TOOL 9

Experiences and Learnings from the first ERN-Industry pilots supported by Together4RD

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Introduction

The principal goal of Together4RD is to stimulate scientific collaborations between European Reference Networks (ERNs) and Industry. Achieving this goal entails overcoming a variety of historical barriers hampering interaction in this space, by adopting a multi-pronged approach which includes practical support for collaborations, as well as policy and advocacy. A key pillar of the activities in Together4RD centres on launching pilots. In 2024, the Together4RD Secretariat interviewed key individuals from both Industry and ERNs, about their experiences in launching the first 3 ERN-Industry pilot projects. These interviews were intended to better understand the respective experiences of conceptualizing and initiating these pilots – from who came up with the original idea, to how the project proposals have taken shape, covering activities up to the launch phase (approximately). The main insights are summarized below, and key lessons have been distilled from each pilot, covering positives and areas of innovation for these pilots, whilst also highlighting ways in which these kinds of collaborations might be improved in future ERN-Industry activities.

NB: it is important to remember that these are true pilots, in every sense: this is really the first time ERNs have openly collaborated with Industry, in transparent public collaborations. In multiple respects, these pilots represent very new ways of working, for both Companies and the non-Industry partners; therefore alongside the plaudits that should undoubtably come from actually having managed to *launch* three tangible projects, there is - as anticipated- a plethora of valuable lessons, which should be shared widely (as many of these not only elucidate some of the challenges in attempting to form public-private collaborations, broadly , but also introduce issues specific to ERNs).

A set of more concise recommendations, distilled from these extensive learnings, are included in this Toolkit as Tool X '**Key Recommendations for both ERNs and Industry from the experiences of the first ERN-Industry pilots**'

For a summary of what each pilot is addressing, see here

Generating an idea – how did these three collaborations begin?

A call was launched by Together4RD in mid 2022, explicitly seeking pilot research project ideas on which at least one ERN and one company could collaborate. These proposals could be submitted, in the first instance, by either ERNs or the companies sponsoring the Together4RD secretariat. Several proposals were received, and after discussions to assess their feasibility by the T4RD Steering Group and facilitated by the secretariat, and to shape ideas into clearer proposals, three pilots were selected for deployment. As it turned out, the initial applications for each of these eventual pilots were in fact submitted by Industry partners. Before drilling down to what worked well in the project initiation phase, for each of these pilots, and where there is room for improvement, it is helpful to explore the different routes each of the pilots have taken, towards their respective launch.

TTP Pilot: Takeda & ERN EuroBloodNet

cTakeda submitted a short proposal outline to the Together4RD secretariat, which then formally connected them with ERN EuroBloodNet, the ERN in which expertise in the condition Takeda were interested in here -TTP (Thrombotic Thrombocytopenic Purpura) - would most naturally sit Takeda had performed such a mapping exercise to better understand the patient journey and elicit where the gaps are for patients in the healthcare ecosystem back in 2022 and drafted several possible projects to address the unmet needs identified, which they brought to a hackathon of external stakeholders. This all proved a useful background for approaching T4RD and the EuroBloodNet team.

From the ERN, the key actors in the pilot are experts in the University of Milan, and the EuroBloodNet research coordination team. They had forged strong connections with the coordination team of the ERN, particularly around a shared interest in using AI to improve diagnosis, and had had some interaction with Takeda in previous years (although not the individuals they ended up working with). Therefore, when the Takeda team submitted the initial proposal to the Together4RD secretariat, the latter was able to facilitate interactions with the ERN.

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RHINE Pilot – Novo Nordisk, ERK-Net and Oxal Europe

Similarly, in the case of the **RHINE** pilot, in rare renal disease, the initial impetus came from Novo Nordisk, who submitted a proposal on Primary Hyperoxaluria (PH). They saw great value and potential in the ERKNet registry, known as ERK-REG, despite it being relatively new (for instance, they were aware that there had already been publications from the registry, and it had been widely presented, which assured them of the research potential). Although an older registry also collected data on PH patients, run by Oxal Europe, there was no real collaboration between those resources, preventing the field from consolidating precious data. Novo Nordisk was initially interested in understanding the barriers to diagnosis for the PH patients, and how this can happen earlier, and then explore what 'best care' looks like for people after they receive that diagnosis. A collaborative project with the ERN and the pre-existing registry thus seemed a good opportunity to understand clinical care pathways and the patient journey in rare renal disease but also to harmonise registry efforts for an ultra-rare disease. The Novo Nordisk proposal came about through discussions across the public affairs and medical affairs teams, and once Together4RD brought in the ERN coordination team, that proposal was further co-created with ERKNet and Oxal-Europe to forge a concrete, innovative and mutually beneficial project.

Rare Bone Pilot – Sanofi and ERN-BOND

Here again, the initial proposal came from the industry partner, in this case Sanofi. Sanofi has extensive experience in building registries and in this proposal, they were interested to explore the extent to which the registry held by ERN-BOND contained adequate and appropriate data to enable a better understanding of the rare bone disease landscape. A particular goal was to better understand the natural history and burden of Osteogenesis Imperfecta (OI). The opportunity of a pilot project was identified by the public affairs and research advocacy teams and brought to the medical affairs team (which explores the wider ecosystem within rare disease, and identifies opportunities to collaborate, whether with patient advocacy groups or academic groups). The coordinator for ERN-BOND was a key opinion leader in the OI field, and had been involved in running registries for many years. The Together4RD secretariat helped to make contact with the coordination team, and a number of discussions exposed the opportunities to utilise the registry that would benefit of both ERN-BOND and Sanofi.

Co-creating a mutually beneficial research project plan

In the **RHINE pilot project**, the actors were efficient in isolating a precise research question

centred on PH. The initial proposal by Novo Nordisk did not contain too much detail but entailed bridging previously distinct registries (the ERK-Reg plus the long-standing registry run by Oxal-Europe). The RHINE consortium did consider a different primary research question to the one it ended up with, which was more concerned with what delays the diagnosis in another disease. This was something Novo Nordisk was keen to explore; however, neither of the registries could really elucidate that, with the data they currently had. Therefore, the partners decided to elucidate the patient pathway and the time from someone being registered as a person with a rare renal disease, to the point when they are diagnosed with a specific subtype, and what specialists they would then consult.

A turning point in agreeing a central research question to shape the RHINE project was that the parties all agreed that as this was essentially a proof-of-concept project, the plan had to be achievable within approximatively a year, and thus they should aim for concrete, deployable and meaningful project objectives without being overly ambitious. The consortium decided not to merge the existing registries, but to combine datasets, through a retrospective data approach. This simplified some of the next steps, such as establishing a governance board involving the 3 organisations involved, and facilitated contracting discussions.

The ERK-NET coordination team brought the proposals to the scientific committee and the registry board, to ensure buy-in of the wider ERN.

Nevertheless, the process of finalizing the proposal still required patience all round:

> "*The final project scope reflects a middle ground after numerous revisions*".

In the **TTP pilot**, some of those involved in the pilot initiation felt that although all parties were agreed that there was scope to collaborate around TTP, drilling-down to a primary research question and project plan was challenging, partially because those involved could identify so many challenges to address.

For the rare bone pilot, Sanofi came with several research questions they wished to work on with the ERN, supported by insights from medical colleagues. However, their representatives were very aware that those questions needed to align with what the ERN partners were interested in exploring:

> "*If our questions were not aligned… or if we were not willing to change them or work together, then I think it would have been a less successful agreement on those research questions and the scoping*."

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What are the key strengths and major added value of these pilot projects?

The very fact that three pilots successfully launched, after years of **very notable and much-bemoaned inactivity between ERNs and Industry**, is itself a major positive. However, all three pilots highlighted more specific ways in which these pilots have broken new ground and offer major added value.

Several industry representatives emphasized that the call for proposals came at a perfect time for them, offering fresh opportunities "to build a brand-new collaboration" in fields and areas which perhaps were 'less-well-trodden'.

All three companies were keen to emphasise that they viewed these pilot projects as the start of, hopefully, long and fruitful collaborations with the ERNs concerned:

> *"[We will] start in a humble way, but with a great ambition"*

For instance, some industry experts noted that entering into more co-creative partnerships like this in future is very much the way forward, and offers advantages over the traditional one-directional (and purely transactional) approach. Those interviewed noted the enormous potential to understand each other's strengths and find common interests, and enrich research. The overwhelming learnings from one pilot project initiation have been that this is all about breaking new ground and trying new approaches to get ERNs and industry working together. And naturally, this has meant that some things have not gone to plan – or rather, some steps of the project initiation process could have been conducted more efficiently. But this can be viewed alongside positives; for instance, most of the parties interviewed responded that a **good level of trust had been built-up** over the proposal preparation process.

Other company representatives were also keen to emphasize that "there was no cookbook here". Ways of working together had to be figured out, step-by-step. Nonetheless, they highlighted, as major positives in the experience, the excellent relationship established, citing **transparency and the absence of any hidden agendas**. Where there were uncertainties, these were mutual, so that helped to cement a real partnership.

The academic experts these projects seemed to appreciate the fact that the companies could, and should, **have a say scientifically, on the course of project proposal**. In some cases, especially, they really highlighted the scientific *advantages* to working with industry. For one thing, there is a recognition that companies like this can bring greater impact to academic research, and faster. Scientific research is obviously important, and is traditionally the 'bread and butter' of researchers: but industry have experience of putting in place

methods, strategies, and tools, globally, and managing discussions with regulators and HTA bodies to help ensure the impact of the scientific research the ERN experts wish to do. And all of this was -at least by the time of these interviews, when all parties had been working together for some time- understood and appreciated. **This was very important, as for partnerships to be fruitful and trust to be built, all actors need to appreciate the broad expertise and experience each other can bring**: in the case of public-private interactions, it is especially important that the industry partner is not viewed merely as a 'bankroller' for the research, who should not have a say on the scientific direction, as explained further below.

For their part, even before this Together4RD-initiated opportunity, Novo Nordisk colleagues familiar with ERNs saw great value and potential in the ERK-NET registry, in particular, even though it is still relatively new. Takeda highlighted significant advantages in working with EuroBloodNet, as an existing ready-made network, is highly beneficial, as it offers the possibility to more easily pool enough data to train an algorithm for AI.

There was a sense across all pilots that collaborating with ERNs should bring major efficiencies for companies working in highly specialised fields:

> *"If we want to do things around diagnostics or education, any existing network is really important for us. [Rare disease areas] may be better taken care of by an existing network collaborating with pharma rather than pharma kind of building from scratch every time".*

Besides the convenience of having a read-made network, several participants highlighted other important advantages of working with an established community like an ERN. This is a departure from the norm, in some ways, as here, Industry isn't assembling its own bespoke group of experts; instead, the experts are already there and are being proposed, in a sense, *to* the Company. This is obviously desirable, as the expert base is much more likely to be unbiased. The openness of this approach, therefore, is very beneficial, although, because it is a new sort of approach, it is not without its challenges (as below).

As another added value, several industry respondents mentioned that engaging in these pilots has raised awareness about ERNs internally. The companies involved in these pilots are large, with a global footprint, and although those engaging directly in Together4RD, as sponsors of the initiative, were of course familiar with the networks, they appreciated the fact that many of their colleagues were not at all aware of ERNs, what they have achieved, and what their potential is.

The interviews with pilot participants also highlighted the fact that different actors within the same ERN also value the collaboration structures these pilots have set in place. One

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expert reported that it was very positive that the coordination team of the ERN was engaged, as they felt able to focus on the scientific components of the project planning, and not worry about legal and bureaucratic issues that wouldn't sit within their usual area of expertise. It is worth pointing out that, for all ERNs, researchers in the many HCPs which make up each ERN are still very much getting to know one another professionally, and these kinds of activities really help to iron out the *way* in which ERNs can operate to support this sort of work. For example, it need not be the case that the scientific expertise in the particular project being proposed actually sits in the coordination team of the ERN – they might have expertise in different conditions under that ERN's broad heading, and thus it is necessary to bring in experts from other ERN centres, to make the consortium robust.

Lessons we can take-away

There have been many positive lessons learned in the conceptualisation and initiation processes of all three pilots; however, those involved in these pioneering efforts also highlighted where there might be room for improvement. In seeking to share some of these learnings, it is important to emphasize that these issues are often not black and white, stemming from the actions -or lack thereof- of one 'side' or the other. Indeed, interestingly, sometimes both the academic/clinical experts and the Industry experts identified the same issues as 'needing improvement' but saw room for improvement in addressing these challenges, from *both* sides.

These pilots – and ERN-Industry activities, generally – represent a departure from the norm

Generally speaking, companies are figuring out how to work with 'the ERN' as opposed to with a single academic centre, seeking to clarify where the difference lies (especially as each ERN is not a legal entity). Although the industry colleagues more used to working at EU level, with understanding of the rare disease research ecosystem, were keen to collaborate with the ERNs, some admitted that they needed to advocate internally to convince some of their colleagues of the added-value here, educating them on the status quo of the networks, and what the vision for their company could be. In the case of the non-industry parties, they are either learning how to work with industry for the first time, or else are ascertaining how to work with a company *as* an ERN, above and beyond any experiences they may have had in an individual PI or university hospital capacity.

When facing new ways of working all round, it is not surprising that new uncertainties and barriers to efficiency are encountered. Representatives from the industry partners explain that companies have processes in place to seek out and strengthen collaborations (or 'partnerships', as one respondent prefers to call them). As explained by the interviewees,

companies typically award a grant to an expert centre/PI, approaching them with a set of research questions for them to address and publish on. Another classic form of public-private engagement centres around clinical trials. But many of those interviewed, from both industry and academic institutions, emphasised that these are all situations where a company is seeking specific expertise from outside their company. Occasionally this drive comes from the other direction, i.e. someone proposes to the company to run a research project that might actively benefit that company. But either way, traditionally, interactions have tended to be a transactional one-way-street, and to have relatively specific goals.

In these pilot projects, however, although the initial proposals came from the industry partners, the project plan had to be developed and agreed in a co-creation process -which was sometimes lengthy – involving all parties, which was consequently often marked by a key question: 'who is really leading and pushing things forward?' Industry was a *partner* at the table, rather than a lead – intentionally so, to make each pilot genuinely collaborative.

A robust co-creation process is essential

As above, the pilots all demonstrated that a robust co-creation process is crucial to build a concrete project plan and agree a mutually beneficial research question. Those involved in the pilots wanted a co-creation process in which all parties contribute to the development of ideas, to turn initial proposals into feasible and meaningful projects aligned on the strategy, the expectations and capabilities of all parties involved.

> *"Although we may have ended up with slightly 'safer' research questions than we might usually have gone for, it was essential for all parties involved to feel comfortable with these, and therefore it was a good compromise."*

The most effective approach, from the feedback received, was to genuinely shape the documents and plans together with an iterative co-creation process. The industry parties involved in the pilots welcomed ERN experts providing input during the co-creation process; indeed, in some cases, more vocal input would have been welcomed, e.g. to hear the academics more explicitly stating their ideas, their needs, what they would like to do.

Finding common ground can be challenging. One key insight from the interviews was to focus research questions on unmet needs that go beyond specific therapies—prioritizing a deeper understanding of the disease itself to drive progress. However, public and private partners, while working toward the same goal, may have different priorities for these projects. It's essential to recognize these differences early on and either accept them or find a way to ensure all parties achieve their desired outcomes

Avoiding assumptions around public-private collaborations

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There are many misconceptions, and unrealistic expectations surround public-private collaborations and interactions. These are not all specific to ERN-industry interactions, but all three pilots shed light on the importance of understanding the perspectives and needs and realities of other stakeholders within a multistakeholder interaction, to make collaborations more fruitful and try to minimise misunderstandings and frustrations. From the interviews, it was clear that the parties involved in the pilots did not feel they were all '*speaking the same language*'. Overall, the pilot initiation process had some major positives, especially in building trust between industry and non-industry stakeholders. However, it took time for everyone to fully understand each other's priorities and needs.

Early on, there was sometimes a tendency to oversimplify the other side's motivations. Some of these issues stem from differences in the way in which companies, hospitals and universities are established, and what fundamentally drives them. For the academics involved in these kinds of pilots, there should be a recognition that companies naturally want to diagnose as many patients as possible to maximize the market for their product. However, an industry representative reported feeling that the ERN collaborators initially perceived that company to be driven solely by a desire to sell a product and failed to recognise that some companies "*[genuinely prioritize] working in a different way and… really want to address health care ecosystem gaps*".

The takeaway message is not as simple as 'ERNs needs to understand what drives industry' – although this is absolutely a need, the truth is that different companies may have different priorities, and will value different sorts of outcomes. Naturally, all need to make sure their products have the best chance of making a return on investment. However, in the rare disease space, companies genuinely pride themselves on working towards the greater good, on addressing unmet needs, and they naturally want their would-be collaborators to understand their ethos and trust their goals.

From the industry perspective, there is sometimes a sense that academics can be a little too focused on the scientific outcomes, especially around publications, and do not always see the wider route to impact for the knowledge and tools generated. One industry representative reported that the non-industry parties in their pilot were, to the company's way of thinking, a little too wedded to academic outputs like scientific publications, whereas they initially envisaged as objective to better understand the patient journey, with the ultimate objective of improving it. The reality is that, for those in academia, scientific publications so often remain the foremost mark of achievement and distinction.

A common frustration—seen beyond ERNs as well—is the belief that ERN researchers primarily wish to collaborate with Industry just to secure funding. This perception can hinder the development of strong, transparent, and trust-based relationships.

"I have things in mind [from a scientific perspective] but can't do that without that money".

This is not necessarily a problem, nor is it surprising, given that companies have more financial resources than ERN institutions. Perhaps it is fair to say that issues arise when researchers see industry purely as a funding source. There is a common misconception that companies are both willing and able to simply hand over significant budget to academics to conduct research independently, without collaboration. This misconception is unfortunate, as it creates false impressions of the way in which companies can actually expend funds, but -more importantly, perhaps- can serve to work against the collaborative spirit needed in the rare and highly specialised domain, when seeking to promote more -and more effective- public private collaboration. Industry has a huge amount of expertise and experience to offer in the design and delivery of projects such as these, and the win:win scenario is one in which public actors seek to leverage that expertise, and recognise the added value of working with a company/companies, beyond the (understandable) desire to plug a financial gap, of sorts. It is important to emphasise that the future success of ERN and industry interactions will absolutely depend upon this message being disseminated and understood, because the reality, unfortunately, is that ERNs are under resourced to do the myriad of things they are expected to do. Funding for registries, in particular, has been far below what is really needed, to make these resources as powerful as they can be. It is therefore natural that the private sector can easily be viewed as a source of redress for these monetary shortcomings; however, Together4RD wishes to emphasize, and promote, and awareness of the wider value industry can bring to a collaboration.

As mentioned above, a real positive for these pilots *is* the recognition of the diverse expertise housed by the three Companies involved here – they complement funds with an ability, for instance, to connect the academic partners with their own in-house data scientists and real-world evidence experts. Although ERN registries are a wonderful tool, and their respective communities may have rich experience pre-dating the newer ERN infrastructures, some of the companies in these pilots also have experience in building registries, with many lessons they can share.

But in some cases, it took some time for these kinds of messages to really take hold. For instance, the RHINE project found it was important to have Novo Nordisk included as an equal partner on a steering committee, so that their expertise could really contribute to the development of the project.

The importance of keeping on track and ensuring continued progress

One major area where all parties tended to desire improvement concerned the timelines for the initial scoping, proposal discussion, and project initiation phases. Although it is possible to view the lengthy deliberations as positive in some ways, e.g. enabling time for the proposal to improve and become more meaningful (as one respondent explained), the sentiment all round is that this process took longer than necessary. Helpfully, some ways to improve, in future, were identified, but it is important to explore the varying perspectives as to why things took longer than expected, in other to learn from these experiences.

In all pilots, there was a sense that all participants felt that the timelines for moving from the initial project discussion, to agreeing a revised project and research question, to then generating a more detailed project plan, were longer than would be desirable. Industry parties and academics alike reported that industry tended to push the ERN partners forwards. The RHINE ERN partners reported that Novo Nordisk encouraged them 'with just the right amount of urgency' and pushing. However: "*the expectations around timelines were not the same*"

The industry participants generally seemed to assign these delays to the significant workloads of the academic partners. Some emphasized that delays are not unexpected when working with academics, and the timelines here were not really very different to those found outside of an ERN; however, there was a general consensus that things should move faster in future.

It *may* be the case that the conditions in which the Companies proposed these pilots originally were not necessarily amongst the top research priorities of the respective ERNs. Although ERNs were established at a high level, to collectively include all rare diseases, this does not automatically translate to all conditions under those broad headings having the same levels of expertise and prioritization amongst the individual experts of the ERN. It may be that the 'readiness' for public-private collaborations, or indeed any research project, is not as high for some conditions as for others. The lack of availability of researchers, to engage with the discussions and project planning, meant that one proposed arm for a pilot, around education, was dropped as it was proving too challenging to secure the necessary time commitments. Again, this illustrates the need to be aware that initial research questions and project parameters may change, from first contact to firming up a project plan.

The ERN/academic experts interviewed about the pilots also acknowledged that the timelines from first contact to really agreeing the project focus and then developing a more detailed project plan, have been too lengthy. Some fully appreciate that this was partially due to their own challenges in prioritising the pilot initiation. However, interestingly, some respondents felt that this is more complex simply than 'industry pushing for a quick agreement and the non-industry parties hold things up' – and that some delays have resulted from the nature of the processes within companies, and the perception that the discussions can be sometimes repetitive at the expense of action and decision-making.

More than one reported a sense that despite the proposals being submitted by the companies, there was some hesitancy to fully commit to developing a plan – several recall sensing 'a lot of internal deliberation' from their respective companies. Another cited the fact that, although the ERN researchers could quite readily be identified, early-on in the process, industry contacts tend to be quite changeable. Colleagues one begins discussions with, at the start of a process like this, may not be the same people one is dealing with further down the line, as there is a high staff turnaround in industry. This can make it challenging to build relationships and keep momentum going, as different people need to pick up the discussions second-hand – this is obviously more of a risk, the longer the process takes.

One consequence of protracted project planning and initiation, which future collaborations might wish to bear in mind, is that as one industry expert pointed out, company's priorities can sometimes change over time, and individuals working in these companies have very little power over such things:

> "*Something that may be a priority today, and could be signed off in a timely way, may not still be a priority five years later*"

One challenging component of the pilot initiation phase identified by multiple pilot participants, is budget discussions. Some of the ERN partners reported that they were expecting to be told, quite early on, what the company would be willing and able to contribute financially, to support the work, in order to define what they could include in the scientific proposal. They found it unusual that the companies asked them to define the budget, in the first instance, because again, people were used to being told such things for more traditional types of engagement e.g. in a clinical trial, the company contract with the hospital and they already have the protocol and are explicit about what budget is available. Companies cannot dedicate a set amount of funding (in the way a Horizon Europe grant stipulates a maximum budget, for instance), for a scientific proposal to then explain how it will *use* that budget ceiling. Rather, the detailed proposal should dictate how much funding a Company is *able* to dedicate, and hence delays in receiving a specific scientific proposal meant budget envelopes could not easily be agreed. However, with the parties sometimes feeling that they did not know what level of budget was actually available (the ERN parties) or what budget would be requested for a revised scope of work (on the company side), it is easy for a 'chicken and egg' situation to develop. Therefore, the earlier in the proposal that budgets can be negotiated, the better. But again, there is a lesson here in understanding and appreciating each other's modus operandi, and it was suggested that budget envelopes should never be the starting point for project discussions, as it is then easy for the project to come across as having a traditional 'Industry as hands-off funder' nature.

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> "*It is important to discuss expectations around resource - because expertise, time, people, understanding and budget are all wrapped into the resources, we're all committing to this*".

Deep-seated issues such as academic workloads, the need for clarity and agreement around budgets, and the relatively high turnaround of staff in the private sector will not be easily changed; however, the impact of some of the challenges behind the lengthy process of agreeing a robust research question and generating a specific project plan may be ameliorated, somewhat, through greater clarity on who is -and who should- be driving these collaborations forwards.

Who takes the lead? The importance of champions or project managers – people to move forwards

Although it is worth emphasizing again that the nature of the call for these pilot proposals could itself be responsible for some of the issues around delays, as explained above, the fact that these kinds of interactions are new for ERNs and industry makes it especially important to consider who is going to drive the process forward and how. In those earlier, traditional and more one-directional interactions typically seen in previous examples of public-private collaboration, the questions of who does what, by what deadline, for what amount of money, were more straightforward. There was a feeling, from both sides, that academic experts and KOLs are more used to working with pharma "when pharma is running the project":

> "*When we do a clinical trial, we have timelines and we are kind of pushing, pushing, pushing because, you know, we're investing 100 million and it's important it happens on time. And the problem here I think could be that we're not certain who is really the driver here. And that's a challenge.*"

Several respondents reported a lack of clarity, on both sides around who was really supposed to be driving some of this work, and, consequently, who was responsible for pushing each stage and seeking consensus and action. It is a new experience for some of these non-industry experts to be asked to do the feasibility work, and the calculations. But because these pilots are viewed as a partnership, there is not that strong sense of 'ownership' one way or another. This means that it needs to be handled carefully and early, and these discussions aired, ideally through a third party, to make sure that the process is not stalling simply because of uncertainty either around who is supposed to be doing what, or because one partner does not actually have the knowledge, the experience nor the capacity to perform certain activities they have never done before.

All pilots, one way or another, stressed the value of dedicated project management

here. In the PH pilot, this was provided by the ERN Coordination Office and was deemed extremely valuable at enabling good progress at a reasonable pace. But all highlighted how important this is, to have someone either within the consortium or within the Together4RD secretariat -which was identified as a major support - or even completely outside. Some of the industry partners felt it would not be wise for the key project management role to sit within the company itself, as it might change the dynamic. Having a dedicated person—such as a champion or project manager—along with a project tracker was seen as essential for future collaborations. This helps all parties identify delays, understand what the consortium is waiting for, and who is responsible, so support can be provided to keep things on track. Without clarity on the cause of a delay—whether it be workload, waiting for input, or uncertainty about a task—it is difficult for others to step in and help.

One learning lesson that is unique to this new situation of ERNs and industry seeking to work together, as opposed to any and all public-private projects, is that ERNs may need to consider who should be the driver within the ERN: what should that internal ERN process look like? Ideally, in future, it would be good to see multiple centres *within* a single ERN collaborating on a project with one company, or even multiple companies. Here, 'the ERN' part of the partnership will involve multiple experts, playing different roles, in different institutions. This exposes a major change in public private collaborations involving networks (as opposed to a unilateral discussion Industry might have with a single Principal Investigator in a single University or Hospital). To make this activity an ERN activity, multiple actors need to be involved, and the ERN itself needs to provide support and endorsement; however, the decision-making processes, and modus operandi for this, is not really clear yet, in most -or even all- ERNs. It will be important for consortia to agree, in future, if decisions always need to come from – or be endorsed by- the ERN coordination team, as this could potentially slow things down and make processes less efficient. Perhaps coordination teams should defer some decision-making to other scientific experts involved in the pilot (who very likely may not sit in the coordinating structure). This is arguably an issue all ERNs are grappling with, for many activities i.e. how to avoid all activities needing sign-off and active participation from the coordinator/coordination team, whilst still maintaining something as an 'ERN activity' in spirit. In public-private collaborations, as in all ERN activities, it will be essential to get this balance right, and for coordinators to feel increasingly able to delegate key decisions to other members of their Networks, avoiding the whole process of project planning grinding to a halt until they are able to rededicate some time and attention amongst their overwhelming number of commitments.

The value of face-to-face discussions

All parties agreed the benefits of an in-person meeting (1.5 or 2 days) where everyone gathers around the same table and thrashes out what the project should look like. Such meetings were cited as key tools to speed up progress, allow all parties to air their views, understand the views and needs of others, and generally build partnerships as well as more concrete proposals. All seemed to agree that short virtual meetings, every 6 weeks or so, were not sufficient to drive forwards the discussions and really agree a firm research question. In some cases, a face-to-face meeting (or meetings) with all stakeholders complimented separate discussions with specific stakeholders, to build trust and address concerns on a one-to-one basis when necessary (another valuable lesson is the importance of taking the time and effort to build trust with parties who have not worked together previously.)

Some chose to begin their F2F meetings by "*sharing concerns, ambitions and limitations*" and enabling participants to address some of the common misconceptions and prejudices, on all sides, highlighted above:

> "*Deep diving… only happened when we spent six hours together or eight hours together. It's very challenging to be able to accomplish that with one hour Zooms with where you really don't know each other*"

Navigating legal issues

As most of the pilots had not yet concluded the contracting phase at the time of the interviews, the learnings here are somewhat limited. The RHINE project was in the midst of this process, however, having advanced relatively easily to contracting due to streamlining the proposal. Data transfer agreements are relatively straightforward here, as only the two academic partners access the data directly. Again, having a dedicated project manager, and being based in an institution which has undertaken contracting with the private sector in the past, has made the process straightforward. The ERN coordination team did mention that it is proving a little more challenging to include their Industry partner in a trilateral contract, which commits all three legal entities involved in RHINE around one study plan (with milestones and budget plan). But they note that this is understandable and not unusual with these sorts of discussions.

Another piece of advice from a different pilot was to avoid allowing legal contacts in the different institutions to discuss these kinds of projects without the key leads being present. The ERN and Industry experts know what they need, and what they'd like to contract, but leaving this to the legal people can bring about a 'total misunderstanding' of what is intended, which overcomplicates the whole process and sets everything back.

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