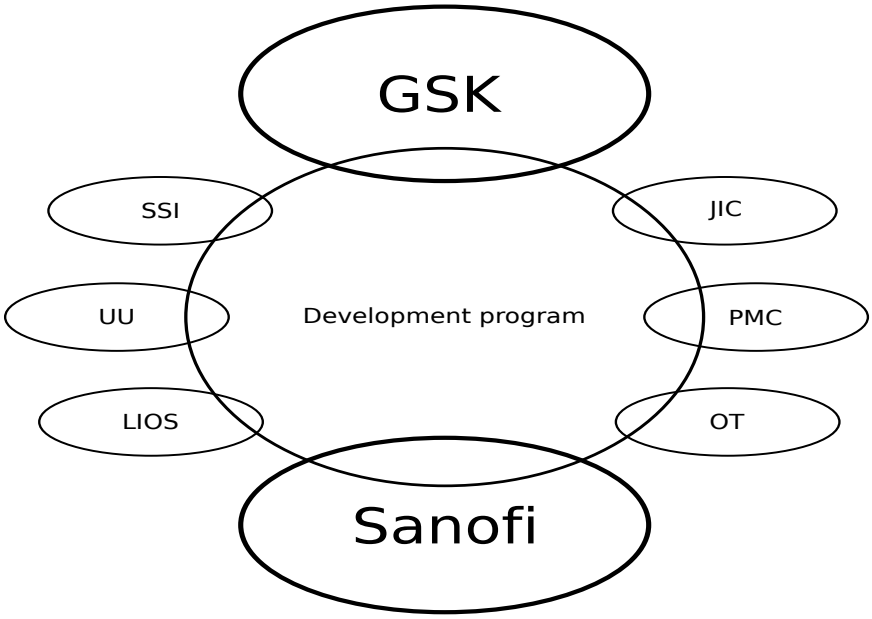

Figure 3: Key actors in the first GSK-Sanofi program.

When this first GSK-Sanofi program was terminated in March 2015, ideas about a second program were discussed between GSK and Sanofi. The persons that led these discussions were the same that then held the PC and PCC positions in ENABLE. They had also been the program leaders (PL) in the first program. The proposal to the PMC, a so-called "two-arm" program, was agreed on at a JSC meeting in September 2015. The concept was that GSK and Sanofi would initially explore and develop two different and complementary scientific strategies, one at GSK and one at Sanofi. The idea was to later concentrate on the most fruitful approach. The "dual" program was proposed to the ENABLE PMC and accepted for funding by the PMC in December 2015.

The program also entered ENABLE in the lead-to-candidate stage. The next major milestone the program can achieve is the selection of a candidate molecule, which had not been done as of April 2018. However, the program has gone through three major events within the ENABLE project. One of the approaches pursued showed some proof of concept in vitro in the second half of 2016 and then in vivo in 2017. Efforts around the other approach were discontinued in December 2017. The decision to discontinue was made based on *a priori* go/no-go criterion. The two-arm program then became one single joint effort. Figure 4 shows the key actors beside GSK and Sanofi in the second program.

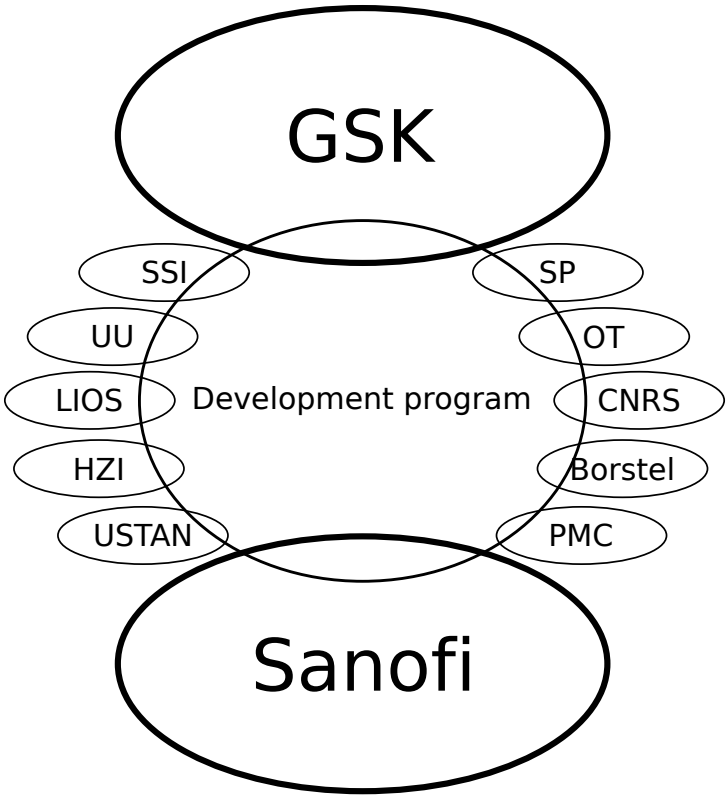

Figure 4: Key actors in the second GSK-Sanofi program

Compared to the first program one actor, JIC, is no longer involved in the second program because that group's expertise was no longer relevant in the new program. LIOS' responsibility is the same in the second program, that is, making compounds to be tested by some of the other actors. When compounds are shipped from LIOS to some of the other actors, OT handles the logistics, as it did in the first program. And SSI still does in vivo testing. Uppsala University (UU) plays a larger role compared to the first program. In addition to microbiology UU performs DMPK (drug metabolism and pharmacokinetics) studies, which aims to understand how the drug gets into and is processed in the body. UU also performs molecular modeling. New actors joining the program are SP, part of a network of Swedish public research institutes, as well as four academic partners (University of St Andrews -USTAN-, Helmholtz–Zentrum Fuer Infektionsforchung -HZI-, Research Center Borstel -Borstel- and CNRS at Strasbourg) that were recruited, following an open call, for their specific expertise able to support the new program. SP is tasked with the scale-up of molecules to support the chemists in the program.

7.4 Managerial tools for pacing the interactions involving GSK and Sanofi

When planning the scientific work in all ENABLE programs flowcharts are used. A flowchart lists all of the experiments/assays that are needed to progress a compound to the next stage (lead or candidate) and acts as a guide to the program team in the organization and profiling of molecules. Figure 5 shows a conceptual flowchart. There are several decision points along the way where compounds can be either progressed further or terminated.

As mentioned earlier, this is a very iterative process, that is, the same steps need to be repeated several times for modifications (small or large) of an original molecule. Several

compounds are tested in parallel and each compound can be tested in all of the assays in one tier at the same time. Negative data in one or several of the assays can lead to termination of that compound. Those compounds that have good characteristics (according to a pre-defined criteria) in all the assays will progress to the next tier. Those that have good characteristics in some of the assays can be resynthesized in order to have sufficient material to run the next-tier assays. This is a process where chemists try to get rid of the negative characteristics of the hit/lead compound while still keeping the positive characteristics. This is done until one or several compounds move successfully through all the tiers and a lead or a drug candidate is chosen.

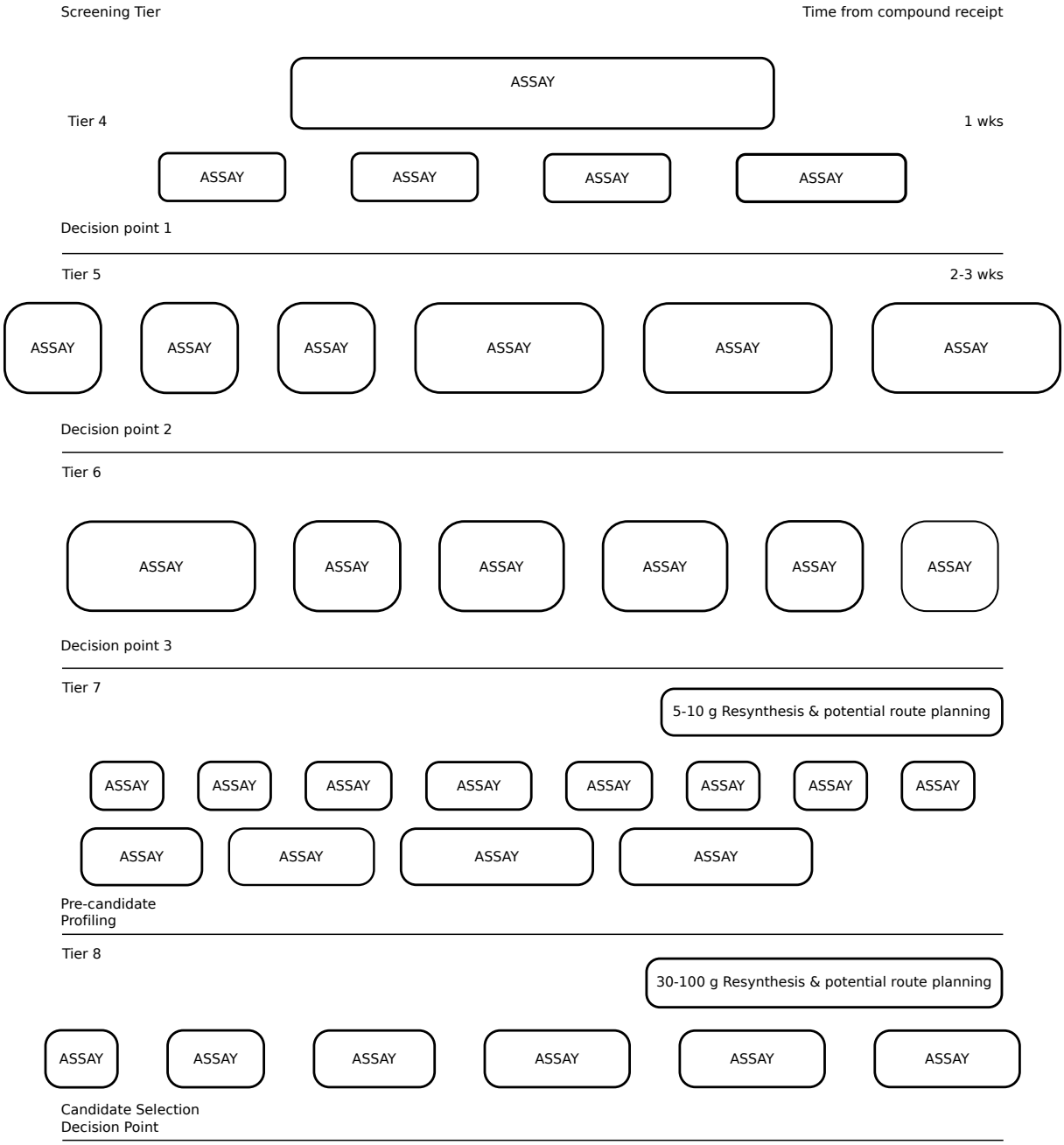

Figure 5: Conceptual flowchart

As indicated in figure 5, each tier has a preliminary timeline allocated in the ENABLE template (to the left in the figure), based on previous experience on standardized

timelines. In the GSK-Sanofi program there is also a project manager, from Sanofi, who uses GANTT charts in order to have a more refined planning adapted to the specificity of the program. Each program is also, as mentioned earlier, asked by ENABLE's PMC to propose objectives that should be achieved in the next three, six and 12 months.

In addition to the assays that are more or less mandatory in the flowchart, specific assays that can answer specific questions are also done. Further, the assays are done at different sites (organizations) in ENABLE, as decided by the program leaders and platform leads. These decisions are made based on both the expertise and capactities of those sites. Some assays need specific expertise that is located at only one organization in ENABLE. Other assays or associated activities can be performed instead at several sites. When the assay is done, the data generated is uploaded to one or several of the digital tools available in ENABLE. There is an ELN (Electronic Lab Book) which is used to capture the experimental details. All compounds in ENABLE are described in a database called CDD. And last ENABLE uses SharePoint to distribute files within ENABLE.

The GSK-Sanofi program has several recurring meetings that help guide and coordinate the activities that are done. An overview of these meetings can be seen in table 2. These meetings are where most of the direct interaction between the various organizations occurs. The meetings are then complemented with interaction via e-mails, teleconferences and phone calls that fall outside these recurring interaction points. At each meeting progress of the program is discussed and decisions are made based on the new data generated since the last meeting. The type of decisions that are made differ in nature dependent on the content of the meeting.

Table 2: Meetings in the GSK-Sanofi program

Meeting	Frequenzy	Participating organizations	Content
Portfolio management committee	Once every third month, except 2018 then once every fourth month	GSK, Sanofi, PMC	Progress update, go/no-go decision
Joint steering committee	Once every third month in preparation for PMC meetings	GSK, Sanofi	Strategic
Core team	Once every week + ad hoc as needed	GSK, Sanofi + other as needed	Coordination of activities
Chemistry	Two times every month	GSK, Sanofi, LIOS	Chemistry issues
Program team	Once every month	GSK, Sanofi + other as needed	Trouble shooting program

One Sanofi member summarized their interaction with GSK and other ENABLE partners in the following way; "In practice we exchange information, compounds, data, prepare compounds, communicate and have scientific discussions".

The relationship between GSK and Sanofi is different compared to the relationship the GSK-Sanofi program have with the rest of the ENABLE partners, reflecting their role as

joint hit-owners of a single program in ENABLE. Both GSK and Sanofi describe their relationship as a process where they give and take in order to reach their goal. As one GSK member commented on their relationships with Sanofi and respectively with other ENABLE partners:

"[With the other partners] it was very much I guess, like a customer – client, like 'can you run this assay for us? Sure, what do you need?'. While with Sanofi it was very much 'lets figure out how we want to do this together, lets figure out what we disagree on and what we agree on and lets figure out how to best go about achieving these goals'. So it was more goal alignment than goal oriented. Whereas with the [other] ENABLE partners it was more about 'how can we generate this data together?'.

In general it was a greater task-focus with ENABLE partners, while it was more strategic interactions between Sanofi and GSK. Both program leaders seem to experience that the interaction between GSK and Sanofi were more intense than the interaction with other ENABLE partners. The ENABLE resources consist of many different experts at many different sites, which are connected intermittently to a program, depending on the specific assay or activity to be performed, while the program leaders are always present in the program.

8 Analysis and conclusion

The compounds progression flowcharts (figure 5) are manifestations of both chronological and event-based pacing (Jones & Lichtenstein, 2008). Each tier has a suggested turnover time in which the assays should be done. In addition to this, the PMC requires each program to suggest objectives that should be reached within the next year. This requirement, together with the timeline in the flowchart, is clear manifestations of chronological based pacing. There are few milestones in ENABLE connected to the progress of programs. Once programs have been accepted at a hit-to-lead stage there are milestones as the program progresses to a lead, a candidate and when it enters clinical trials. The second GSK-Sanofi program entered at a lead stage and thus the first expected milestone is candidate selection. This is one manifestation of event-based pacing. However, successfully moving a molecule through each flowchart tier is also manifestation of event-based pacing, as it "reduces uncertainty by demonstrating through each completed event that the project is on track" (Jones & Lichtenstein 2008, p.237). In addition to this, all the recurring meetings can be seen as manifestations of entrainment-based pacing, which coordinate in a more flexible way the various activities. This includes also the PMC meetings where major decisions are made also about whether or not to continue at all with these activities.

Summing, up the three manifestations of temporality are visible in general in the ENABLE project as follows:

1- Chronological pacing:
Timelines – suggested timelines for the successive tiers in the flowcharts. PMC requires suggested time-based objectives (i.e., goals reasonably achievable at a certain date).

2- Event-based pacing:
Flowchart's specific results and key events, with associated decision points. There are no official milestones except candidate selection, but the program team continuously

verifies if planned tasks have been completed according to the flowchart and if the expected events have occurred. This is a way to check the progress of the program and assess the remaining distance toward candidate selection.

3- Entrainment-based pacing:
Meetings and discussions aimed at coordinating and synchronizing the whole ENABLE project and single programs' various activities are the dominating steering tool. These meetings range from weekly or ad hoc to handle current and operational issues to trimestral for strategic decisions (see Table 2 above). Even if PMC meetings are very important as they can officially set a temporal end to a specific program or renew it for the next three months, the decisions made in such meetings are build on the many "smaller" decisions made weekly during the core team and other meetings in order to coordinate on a smaller timescale the various activities.

How do these manifestations of temporality relate with the interactions within ENABLE, and specifically those involving GSK and Sanofi, as well as the other organizations intervening in their program(s)?

On a general level, the prominent role of entrainment-based pacing in the form of meetings implies that the actors seem to prefer to apply a more flexible and interaction-friendly kind of pacing, compared to more rigid chronological (deadlines) or event-based (milestones) pacing. Meetings are per se a form of interaction at actor level between the various involved organizations. The actor bonds (Håkansson & Snehota, 1995) between GSK and Sanofi, which partly pre-existed ENABLE, seem to be reinforced by entrainment-based pacing simply because the various individuals *have to* meet and discuss several issues, including making "unpleasant" decisions, such as terminating one's arm of the second program. However, such a decision is accepted by the affected party because it will be able to continue somehow the program (or the participation to ENABLE) via the activities successfully undertaken by the other partner. Alignment of the goals of GSK and Sanofi is ensured owing to the discussion of the joint organizaitonal body (JSC) which take into account not only the scientific progress of the program but also the perspective of the relationship which binds the two companies.

We do not instead have sufficient data yet about the actor bonds in the interactions with the other organizations. However, the fact that some of these actors have remained involved with GSK and Sanofi when moving from the first to the second program (e.g., Uppsala University, LIOS and OT) suggests that some kind of bonding may be emerging. This might well be the case especially for LIOS, who plays a key role for chemistry meetings and related interactions. Penetrating actor bonds around GSK and Sanofi will be part of our further research.

As for activity links, the whole idea of ENABLE's flowcharts is about first of all specifying which specific activities (assays etc.) need to be performed in each program, by which actor and within which specific timeframe. However, these flowcharts are not so detailed to prescribe how the activities of two or more organizations are to be linked to each other. It is instead by means of entrainment-based pacing (meetings and informal discussions) that the more specific and detailed linking of activities occurs. This kind of pacing seems to have reinforced the activity links between GSK and Sanofi, who have a long-term history of coordinating their activities, starting from the very idea of creating

an ENABLE-like project together and then moving to a great deal of joint planning and scientific activities: the activities of these two partners are so closely linked that they divided their labour on two different tracks for their second project and were able to re-join their activities when one of the tracks proved unfruitful. However, from our data it is difficult to discern any deeper activity links, i.e., permanent form of adaptations, in the interactions involving the rest of ENABLE partners. Possibly, the interactions involving recurrent partners LIOS and OT have given rise to some activity links, in the areas respectively of chemistry synthesis and chemistry logistics. Having been involved in both GSK-Sanofi projects and following the deadlines imposed by ENABLE flowcharts have likely created some convergence in the activities of the involved parties, but it is difficult with the current data to assess the true strength of these links, and how they are related to event, chronological and entrainment pacing. Consequently our further data collection will focus on penetrating more in detail the activities and activity links of other ENABLE partners.

Coming to resource ties, a more complex pattern emerges, depending also on which type of resource (see Baraldi et al., 2012) one looks at, namely products/molecules on the one hand, and competences and (laboratory) facilities on the other hand. The whole idea with ENABLE was to bring together and connect the competences and laboratory facilities of several organizations (especially those belonging to the "discovery hub": e.g., LIOS, OT, Uppsala University) so that they could be systematically and efficiently applied to molecules (i.e., potential products) coming from other organizations, namely "hit owners". Most hit owners also brought to ENABLE's joint pool of resources their own competence of drug R&D, especially the experienced drug developers GSK and Sanofi. While the resource ties involving competences and lab facilities seem to be stronger, clearly between GSK and Sanofi, but possibly also involving LIOS, OT and Uppsala University, organizations who all collaborated with GSK and Sanofi in at least two projects, the resource ties involving products have not likely become any stronger: indeed any of the several molecules handled within a program is considered as highly provisional by the involved parties as a new assay can unveil a negative features of it which requires discarding it. It is possibly only for molecules that have progressed long enough and received a lot of time and efforts "invested" in them that some stronger resource tie between hit owners and other parties might emerge. However, we do not have yet data to verify how the depth of resource ties involving products change as they progress along their programs: this is an area that we will investigate further by following longitudinally with greater details one or several products/programs.

Our main preliminary conclusion is that, interestingly, the temporality manifestations via event, chronological and entrainment pacing do not seem to have weakened any interaction among the parties: basically, we have so far no evidence that these temporal markers are related to shallower or weaker activity links, resource ties or actor bonds among the involved organizations. Instead, in a certain way, the temporal pacing has reinforced the activity links and especially the actor bonds in the relationship which pre-existed ENABLE, namely GSK-Sanofi: it seems like the time pressure to which this relationship is exposed via the various pacing markers is something that the two counterparts expect and even encourage, possibly as a way to be able to quickly and almost routinely discard molecules that do not match strict requirements. In this sense, possibly weakened resource ties involving products (i.e., molecules) are a positive outcome in early development stages as the ones we could observe inside ENABLE.

An important limitation of our study is that focussing on GSK and Sanofi, who are the two actors who play a significant role in ENABLE also had a pre-existing relationship, restricts our search for the connections between temporality and inter-organizational interactions. Therefore, our further research will be oriented to penetrating more in the interactions involving organizations within ENABLE which lack previous relationships among each other, including taking the perspective of hit owners who, unlike GSK and Sanofi, have a much more short-term connection to the project, entailing the possibility of leaving the project if their program were terminated

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