Clemens Blümel, Stephan Gauch, Anne K. Krüger

ORGANIZING TRANSLATIONAL RESEARCH

Report on the Establishment, Organization, and Evaluation of the Translational Research Process in leading US Organizations

**BERLIN
INSTITUTE
OF HEALTH**
Charité & Max Delbrück Center

ORGANIZING TRANSLATIONAL RESEARCH

Report on the Establishment, Organization, and Evaluation of the Translational Research Process in leading US Organizations

EXECUTIVE SUMMARY

This report aims at contributing to a clearer picture of the organization of Translational Research (TR). It focuses on organizational structures and practices found in three major research organizations dedicated to TR.[1] The report provides a thorough description of **organizational processes and practices** used to establish, organize, and evaluate TR in key research organizations, relating them to specific institutional settings, different expectations from different actors and how established routines facilitate barriers or enablers for organizational transformation towards TR. The organizations are anonymized and being referred to as "Organization A", "Organization B" or "Organization C" throughout this report. If interview statements are directly focused on the organizational units responsible for TR, these units are referred to "TR Unit" followed by the organizational abbreviation to which they belong.

We have asked the following questions:

1.   How does the **institutional setting** of these organizations influence their organizational structure and practices?

2.   What solutions for **establishing, organizing, and evaluating** TR are employed by these organizations?

3.   How do these organizational solutions relate to the **understandings of TR** in these organizations, i.e. which understandings of TR shape the solutions for establishing, organizing, and evaluating research in these institutions?

4.   What can the different cases of organizing TR tell us about the **connection between TR definitions and organizational core activities?** By comparing the three cases with each other we aim to **identify commonalities and differences.**

The report is based (1) on a **document analysis** of official documents that are provided by these organizations and (2) on **expert interviews** with key actors of these institutions.

The overall results of the analysis of the three organizations are the following:

1.   **There are three dominant ways of understanding TR: (1) from bench to bedside, (2) from bench to public health, (3) industrialization of medical research processes.** However, these notions of TR are complemented by very **specific notions of TR relating to individual roles and positions within an organization.**

2.   **TR promotes new roles** to organize research processes such as **the clinician scientist** but also, in terms of the supporting research processes, the role of **the research "navigator".**

3.   There are **different ways of identifying goals** in TR. They range from **approaches focusing on interaction and negotiation** between organizational hierarchies (TR Unit A) to **approaches oriented towards attaining funding** (TR Unit C).

4.   The technical infrastructure available is l**ess important than shaping processes to match actors to technical infrastructures.** Moreover, new technical infrastructures have been implemented that themselves support a matching of actors, i.e. directories of researchers.

5.   **There exists no clear-cut concept of how to organize TR. However, TR holds the potential for internal capacity building.** Research managers are thereby either motivated by attracting excellent researchers or by responding to external funding programs. In general, research managers show a strong willingness and openness towards an **ongoing learning process** regarding the organization of TR. Researchers highlight that the TR paradigm had less impact on their research, but a **positive impact on a better organization of the research process.**

6. Nonetheless, **commonly shared predominant aspects of how to organize TR** can be delineated that demonstrate an overall understanding of organizing TR as providing **support and service:**
   a) **Matching:** to connect researchers with each other but also with adequate service personnel such as project managers, administrators, research nurses, Ph.D. candidates etc. in order to relieve them from anything but their own research.
   b) **Technical infrastructure:** tool for providing information about researchers and thus for matching people and for making the research process more transparent.
   c) **Guidance:** to help researchers to follow through with translational processes, in particular, while initiating and conducting clinical trials, in order to provide more time for research and to create "protected space" for them.
   d) **Process integration:** to guarantee a "smooth" research process whereby quality management is already integrated.

7. **Self-organized processes** are often followed up by specific needs-driven processes of guidance to ensure a smooth transition of researchers and clinicians into translational approaches. **Process integration** and **education towards process knowledge** complement this and facilitate consistency in the long run.

8. **Education is very important (1) for providing extensive knowledge about research and clinical skill**s and **(2) about the TR process as a whole** and **(3) to facilitate the future of TR through the socialization** of students and Ph.D. candidates into the TR process.

9. **Research evaluation plays a minor role** in two of the analyzed organizations. Only regarding the funding organizations, i.e. the CTSA program, evaluation metrics such as publications are considered important in one organization.

10. **Research quality management has not changed due to TR.** It has been in place already before and is still considered important for guaranteeing excellent research. However, the focus on TR has led to an **increased awareness.** Teaching is considered to play an important role in this regard.

11. Until now, **there does not exist much TR-specific quality management or evaluation of TR processes as such.** Only at TR Unit C, velocity of transferring research results into clinical trials was reported to be of importance. Yet, some of the organizations are working on such metrics.

12. **The impact of the institutional environment on the organization of TR differs.**
    a) **External funding programs** can influence topics and evaluation criteria. **Internal pilot funding** enables high-risk projects. Yet, **the immediate influence of funding on TR research practices is limited.** Some interview partners, however, argue that the CTSA program has led to an **improvement in process integration.**
    b) For others, their **local research environment** is much more important. Their focus thereby rests on making themselves known among the community for **recruiting the best people.**

13. **Organizing TR involves incorporating the outside world.** TR always involves external actors that are either addressed as the **recipients** of research results such as the industry or patients or as possible **cooperation partners.**

TABLE OF CONTENTS

1 INTRODUCTION

Translational Research (TR) is a highly influential concept in the debate on re-organizing medical research and innovation between laboratory and clinic. However, the debate on how to organize TR seems to be quite fuzzy due to multiple understandings of the concept. Particularly, it is not yet clear how these diverse understandings are linked to specific models of organizing TR. Understanding this aspect is crucial in the context of founding new research institutions dedicated to TR. The Berlin Institute of Health (BIH) can be understood as such a new research organization aiming at fostering TR.[2] In the future, existing institutes and clinics of two research organizations in Berlin are expected to benefit from new organizational innovations fueled by the conceptual framework of TR (BIH 2015c). To achieve this goal, new organizational routines and processes have to be developed and a guiding institutional framework has to be set up (BIH 2015a, 2015b).

While the first report focused on the different overall understandings of TR in the scientific debate (Blümel et al. 2015), this second report will focus on individual case studies. For the selection and the organizational analysis of these cases, we rely on our conceptual framework of different TR dimensions developed in the first report. The analysis conducted in the first report resulted in a set of dimensions of TR, which organize the current discourse both within communities of practice as well as in policy. This set comprises scientific, economic, organizational, moral-ethical, educational as well as policy dimensions. We proposed that understandings of TR relate one or multiple of these dimensions to, on the one hand, either the problem of "waste in research" or the "valley of death" and, on the other hand, to solutions to overcome either an innovation or an implementation gap. Reviewing concepts and models of how to organize TR, we found that there is no dominant way of doing TR but a concentration on a selection of activities, which can be organized according to these problems and dimensions.

Based on the findings of the first report, this second report focuses on (1) models, processes and practices of organizing TR, (2) the organizational settings in which different understanding of TR are employed, as well as (3) the organizational goals for evaluation and stimulation of TR in key research organizations. We thereby emphasize that TR should not only be addressed as a particular type of research but furthermore as a means to organize research successfully. The second report is oriented towards an in-depth analysis of the organizational dimension of TR. The reasoning for this focus is twofold. First, an analysis of the organizational dimension based on case studies can provide useful "hands-on" knowledge about challenges as well as enablers of organizational transformation towards TR. Yet, second, this knowledge comes with the caveat that institutional setting and strategies of using TR are mutually dependent upon each other (Heller und Melo-Martín 2009).

We have selected three leading research organizations for our case studies. These organizations play an important role in promoting and diffusing the TR concept. They can thus be considered as leading organizations in TR and clinical practice. In each organization we analyzed organizational practices based (1) on a document analysis of official documents that are provided by these organizations and (2) on expert interviews with key actors of these institutions. Four main questions are to be answered by discussing and comparing these cases:

First, how does the institutional setting of these organizations influence their organizational structure and practices? An example of such interactions is the influence policy initiatives and funding instruments have on the organizational framing of TR. The first report already highlighted the importance of such policy initiatives. Particularly, the CTSA initiative of the NIH established a policy environment that had been important for the founding of many research units dedicated to TR in the US. This report will develop on these initial findings to further elaborate on these types of interactions.

Second, what solutions for establishing, organizing, and evaluating TR are employed by these organizations? We analyze the ways in which these organizations internally employ resources such as funding and promote TR by establishing incentives and evaluation structures and routines. Besides routines and strategies towards TR, the role of technical systems and infrastructure for TR is analyzed in this context. We furthermore investigate if TR is related to quality assurance processes focusing on "substantiating" research in biomedical science.

Third, we focus on how these organizational solutions relate to the understandings of TR in these organizations, i.e. which understandings of TR shape the solutions for establishing, organizing, and evaluating research in these institutions. Where applicable, we will further focus on how different stakeholders in organizations interpret the notion of TR and thus the organizational success. In the process of "organization building" these understandings influence the construction of goals and role models for organizing education, evaluation processes and the management of resources.

Finally, we ask what the different cases of organizing TR tell us about the connection between TR definitions and organizational core activities. By comparing the three cases with each other we aim to identify commonalities and differences. We furthermore seek to relate different organizational strategies and processes of establishing, organizing and evaluating TR to the particular institutional setting of these organizations, i.e. the local cooperation structures.

In short, the second report focuses on organizational structures and practices found in major research institutions dedicated to TR. The report provides a thorough description of organizational processes and practices used to establish, organize, and evaluate TR in key research institutions, relating them to specific institutional settings, different expectations from different actors and how established routines facilitate barriers or enablers for organizational transformation towards TR.

The report is structured as follows: First, we provide an overview of the methodology employed, i.e. the process of the selection of cases, our interview methodology and the material we utilized for compiling the report. Second, we present our interview results, which will be introduced case by case. In this section, we particularly aim at reconstructing the organizational practices and understandings attached to TR by asking key actors at the selected organizations. The third section focuses on a synthesis of commonalities between these organizations. In the last section, we conclude by relating these different strategies to their specific institutional settings and discuss how these findings can provide practical knowledge to support the establishment of TR in Germany, specifically at the BIH.

2 METHODOLOGY

Since the aim of this report is to provide insights about organizational practices and routines in TR related research organizations, a case study oriented approach was chosen. In organizational studies, case study oriented research designs are preferred when it comes to understand the organizational context in which routines, understandings and processes are embedded. For our specific aim a mixed methods design was applied. We analyzed organizational characteristics, statistical and quantitative material about the size and organizational setup of a set of selected organization active in TR in order to select our cases. To analyze the organizational practices in-depth expert interviews with TR dedicated actors within the analyzed organizations were conducted. In the following, the methodologies, which guided case selection, the field manual construction and the collection and interpretation of data are described.

2.1 Case selection

In total, three case studies were conducted. The selection of these three cases is based on criteria we derived from an analysis of dimensions in TR, which have been developed in the first report. We found scientific, economic, organizational, moral-ethical, educational as well as policy dimensions important in framing the debate. We selected the organizations for this report according to activities in these different dimensions of TR. Due to the goal of this report, we concentrated on organizations that are particularly active in the organizational and scientific dimension of TR. To arrive at a final set of organizations we used a two-step procedure. In a first step, we collected publicly available information about size and kinds of activities that can be related to the aforementioned dimensions in TR and in a second step, a preliminary selection of cases was further discussed with experts in the field of TR.

All of the selected organizations are highly active in TR and have established formal organizational structures. The activities and outputs of these organizations in TR could also be revealed in a preliminary bibliometric analysis of publication output of TR related articles in peer-reviewed journals, which have shown that these organizations can legitimately be labeled as leading in research activities.[3]

All organizations are situated within the United States. This is partly due to the fact that US-based organizations currently are among the most prominent within TR. Moreover, the US provides an established policy context that led to the establishment of research facilities, which dominate current debates about TR.[4] This policy context was obvious in major funding measures, which provided the financial and organizational means, by which in turn new organizations could evolve. A particular important funding measure influencing the debate is the Clinical and Translational Science Awards (CTSA) program, which has been introduced in 2006 and renewed in 2013. It is considered to be the most important policy framework for fostering TR. It was funded by the National Institutes of Health (NIH) and aimed at strengthening TR by institutionalizing new research sites. Since 2013 CTSA is awarded through the National Center for Advancing Translational Sciences (NCATS) that has been founded as part of the NIH.[5] In 2013, the NCATS awarded funds with a total amount of more than $ 650 Million. CTSA financed the establishment of several new organizations at major research enterprises in the country. NCATS did not only provide financial resources for each organization, but did also serve as a platform for communication and cooperation, which has been intensely used both nationally and internationally. Therefore, the NCATS provides useful resources for identification of TR research organizations.

2.2 Interview methodology

The interviews have been conducted as qualitative expert interviews. Experts in this context are understood as actors in organizations, who have privileged access to information and both formal and informal knowledge stocks (Deeke 1995). Expert interviews are usually conducted as field manual based interviews (Flick 2010). Manual based interviews are semi-structured interviews which abstain from standardized interview batteries (Deeke 1995). We developed a field manual with a set of problems and questions, which could be influenced by the course of the interview and position, knowledge and interests of the interviewees.[6] The field manual covered three main domains of questions:

The first domain related to the organizational understanding of TR. The questions in this domain focused on how TR was framed in the respective organization according to the specific experience of the interviewees and his or her ideas about the future prospects of TR based research.

In the second domain, we asked about the organizational practices related to TR. Furthermore, we asked about the established routines to fund and evaluate research. Against the background of increased data management requirements in health research, we also asked about the role technical infrastructure plays in these organizations.

In a third domain of questions, we focused on the individual assessments and interpretations of the organizational environment, i.e. the interaction between the organization and external organizations such as other research organizations or industry. The focus of these questions rested on the roles specific actors and actor groups play regarding e.g. the communication strategies of the organizations.

_____

3   *Our preliminary results of the bibliometric analysis show that CTSA funded organizations lead among the most productive research organizations in terms of publications. (Blümel et al. 2015).*

4   *In our first report, we specifically emphasized the policy context as influential level of analysis for the semantics of the term. In considering the policy debate we particularly emphasized the importance of research funding measures and policy papers (Blümel et al. 2015).*

5   *https://ncats.nih.gov/*

6   *The field manual can be found in the appendix of this report (chapter 8)*

In each organization, two types of actors that hold different positions with different roles in the organization were interviewed: Research managers and principal investigators. We assumed that the different positions shape the understandings of the TR concept. Furthermore, these positions can also influence the priorities and the importance of specific TR related criteria such as "innovativeness" or "quality". The interviewees were selected based on a screening of the organizations' representations on the World Wide Web. We identified 18 actors in the three different organizations of which five were willing to participate in an expert interview. The interviews were conducted via phone and lasted about 60 minutes. For an overview of the interviews conducted and the positions of interviewees see table 1.

Table 1: List of Interviewees and their roles.

POSITION	INSTITUTION	ACRONYM
Research Management	TR Unit A	A1
Researcher	TR Unit A	A2
Research Management	TR Unit B	B1
Researcher	TR Unit B	B2
Research Management	TR Unit C	C1

3 INTERVIEW RESULTS

In this section, we present results from the expert interviews. The interviews were conducted to answer the second question on how these key organizations establish, organize and evaluate TR across different domains. We furthermore seek to answer the third question about the understanding of TR that shapes the construction of goals and role models for organizing education, evaluation processes and the management of resources by people who work in key positions at these organizations. This information cannot be collected via websites or reports but depends on personal experience. Together with the case descriptions, this information is used to relate different organizational strategies and processes of establishing, organizing and evaluating TR to the particular institutional setting of these organizations.

The expert interviews have been conducted in May and June 2015 as telephone interviews. In the following, we present the outcome of these interviews by four main domains: The understanding of TR, education towards TR, the organization of TR research (including processes related to infrastructure and funding measures) and TR beyond the organization, i.e. the role of external actors.

3.1 Organization A

At TR Unit A, we were able to conduct interviews with two professionals in managing and scientific positions. In the first interview (A1), the interviewee was interested in *"mutual learning"* since research management aims at carefully monitoring the global debate and the diffusion of the TR concept. Our interview partner was particularly interested in who else we were interviewing and how the situation in Europe was concerning TR. It therefore seems that, despite their prominent position in TR, there is still willingness for adaption and learning and that TR is considered to be an on-going challenge. Additionally, she mentioned initiatives in Japan, which were worth investigating, since they differ significantly from American and European strategies. In her opinion, they follow a different approach, which she labeled an *"engineering approach to TR"* by first *"fixing"* and *"solving"* problems.

"I talked to the Translational Research Centers [in Japan]. They have a very different model. […] Japan has a very different model trying to get to the same endpoint. […] Their methodology is extremely different. They take a very, what I think to be… an engineering approach. They have a problem they want to solve. They identify what they call themes. Projects at different stages of the Translational Process and a lot of their resources nurture these themes rather than a more a chaotic approach that we offer. […] They are very focused on developing therapeutics." (A1)

In the second interview, the interviewee (A2) signaled an increased interest in organizational models for TR:

"Where can we find alternative models for TR?" (A2)

This was a recurring question in the interviews. This again provides reason to belief that in this case there is still a willingness and perceived need towards improvement of overall TR practices and optimization of routines in TR.

UNDERSTANDING TR

We started our interviews with questions about the understandings of TR in relation to the daily practices. At Organization A, A1 emphasized a context-dependent understanding of TR. A1 emphasized her personal background as a research manager that influences her perception, which is highlighted by her first statement:

"I have experience in managing research for 24 years, but I am not a biomedical researcher." (A1)

Rather, our interview partner emphasized her professional training which shaped the perspective towards TR:

"I am not a medical scientist myself. […] As an economist and administration scholar with an MBA, TR from my perspective can be primarily considered to be an organizational issue. […] Translation to me is any discovery from the bench to the bedside to the population, and back to the bench. […] We describe them using a paradigm of Ts. Translational domains. From T0 to T4." (A1)

The understandings of TR at TR Unit A are very much influenced by organizational models: To A1, TR can be understood as circular attempt reaching not only from bedside to bench but also vice versa. TR is grasped as a process, more precisely, by its phases. A1 elaborates that TR covers all steps from T 0 (research at molecular level) to T 4 (development of therapeutics).

In the second interview at Organization A, our interviewee did not relate to a specific understanding of TR. Rather, it was pointed out how TR has influenced organizational culture: Concerning the question how the understanding of TR changed daily work, A2 elaborated on the history of the Clinical Research Centers (CRCs) at the Medical School of this institution in which knowledge of clinical research was initially concentrated:

"Translational can be in both directions. Traditionally, we think of translational research as bench to bedside, but it can certainly be bedside to bench. […] So, yes, the whole concept is a radio concept, so before that special physician came into being, there were program directors of the respective CRC, every clinic having on program director and associate program director. So these two people provided the medical oversight." (A2)

To her experience, the concept of TR and the new roles associated with TR just made this process *"more streamlined"* (A2). But it seems as if there was also much personal continuity in the organizational units:

> *"In every CRC the associate program director was asked to become Medical Research officer. […] So we continue with what we were doing, but we do it in a more concrete organized form and a more concrete delineation of what the responsibilities are." (A2)*

The major difference to the previous situation is the increased awareness of organizational capabilities addressing these problems:

> *"Previously, it was more of a hay." (A2)*

Meanwhile the new organizational competencies are known across the campus and the processes seem to be transparent to the researchers:

> *"The [Organization A] has this program, […]. It is now much clearer cut, so that the scientists know that this program exists and how it works." (A2)*

Education towards TR

A1 perceives the main input of the TR Unit A in the realm of education, where this institution can build on the expertise of the faculty:

> *„I think education is very important. We like to point out there is a pretty easily defined path to learn how to become a basic lab science investigator. The Ph.D program is pretty well developed and we have a good track record in training Ph.Ds. The same is true for MDs and clinicians. But clinical investigation requires a whole lot of educational support. We spend a lot of time on education there. Education plays a very important role teaching investigators to become clinical investigators." (A1)*

There are very specialized educational programs that do also concentrate on regulatory aspects. However, these programs are very focused on closing the gaps in the educational programs at Organization A and not of the biomedical research community in general. The unit in this respect can be understood as primarily serving organizational needs. That is why A1 perceives this TR Unit to be deeply embedded into the organization of the Medical School and the University contrary to interview partners from other organizations. On a more abstract level, this educational aspect has been related to the diffusion and implementation of the concept. According to A2, the education programs are instrumental to this goal:

> *"I think education is always important. It depends on the translational work one is envisioning. […] Clinical researchers could be educated more in terms of translational approaches. […] Education programs are also venues to cross talks. […] Researchers come from all domains and share work together." (A2)*

Education therefore plays a very important role in finding out what the gaps between these domains are. According to A1, the educational flagship is the KL2 program, which is a specialized program. Contrary to other assessments, A1 sees the KL2 program only related and *"restricted to the needs of [our] University" (A1)* not taking into account any other institution. The goal of KL2 is to make sure that they are able to do the desired kind of research:

"We do evaluations of the day, to be sure that they learnt what we want them to learn." (A1)

These organizational identity markers can be found also in other statements of A1. A2 emphasized the scientific needs in educational programs: A major problem from her perspective is the lack of knowledge in genetics and genomics, which from her perspective should be brought also to the clinicians:

"The clinical researchers could be educated more towards translational approaches or even possibilities." (A2)

According to A2's understanding, this laboratory knowledge is needed to perform TR research:

"We have many courses in genetics and genomics for people of different levels of understandings, so that could be a way that is approaching." (A2)

But these programs should not be understood as a duty but rather as an opportunity:

"It depends on the ambitions of the researchers."(A2)

Organizing TR

For A1 the organizational identity plays a major role in facilitating TR:

"We are all [Organization A], we need to work together." (A1)

Although A1 has a background in economics and management, the approach of organizing TR is rather influenced by semantics of informality and primary relationships than by professional communication or formal interaction:

"To us they are family." (A1)

The notion of "shared learning" between TR Unit A and the cooperating facilities has been mentioned as well. Instead of imposing an organizational model onto the solving of organizational problems, the process of problem solving seems to be very much bottom-up:

> *"So, we take the name of our organization very seriously […] we try to gather resources and inputs together and we add whatever we believe to accelerate the reaction." (A1)*

The goal is to convince researchers to conduct this specific kind of research and to convene researchers from different fields:

> *"Everything starts with a request like 'help me build a team'." (A1)*

And once these teams are convened, they seek *"to provide them with something that their own current organization is not providing"* (A2). This can be mentoring, funding or technical infrastructure. To A1, furthermore, roles and position in this process seem not to be very clear-cut. There are no strict definitions of responsibilities, but there is an emphasis on professional expertise:

> *„We have been around for eight years. We learnt a lot about how to manage ourselves and what we have come to think to be a good structure for us. We have a PI who is also [in a leading position in Clinial and Translational Research at our Medical School]. Then we have three Associate Deans, who are also Clinical Investigators in their own right. And then there's me. We organized ourselves into approximately ten or eleven programs. Each program is led by a senior member of a […] Faculty from one of our hospitals or schools, who devote approximately a day a week. Then it is staffed, depending on the complexity of the program, by anywhere from one to 30 or 40 people, who provide their expertise to implement the program. Each of the programs […] is under the strategic direction by a senior member of the faculty by a full time content expert. So, for example: Our regulatory program is led by a lawyer. Our informatics program is led by a computer scientist. Our education program is led by a Ph.D. in education. So, there is a lot expertise embedded." (A1)*

A1 therefore recognizes that there is already a lot of expertise present at the campus. However, people need to be put into contact and also need more training in terms of TR:

> *"There is a lot of expertise embedded at [Organization A]. […] Because there is so much research […] We need mentoring, we provide TR introductory courses. That initiation needs to be done locally." (A1)*

Contrary to A1, A2 sees the role in TR Unit A much more clear-cut. The competences and tasks of her position seem to be fairly well described:

> *"For instance, in organizing drug study, the medical research officer is available to the study design, protocol planning, working with the grant, we are awake to guide the basic science people." (A2)*

Her main role as a Medical Research Officer is to *"provide medical oversight" (A2)*. To provide oversight means that knowledge of the process and the criteria for conducting studies is brought to those who are not familiar with these institutions like the Institutional Review Boards (IRB):

"Every study needs medical oversight, meaning that there has to be a responsible physician who is responsible for everything that may go wrong. [...] The Medical Officer cosigns and controls. Basic scientists cannot do research without having these expertise. So, even if it is a simple blood drug, we do provide oversight. I can identify persons who are in charge to provide medical oversight, I can provide immediate oversight, meaning to know what is necessary." (A1)

Because of her professional background, the role of A2 in organizing TR is to apply certain kinds of scientific tools to assist the researchers. These tools can be diverse:

"If we use for instance tools in radiology such as MRS to matters of fact in physiology, this is TR because we use normal diagnostic tools to an area that did not really have that. This process of requests is initiated by special web request services, but there are also many requests outside that mechanisms, because they know I am the person to answer. [...] The main responsibility in my role is to maintain the institutions of the CRCs [Clinical Research Centers]. Historically, these were the main units in which clinical research was carried out. Now, that these centers are funded by the NIH through the CTSA, resources are much more made available to the scientists. Clinical Research Centers have many facilities that are available to scientists." (A2)

A2 insists on the heterogeneity of these Clinical Research Centers, which make it difficult to compare these units:

"There are clinical research centers for nurses, who can do plant research, for radiology and so on." (A2)

Her role is to orchestrate the different requests to services at the Clinical Research Center, so that the process for the researcher but also for the organization is improved:

"Some of these processes are charged, some are not: [...] We can help investigators make it more efficient, we can direct them towards other resources, we know those people with study design and protocol development." (A2)

A2 also emphasized her personal role in the process of organizing TR:

"My role is to try and facilitate TR the best I can in terms of providing medical oversight and mentoring." (A2)

Goal setting

At Organization A, statements from our interviewees indicate that the organizational development is an open process. This bottom-up strategy in organizing TR applies to the ways problems are identified and goals are found and formulated. We therefore wanted to know: "How do you define your goals at your organization?" According to A1, there is much communication in this respect. The process of goal setting is not a structured or streamlined process with defined steps but a rather informal approach:

> „We work very closely with institutional leadership of our major institutions. We meet early with the heads of Clinical and Translational Research at the major hospitals. We meet with the Senior Vice Presidents of Research at the hospitals. We meet with the Deans of the School of Public Health and Medical School. We meet with the CEOs of the hospitals. So, we are hearing from them what their goals are for Translational Research. We also meet with Investigators, because we invest a lot of time and effort on training. We talk to researchers who are in their research year. We are also talking to Senior Residents and Instructors and people who are launching a career in Clinical and Translational Research. So, we are gathering information from them about what they believe they need. […] So, there is a bottom-up, more or less chaotic approach. We do this by talking to people […] we spent a lot of time talking to research program training directors." (A1)

These statements suggest that there are no guidelines or patterns which are formulated at the top of the hierarchy. Goal setting is rather described as a process of finding problems jointly with the researchers at the organization. There are no fixed organizational goals for TR but rather the ambition to identify the needs of the researchers.

Funding

Announcing funding possibilities is a primary goal for the TR Unit A, so it is important for them to spread these opportunities around the campus:

> "We are funded by grants of [our] Medical School available to anyone with an appointment [at Organization A]." (A1)

According to A1, funding processes and service for researchers cannot be separated from each other. They all address the main challenges and barriers for TR that are *"money and time!" (A1).* Both interviewees observe increasing economic pressures put on the clinical researchers:

> "Clinicians are more and more pushed to serve more patients. […] Protected time for clinical investigators is so important. […] Once they have protected time they have possibilities to conduct research." (A1)

A1's job is to create conditions, which allow researchers to get these spaces without putting too much effort in controlling these persons in the funding period. From A1's perspective, the KL2 program is such a protected time that *"provides researchers with protected time for two years" (A1).* It is supposed to enable researchers to acquire new knowledge and to conduct research in a special environment.

However, funding does not appear to be the only important means for addressing the major barriers in TR. Importantly, these funding instruments are not seen as decoupled from human support structures. This support is also regarded as fundamentally necessary for concentrating on research:

> *"We provide the nurse, we provide the research coordinator etc. […] we provide the resource for free." (A1)*

Role of Technical Infrastructure

To A1, the technical infrastructure is another service for researchers. Building up technical infrastructure is seen as a support activity, basically to connect researchers:

> *„Certainly, an application we build early on [Organization A web service], which allows investigators to find each other [at this organization], was very important. Because people use it a lot to find mentors, collaborators, resource sharers. But it was also a statement of our philosophy to approach persons. Faculty employees of 17 different institutions [are involved]. We're all [Organization A]. They need to work together. So, [Organization A web service] was a really big win early on and it continues to be the web page that is most frequently visited, both by […] investigators [of this organization] and from outside. I think we have a million hits a year." (A1)*

For A2, this data management function is only of little importance. However, A2 refers to another data management system that she considers important for TR:

> *"CTSA came up with a data management system called REDcap, so that is something which is available, so if you develop a tool that is available to all, that is important for TR." (A2)*

The rise of CTSA and the increased usage of REDcap[7] informatics tools seem to be closely related from the perspective of A2.

Evaluation

Organizing evaluation processes does not play an important role for organizational development at TR Unit A. In the interview, the question of evaluation seemed to be rather unexpected:

> *"Evaluation? Are you interested in success criteria?" (A1)*

Strengthening or improving biomedical evaluation schemes at Organization A is not a primary goal of the TR Unit according to our interviewees. Instead, there is the notion of protected space that the institution seeks to provide. The underlying assumption seems to be that, once researchers are provided with time and space, they will more or less automatically do highly respected research. This might also explain why they do not have a metrics system for evaluating research, although the organization funds research since a couple of years:

---

7   *RedCap (Research Electronic Data capture) is one of the most widely used software programs which allows for data sharing and management in clinical research. See: http://project-redcap.org/*

> *"This [evaluation] is such a small component of the translational structure. I don't think we really have enough by way of metrics to answer that question [regarding evaluation] in a very complete way. We are beginning to collect metrics to answer that question [of evaluation], but I think I cannot answer this question in a way that is useful to you. Up to now there are no metrics." (A2)*

This statement also suggests that collecting metrics for evaluating research is a rather unexpected activity for organizing TR at TR Unit A. If there are metrics, these are not collected to change the behavior of the researchers but to inform the organization.

These understandings of organizing TR can be found in what was presented as the most important challenges and problems in TR. These are, according to A2, not the quality of biomedical research but questions about how to find and connect people from different domains:

> *"Usually, we think of Translational Research as from bench to bedside but it can certainly be from bedside to bench. The basic problem is to carry out the right persons. The [TR Unit A] has provided tools and managed link people." (A2)*

According to A2, this is a *"shared problem definition"* at TR Unit A. Connecting the *"right people"* also at different career stages is then the most important challenge:

> *"The [TR Unit A] tries to figure out the right resources for all of our faculty, also our junior researchers. We have many small grants and try to enable research at all stages." (A2)*

Thus, the biggest problem for TR Unit A is recruiting qualified scientific junior researchers who want to specialize in TR. There seems to be strong competition about highly skilled researchers among the well-reputed scientific organizations.

However, A1 insists on the uniqueness of each research organization and on the uniqueness of research practices that do not allow for strategic planning:

> *"There is no one best way. We are talking about research! (pause) It's not making a widget, it's not engineering, you cannot optimize research, but you can lower barriers, we can make it easier to do research." (A1)*

TR beyond the Organization

At TR Unit A, TR is not restricted to the organizational boundaries of medical research facilities. Translation does also include to move out of the clinic to the patients communities:

> *"We have a rather robust collaboration with the [regional] Department of Public Health, where we are trying to evaluate some interventions to improve public health in [Organization A state] in four [of these] domains and we are working with community partners, who have adopted the interventions at community level and we are going to evaluate their effectiveness. […] This collaboration was a consequence of [TR Unit A] coming into existence. […] The NIH has asked us and all the CTSA to devote some of our resources engaging in a type of research called 'Community Based Participatory Research'. Where you work on a shared research agenda. […] Working and fighting diseases also at the community level is one of the major goals." (A1)*

They also recognize further engagement that has increased the perceived impact of their activities. They engage with other relevant stakeholders that are not necessarily part of the technical/health domain, but also include policy institutions:

> *"Our feeling was that this [Community Based Participatory Research] was much less powerful than the potential of working with an organization […] that could have a much larger systemic influence. So we decided we wanted to work with the State Department of Health." (A1)*

This shows that TR has a wider scope than in most understandings in the German policy debate. Their understanding of TR is that some of the resources of the NIH should be put into the community level and policy level. That is why this university decided to cooperate with the regional Department of Public Health at this level. Their understanding of TR thus expands towards public health and thus focuses on the implementation gap.

Furthermore, there is exchange of expertise between TR Unit A and other CTSA institutions:

> *"We learn a lot from other CTSA colleagues, we offer everything back to them, sharing best practices. That's where the learning is, […] like the comprehensive Cancer Centers. That's an institution where we particularly learnt what not to do. We learn from others and figure out a different model." (A1)*

Similar answers came from A2:

> *"For any institution the CTSA is a great resource. […] There is a lot of collaboration across CTSAs. Let's say, we have CTSA and XY has a CTSA. If we think they have a resource, we talk to them." (A2)*

However, the CTSA or the NIH are not the main addressee for their activities:

> *"I do not worry so much what the NIH does, we are interested in people who want a career in Clinical Research at [Organization A]." (A1)*

Nor do these funding programs define the criteria or benchmarks which are relevant for the unit. Instead, utilization of knowledge and satisfaction with applications and infrastructures is the major goal, which is pursued at this organization:

> *Q: How do you convince your stakeholders? A: "We are struggling with this question. It is very difficult to isolate our contribution to the grand goal of improving health. NIH CTSA is not important for internal standing of the [TR Unit A]: The CTSA looks at publications, these things […]. We look more at utilizations." (A2)*

Contrary to the NIH, A2 admitted that these are *"very mushy, demand oriented, subjective criteria"* (A2). Thus, the prior organizational environment for TR Unit A is the local research network in the region. Addressees of initiatives and activities of this TR Unit are local research institutions. These are the audiences to which goals of the program are communicated and which ought to be reached:

> *"Q: How do you communicate your research to an expected wider audience? A: So, that's a great question, we have done a lot of advertising in the areas, in the organizations beyond nearby facilities where we expect the researchers. We now plan to expand to [Organization A] College, so a lot of advertising is with those who run these programs in these institutions." (A2)*

Outreach is thus an important task. A lacking local awareness can therefore produce disappointment and dissatisfaction:

> *"You know, after two years of the program, we went to the medical school and talked to the postdocs and they were completely surprised that the program existed. […] There is such a need to push forward that people are informed." (A2)*

TR Unit A seeks to tackle the problem of a lacking local awareness by developing tools such as *"online tutorials"* (A1) and easily accessible materials. To sum up, TR at TR Unit A seems to be primarily oriented towards strengthening the position of this University and to bring forward the idea of professional capabilities in clinical research in general. Among Organization A Medical School there is no agreement about how to do TR but much willingness to cooperate and find gaps at all stages irrespective of external demands and expectations.

3.2 Organization B

The TR Unit B is also a major grant recipient of the CTSA program. The positions of the interviewees were slightly different but nevertheless comparable to those at TR Unit A. The interviews lasted less than an hour due to time constraints of the interviewees.

Understanding TR

B1's understanding of TR is very much that of a domain crossing activity. He highlights the organizational and procedural aspects of TR:

> *"Well, I think of it very simply as anything pre-clinical going into the clinical space. I also think of it as another transition much further down the line in terms of diagnostic or therapeutic or prevention product development. Further down the line, when there is a translation from research into operational use. Those are quite different, but I try to be inclusive when I think of translation, because I think both of those are very important transition points that benefit from a lot of focus, because they are such important points in the process of taking ideas and getting them into the clinic." (B2)*

The predominant question to him is *"how knowledge can be brought into human studies" (B2).*

Concerning the question whether TR would have changed practices of medical research B2 was rather skeptical. His personal assessment of the concept of TR is that its influence on medical practice is limited:

> *"I am old enough to know that this whole stuff of TR is overlaid stuff of what we have been doing and called 'Evidence based research'." (B2)*

He has no clear concept of TR and is not sure what it really refers to and to what extent it changes the analysis of medical research practices:

> *"Currently I don't know what the advantage of the TR descriptor is, that is to my perception almost too broad to be useful. It makes everybody doing TR that does anything clinical. It seems to me to lose the identity of one within the other. This does a dis-service to both in a way. […] I am not sure how useful it is." (B2)*

To explain these inadequacies, B2 gives the example of his own professional field:

> *"In clinical pharmacology, there is a rebranding the field as Translational Science." (B1)*

Moreover, he highlights differences in impact of TR for different actor groups:

> *"What I do is on the early side of translation. Translating from pre-clinical into clinical. I am not sure that there is anything different. I don't do things differently. I pay attention when I hear and see the world 'translation', because that is what I do. But that's just another word that I have to keep track of. I think there may be more of an impact on the far side of that, which is the translation from clinical research into clinical practice." (B2)*

B2 hereby highlights the issue of an implementation gap in TR, arguing that in terms of early research phases, there is only a minor impact on daily routines.

Education towards TR

To B1 and B2 education seems to be especially important at the doctoral and postdoctoral level because at these levels people can be socialized into TR. As an overall goal of organizing TR, B2 emphasizes the importance of understanding the medical research process in total:

> *"The persons have to understand the 'whys of the process'. We will sit down in a room, in a studio concept and have experts all talk to him [Ph.D. candidate] about how he might be designing different parts of this [his research]. Any one of them might have a role in the future as a collaborator or as a consultant." (B2)*

This statement highlights the importance of Ph.D. candidates as a valuable resource, who bring in new ideas but are simultaneously socialized into what TR is about. Moreover, this approach puts a strong focus on the interaction with experts from multiple backgrounds in early phases of education. They thereby aim to educate future promoters of TR.

There is a kind of missionary note in B2's statements about Clinical Research:

> *"Clinical Investigation provides approaches to bridge different fields. Without this knowledge you cannot make the right decisions." (B2).*

Organizing TR

Funding measures have a significant impact on the process of organizing TR:

> *"At [this University] there are many different folks here that can help in the process of taking a product from the laboratory into pre-clinical studies, into humans and then into the field. That has been formalized, to a significant degree, by these CTSA grants." (B2)*

At Organization B so-called *navigators* play an important role as they facilitate support towards next steps and relevant people to address. According to B2, persons in these positions have various backgrounds:

> *"One of the points of entry I will refer everybody to, in addition to me helping them, I refer them to what are called Navigators. These navigators are folks with some different types of backgrounds, but most of them have been research coordinators. Some of them are nurses, some of them are masters level people. They are not typically Ph.Ds. They understand the overall process, mostly in the clinical space, but also understanding a lot of the interfaces. […] When someone comes in looking for help, the navigator grabs hold of them and says: 'Ok, given where you are, this is the next step. These are the people you need to talk to.' Then they make arrangements to talk to those people." (B2)*

They understand the process and are able to give advice to the researchers with specific personal assistance. These navigators also guide people without experiences in human subject research to persons with clinical experience:

> *"The navigator would tell them, you need to talk to me [, i.e. B2]." (B2)*

Additional staff allows for the orchestration of different needs, e.g. to design and organize TR research carefully, and is thus regarded as creating a chain of people who depend on each other's research and make sure that results can still be saved even when mistakes happen. These new practices of organizing the research process are regarded as the primary goal.

B2 interprets his own role as:

> *"My role is providing support to investigators. [...] We bring people through the process, who have never done clinical research. We are helping go through that process, to go from an idea that they have, with solid data, in a laboratory. We help them through this very complicated process, to go through the pre-clinical safety studies and the regulatory science to get them into humans. [...] We provide much infrastructure and consultative advice and solid support. We subsidize the laboratory support. We subsidize, to some degree, the clinical trial support. By providing real resources for these laboratory scientists, the Ph.Ds to do clinical studies." (B2)*

This statement highlights the strong interaction between a provision of resources, mentoring and overall support from experienced investigators and the relevance of a division of labor. The overarching goal is to enable basic researchers to adapt their results to requirements of clinical trials. To this end, support and (human) resources are provided in order to help the researcher to focus merely on his or her research.

Implementation seems to be a primary motivation for engaging with TR:

> *"This whole area of implementation research... on that end there may be a lot more going on. We have initiated implementation science journal clubs. We have an implementation faculty. [...] They don't say translational, usually, but they say implementation. My understanding is that those are similar. [...] I think on that far end that [TR] is very useful. [...] The early end is not very different. [...] TR is much more feasible to get things into the clinic." (B2)*

Translation is thus understood as the implementation of basic research results into clinical studies.

Funding

Although first skeptical about the TR concept, B2 noticed clear improvements through the TR movement and the CTSA funding in particular. According to B2, the situation has improved significantly:

> *"At [Organization B] there is a very much better integration of all these processes." (B2)*

This aspect complements his earlier statement made regarding the interaction of internal processes and policy funding mechanisms. He recognizes the positive impact of the NIH funding programs on this development:

"CTSA is clearly facilitating TR. We have organized resources that it is much more likely that anyone will get you to what you need." (B2)

Evaluation

According to B2, evaluation does not play a specific role in TR, because TR does not change the understanding of quality in the realm of clinical research. He neither recognizes a new understanding of research quality nor an increased interest in evaluation activities because there has always been a quality monitoring:

"There are multiple sets of oversights associated to quality. Quality and oversight have always been part of clinical research. There is quality inside the laboratory. There are no specific quality processes since the CTSA." (B2)

Regarding the evaluation of scientific output B2 finds that *"publications are important in order to get the funding again"* (B2). This statement reflects an external focus of output-oriented evaluation criteria, among which the most prominent are usually publications in peer-reviewed journals as well as derivates representing recognition of these publications, i.e. citations. It seems, however, that in terms of defining success and good research these types of indicators play a minor role. This is also highlighted in another statement of B2 regarding research quality in TR:

"I think the only issue there is, that these grants have made access to [technical] resources readily available. All these resources have built-in the quality management programs that are required. And the investigators that are newly taking advantage of these resources, laboratory or clinical, are learning about the importance of these quality management things. In that sense, people that didn't know about it are learning about the quality management within the lab and within the clinic and the clinical research support structures. The whole idea of quality management within the laboratory and the clinic are different because of the translational turn of evolution." (B2)

B2 therefore argues, that there is no need for new quality management concepts, but rather diffusion of knowledge about these concepts among the practitioners. Especially, for those actors that bridge the gap between the laboratory and the clinic.

However, the amount of resources that went into communication of knowledge about the research process and about how to use tools that have been made available has changed:

"The resources have been made more accessible in recent years. The actual processes to assure quality have not changed a lot: Quality management processes within the laboratory are not different from before." (B2).

Role of Technical Infrastructure

B2, deemphasized technical infrastructure as a constraint for researchers because using data management tools is not obligatory:

> *"Those are options, we recommend these instruments, but what is more important is: Making people aware that there is a right way to do these things." (B2)*

B1 furthermore highlights that the CTSA promoted database is adapted to their particular needs:

> *"We use that REDcap thing, but we tailor these things to who accesses the data, used the data and so on." (B1)*

B2 also elaborates on the role of the technical infrastructure of promoting interaction between researchers:

> *"When I first finished my training here, […] at that time there were a few pieces of the infrastructure. But there was no point of entry. You had to know where to go. It was a little bit better than random that you would find the resources you needed. What's happened here is that we've added resources and we've organized the resources in a way, it is much more likely that, by talking to any one person within this much larger umbrella, as a point of entry, will get you what you need. You will stay engaged throughout the continuum of the translational science. A fair bit of resources go into that. I don't know if it is efficient, but it is productive." (B2)*

In total, technical infrastructure is promoted not as constraining research through more bureaucracy. Technical infrastructure is rather described as a valuable asset in facilitating interaction among researchers.

TR beyond the organization

Although B2 is quite skeptical about changes from his personal experience – *"I don't do things differently." (B2)* – the recent policy changes have triggered expectations:

> *"In the States the NIH packages several programs under translational research especially CTSA. These programs seem to have an impact in the debate." (B2)*

To B1, it is the implementation idea that results have to come closer to the patient, which is a new element in the debate. This is also understood as fitting the interests of the pharmaceutical industry:

> *"Drug companies will profit from these implementation efforts." (B1)*

3.3 Organization C

At the TR Unit C we were able to talk to a person with a mainly economic and administrative background that has specialized in managing research institutions. In the case of this unit we can only rely on one interview from Research Management. The interview took about an hour.

Understanding TR

TR according to our interviewee is understood as:

> *"Any research that is focused on moving discoveries or findings knowledge from one phase of the translational spectrum to the next. According to this definition, almost all biomedical research can be called translational. Except research that is at the very, very, very beginning, that is purely just discovery and elucidating mechanisms and things that are not necessarily envisioned to move into human health research at some point. […] I don't think it's necessarily new. I think a lot of attention has been drawn to the barriers and challenges that exist between moving discoveries from one setting into another setting." (C1)*

However, our interviewee primarily emphasizes *"moving things into the real world" (C1)*. TR therefore is not necessarily new according to C1, but has pushed the notion of moving things from research into testing and *"the real world"*. TR in this respect can be understood as *"highlight[ing] where those gaps are"* (C1) that still obstruct this process.

The reason for the spread of TR is, according to the research manager, that the academic and clinical research world is in a deep crisis:

> *"Academic organizations are notorious for developing failure." (C1)*

That inefficiency is partly explained by a lack of an optimized allocation system in contrast to industry:

> *"The business has been doing this forever: having the right people at the right place at the right time". (C1)*

It is now that these problems have become obvious because of the industry, which she considers to be the most influential force in biomedical research. One reason for the increase in TR is the increased economic pressure:

> *"I think there are a number of forces. Honestly, I think economic forces are probably one of the biggest issues facing the research enterprise right now. Historically, NIH has funded the basic sciences and very pure laboratory research and industry has been the one that has been funding [implementation], because they wanted to find the new blockbuster. […] Now there is more research in TR but money is spread among many more different types of science and recipients." (C1)*

C1 also emphasizes that the crisis of the pharma industry is a relevant factor in how the concept of TR is applied:

"One issue is that the era of the blockbuster is over. They are unlikely to find major blockbusters going forward. The other issue is that the clinical trial process is a very inefficient process right now. So R&D departments in pharma have to spend an enormous amount of money just on the phase 2 clinical trials. [...] The model of how the clinical trials are done is changing and needs to be changed." (C1).

The clinical research from her point of view has become so expensive that the pressure on reconfiguring the whole process is very high. She thus emphasizes the innovation gap in biomedical research where the economic potential of biomedical research cannot be exploited due to a "broken middle" in the process. From the perspective of our interviewee TR can be best understood as a massive effort to put the whole research world closer to the business world.

Education towards TR

The role of education in diffusing the concept of TR and closing the gap in the innovation process is particularly highlighted:

"We just hired a new education program manager, [because] education is a huge part of the [translational] activities [at Organization C]." (C1)

They furthermore have TR courses that are supposed to help researchers in overcoming the gap:

"We initiated courses – what resources do researchers need to cross these valleys of death." (C1)

Organizing TR

According to C1, the main efforts at her organization have been put in the improvement of the allocation process regarding human resources:

"This process has to be changed, so that best people do the job." (C1)

Moreover, efforts have to be made to make clinical research less expensive and more efficient. C1 strongly emphasizes the need for a high level of division of labor and the relevance of matching and connecting people in a project context. The goal is to relieve the experienced researchers from other things than research. The role of the research manager is to establish these teams that consist not only of researchers, but also of people from different contexts within the TR process. This idea is mainly driven by a cost-saving and efficiency motive. The motive of cost-saving is further strengthened by the perceived need to outsource certain activities and focus on core competences at TR Unit C:

"For example, when you are moving things from the laboratory space to person human testing there is a number of steps that need to occur. Toxicity testing, PKPD [8]. A lot of that needs to be outsourced at [Organization C]. So, what we do is, we match up investigators with project managers. The responsibility of the project manager is to make the connections on behalf of the investigators to get the work done. Same thing with doing contracts, doing budgets, doing any sort of the regulatory paper work. We don't want our investigators spending time on things that could be done by other people who are much more experienced and knowledgeable about those things. So, we create teams of people to make the entire process work better. That's the model that we try to use to make translational research more efficient." (C1)

Today, Organization C is part of the NIH CTSA funding. However, activities to increase efforts in TR have been prior to the CTSA grant announcement. It has been strategically analyzed in which fields of research this organization required external expertise and collaboration. These fields have been identified and measures have been taken to reduce the gaps. This is particularly true for regulatory knowledge regarding clinical trials.

"At the beginning, we had no one in this field. Now the regulatory body is run by seven people." (C1)

An important process to enable TR at this organization was therefore to strengthen service activities. This has been done primarily by systematically recruiting supportive stuff and building teams with experienced researchers. C1's role at TR Unit C is *"facilitating and supporting research: Matching infrastructure to people, matching people to people" (C1). In this regard, they are "not just connecting researchers with researchers but researchers with staff"* (C1).

The position of the research management is thus understood as being permanently receptive to requests from the scientific staff:

"I am interested in this question […]. If I cannot find it online, I will ask these people [at TR Unit C] and we help them. We are all about connecting people." (C1)

Thus, the most important enabling factor for TR is considered to be *"appropriate time for doing science"* which is sought to be reached through an omnipresent service for researchers in order to facilitate the research process.

Goal setting

Strategic planning at TR Unit C takes a lot of time and resources:

"We spent a lot of time for ideas and we spent nine months to answer the question: Where can we invest money with the biggest impact to foster translational research?" (C1)

---

8   PKPD describes the combination of pharmacokinetic and pharmacodynamic modelling approaches.

This unit follows a very standardized scheme in identifying key action fields. According to our interviewee the goals are clearly oriented to meet the CTSA requirements in terms of publications and output:

"The process aligns closely with the CTSA grant. The five year period is also the time frame for the strategies."
(C1)

C1 strongly highlights the relevance of CTSA as a source of funding. However, this also poses a problem to strategic planning because the development criteria have been very closely related to the one of the funding body and were not compatible with the developments in the field:

"By the time you get funded, things have changed again. […] Funding and strategy doesn't keep up." (C1)

C1 elaborates on that incompatibility by highlighting the recent trend in community medicine, which caused problems for the organizational strategy process at TR Unit C:

"You can't necessarily change your scope within a year! In 2013 there was no focus on community engagement in the NIH programs." (C1)

This has changed during the operation of the funding periods. According to C1, TR Unit C therefore had to change its focus and to integrate community health into its strategic initiatives.

Funding

The managing body at TR Unit C reacted on that changing funding environment by widening its scope to different grant givers:

"There are now different projects and initiatives besides the CTSA grant. There are different initiatives with which the organization needs to keep up." (C1)

Despite the fact that TR activities seem to be largely influences by the CTSA grant cycles, C1 also highlights the fact that an extension of funding opportunities is a desired goal.

At this time, personal pilot funding is an established funding measure:

"We give out a fair amount of pilot funding." (C1)

Evaluation towards TR

Evaluation procedures seemed to play an important role at Organization C. C1 connects the introduction of evaluation procedures with efforts to strengthen research integrity:

> *"There are a number of quality initiatives at [Organization C]. One of them is a very tightly regulated Quality Assurance Office, which is ultimately responsible for ensuring research integrity across [Organization C]. TR evaluation […] [is] tightly coordinated with research integrity." (C1)*

There is "a bulk of measures" but it seems unclear how to compare those figures:

> *"When you produce a set of metrics for a certain unit, you may not come up with the same results." (C1)*

Many different metrics seem to be in place. A focus on timing seems to be consistent with the previously mentioned emphasis on efficiency as the primary goal for organizing TR. Accelerating the velocity of research processes reduces primarily the costs of conducting research, which is the required response to the mentioned *"economic pressure of biomedical research"*:

> *"There are a number of metrics that we use. An excellent example of metrics in translational research are 'timing metrics'. So, for example, we look at how much time it does take to have an IRB application reviewed and approved. How much time does it take from study approval to enrolling our first participant? Say, we have a target of enrolling 20 participants in a given trial: How many participants did we actually enroll?" (C1)*

Regarding quality requirements, the interdependence between funding initiatives and quality criteria is highlighted by C1. As mentioned above, one major aspect to C1 is speed and efficiency of processes. This involves at the same time a harsh critique about the overall current orientation within academia, which, at the same time, has been positively influenced by the CTSA mechanisms and requirements:

> *"Honestly, I think the overall standard structure of academic environment needs to have an overhaul, or at least, if not an overhaul, a re-positioning of the way that they think. I see that happening in a number of institutions. I do think, the CTSA is a critical element to this, because it forces people to focus on this, in a way we've never had nationally." (C1)*

Besides timing, other areas of TR are also tracked in terms of internal evaluation and strategy development that clearly branch out into the economic domain:

> *"There are number of metrics across all of our areas. In regulatory, we keep track of how many INDs or IDEs we put in and how many are successful. […] We give out a fair amount of pilot funding to our investigators to try new things. One of the things that we look at there is the return on investment. Saying, ok, when we put in $ 10.000 into this and they came back and won a million dollar grant on it." (C1)*

Besides those metrics that relate to efficiency, there are also evaluation criteria in place that relate to the scientific domain. Yet, these seem to be more of an "on-top" criteria regarding TR. The statement relating to the scientific dimension is rather short compared to the evaluation criteria that relate to the aforementioned aspects:

> *"We also look at things, like traditional academia, like publications and grants." (C1)*

Unfortunately, due to the fact that we have no interviewee with a researcher, we cannot access if this is a shared opinion within Organization C.

Technical Infrastructure

Technical infrastructure is also regarded as a way of making research more cost-effective. A strong focus is put on the efficient use of existing data involving new technologies, such as big data:

> *"I think consumer empowerment, patient empowerment is going to be a major element in it. What I would like to see: I can imagine an entirely different infrastructure for doing clinical research that is based on using electronic health record data. The process right now for doing a multi-center clinical trial is that a new infrastructure is set up with every single trial. Which is completely inefficient. We should be able to take data that already exists in electronic health records […] and figure out which treatment is working the best for these patients. It's a big data thing. I think that is going to be a major change. […] The whole big data, being able to use data to make decisions, is going to change the entire translational research enterprise." (C1)*

TR beyond the Organization

Because of the perception of a *"crisis in biomedical research"*, our interviewee at TR Unit C emphasized expectations from outside, especially from the funding agencies but also from other stakeholders that need to be addressed by communicating results. To achieve accountability, a specific kind of research is preferred:

> *"We want the research that informs policy, [but] we are not those that create policy." (C1)*

"Useful" research is the expected outcome at TR Unit C. However, criteria of usefulness can change according to dynamics in the funding environment. That also explains the recent shift towards community engagement, which has been taken very seriously.

Nonetheless, this is always considered to be TR. This highlights the flexibility of the TR concept that can address different problem dimensions in (bio-)medical research and practice.

Besides funding agencies, the FDA as a potential stakeholder in TR is important:

> *"Well, I think that the FDA is critical, in terms of making policy decision about what kind of data they will accept for moving things along the pipeline." (C1)*

Also patients and health care consumers are regarded to be important by putting pressure on the systems:

"The consumers, patients, are going to play a major role in changing the translational environment. Activated patients, activated consumers of health care, may be the biggest impact in translational research that we have."
(C1)

4 DISCUSSION OF COMMONALITIES AND DIFFERENCES IN THE CASE STUDIES

The different organizations display several commonalities in their ways of organizing TR. However, they also show several differences in terms of understanding, organizing, evaluating and communicating TR. Even within the organizations different understandings of TR persist. Due to different positions and roles in each organization, different meanings of TR and the different understandings of the TR process could be found.

In the following, we will discuss the results of the interviews by comparing statements regarding understandings, education, organization and evaluation of TR. We also take key figures and formal characteristics of the respective organization into account as additional information. Moreover, we highlight commonalities and differences in reactions towards the institutional environment.

4.1 Understanding TR

The interview passages towards the understanding of TR exhibit major differences. Although the interviewees seem to refer to similar notions of the TR concept, they emphasize different aspects that relate to different problems to which TR is presented as a solution. This does also relate to findings of our first report where we found different dimensions in the understanding of TR that refer to different problems and suggested solutions. They furthermore describe the TR process in different ways (see Table 2).

Table 2: Synopsis of understandings of TR in the interviews.

ID	POSITION	SYNOPSIS	DOMAINS
A1	Research Management	TR is primarily an organizational issue. TR follows a phase-oriented model from T0 to T4. TR is a process of transferring knowledge from bench to public health and back.	organizational, policy, ethical, social
A2	Researcher	TR is not new. TR supported streamlined existing processes. TR led to organizations being more aware of problems in these processes.	organizational, scientific
B1	Research Management	In some fields TR is a re-branding of establishes processes.	organizational, scientific
B2	Researcher	TR is too broad of a concept. TR is any moves from pre-clinical to operational use. The impact of TR on daily practice is limited. Impacts of TR are at „the far side" and rather not in basic research.	organizational, scientific
C1	Research Management	TR is driven by economic forces. TR is moving knowledge and discoveries across stage towards application. TR has organized the focus on barriers between research and application. In biomedicine almost everything is TR. TR is efficient allocation of resources and has been adapted from industry.	economic, organizational, policy, ethical, social

The first interviewee at TR Unit A particularly stressed an understanding of TR as consisting of different phases: *"TR covers all steps from T 0 (research at molecular level) to T 4 (development of therapeutics)"* (A1). This definition represents a view in which each phase of TR can be clearly separated from another. By contrast, B2 at TR Unit B presented an understanding of TR which does not refer to phases but rather to different domains: *"I think of it very simply as anything pre-clinical into the clinical space as diagnostic, therapeutic benefits, taking ideas and taking them into the clinic"* (B2). B2 thereby particularly stressed the aspect of an implementation of TR. Finally, our interviewee at TR Unit C with a background in management and business administration stressed the economic aspect of TR. In total, we found that there is an overall shared level of understanding TR. Yet, we also find, that the understandings of TR that go beyond these very abstract framing of TR, is deeply rooted in the activities connected to the roles and positions of the interviewees. This implies that regarding the implementation of TR in an organization such differences have to be understood and become part of the strategy to communicate TR within an organization.

While the given definitions of the TR process are rather broad and localized in the roles of the interviewees, the expected outcomes and changes which are associated with TR are very specific: To our interviewee at TR Unit C, TR is an attempt to tackle the cost and resource crisis in biomedical research where increased efficiency and innovations are the desired outcome. This refers primarily to what we have framed the economic dimension in TR in the first report. Our interviewees at TR Unit A and B both highlighted the importance of organizing interactions between diverse actor groups. Goals are identified by mutual alignment and negotiating between actor groups. The goals within the organizations rather aim at the organization of the process of TR than on the research itself. The idea is that a well-organized process automatically creates an adequate output.

4.2 Education towards TR

All of our interviewees agree that education plays a major role in TR. Statements like *"education is important"* (C1), *"educational programs should be strengthened"* (A2) or *"changing educational programs is necessary"* (C1) indicate much agreement among the different organizations. So again, similar to the results we have found regarding different understandings towards TR, we find that there is an abstract level of similarity between organizations. There are, however, slightly different interpretations between organizations regarding which aspects of educational activities should be particularly strengthened (see table 3).

Table 3: Synopsis of Education towards TR in the interviews.

ID	POSITION	SYNOPSIS	DOMAINS
A1	Research Management	Scientific education in TR is very important. Education towards TR is more complex than traditional and requires a lot of additional effort. Education in TR aims at transforming lab investigators into clinical investigators. Deans of the medical schools are tightly integrated into TR Unit A.	educational, scientific, organizational
A2	Researcher	Education programs in TR should be geared towards interaction between actor groups in laboratory and clinic.	educational, organizational
B1	Research Management	NA	NA
B2	Researcher	Education also involves procedural knowledge.	educational, scientific, organizational
C1	Research Management	Education is a very important part of the activities of TR Unit C. Courses are in place to bridge „the valley of death".	educational, ethical, economic

At TR Unit C an emphasis is put on biostatistics and regulatory aspects among practitioners, while the interviewees at TR Unit B stressed the need to teach knowledge about the clinical process which should be particularly brought to basic researchers at the doctoral and postdoctoral level.

> *"Clinical investigation provides an approach to bridge different fields. Without this knowledge you cannot make the right decisions." (B2)*

At TR Unit C, education is primarily oriented to fill the identified gaps in knowledge which have been strategically identified to increase outcome and efficiency of the organization: Educational programs are therefore important to overcome the innovation gap and *"to cross these valleys of death"* (C1). At TR Unit A, laboratory knowledge like genetics and genomics is considered far more necessary to realize the potential of TR.

Furthermore, educational programs are not only regarded as means towards fostering TR in the future. At TR Unit A, education is also regarded as a "protected space":

> *"Education programs are also venues to cross talks. (…) Researchers come from all domains and share work together." (A2).*

Education therefore does not only play a role in finding out what the gaps are but also provides room for discussions about closing those gaps.

Overall, there is a distinction between two overarching aspects regarding how TR should be implemented in education. First, we find strongly scientific aspects relating to the actual content and skills that are relevant to TR. These also include aspects that relate to technical infrastructure. Second, we find a strong focus on procedural knowledge, which relates to understanding processes and strategies to either take results to "the next level" or having an understanding of the overall process from research result to clinical application. This also includes aspects that relate to identify specific actors, which are relevant within this process.

4.3 Organizing TR

Regarding the organization of TR, our aim was to identify how practices in organizing research and in research as such have changed since the establishment of TR at a particular organization and how the interviewees themselves perceive their role in these processes.

Table 4: Synopsis of organizing TR in the interviews.

ID	Position	Synopsis	Domains
A1	Research Management	The understanding of organizing TR is organizational and geared towards integrating diverse actors. Organizing TR is based on a strong organizational identity and a comprehensive culture of providing services to researchers. Goal setting in TR is based on a governance organizing interests between leadership and researchers through regular interaction. There is a high level of division of labor. Funding and service are deeply interwoven.	organizational
A2	Researcher	The understanding of organizing TR is technology-centered. Organizing TR is primarily an issue of organizing access to infrastructure. Distributing funds is an important aspect of organizing TR.	organizational, infrastructure
B1	Research Management	NA	NA
B2	Researcher	The understanding of organizing TR is holistic and procedural and aimed towards integrating diverse actor groups. Organizing TR involves including different actors into the process of TR at early stages. Organizing TR also involves organizing the diffusion beyond the organization. CTSA has improved the situation by leading to better integration of processes. Research is supported by a special position called navigators. These support students both professionally as well as facilitating contacts to relevant actors.	organizational, scientific
C1	Research Management	The understanding of organizing TR is aimed towards the ends of innovation. TR is driven by a division of labor. Organizing TR also has a strong component of facilitating the transfer beyond the organization into practical applications. Recruiting is a very important aspect of organizational change towards TR. Goal setting is strongly based on CTSA requirements.	organizational, economic

Regarding the understandings of TR we could already see differences even between research managers at the organizations under study. These differences became also apparent in the question of the organization of TR.

First of all, there are striking differences in the assessment of whether organizational practices have changed with the institutionalization of TR. B2 at TR Unit B stressed the continuities in clinical research and compared TR to the trend of evidence-based medicine that also tried to change clinical research practices. Contrary to that view, our interviewee at TR Unit C stressed the need of reform in the biomedical research and more specifically in the process of transferring results from basic research into clinical research, which she considers to be "very inefficient".

Regarding the organization of TR we also found striking differences. At TR Unit A the processes of goal setting and strategy building follows a bottom-up approach. There is no strategic process where key priorities or activities are defined. Instead, goal setting and strategy building are carried out in discussions with the people involved:

> *"We do this by talking to people (…) we spent a lot of time talking to research program training directors." (A1)*

On the contrary, goal setting at TR Unit C follows a very defined and structured approach: Key areas of actions have been identified where Organization C should invest in. These key areas at Organization C were regulatory knowledge and the biostatistics field. This already happened before the CTSA grant announcement. They have now redesigned their goals according to the CTSA requirements in terms of research topics but also regarding research output such as publications. At TR Unit A it works the other way round. Goals and plans are primarily formulated to respond to the needs of the researchers at Organization A and of the local research network. Requirements of the CTSA are instead played down. Therefore, Organization A does not permanently need to adapt its research program to the changes in the research funding environment and the policy expectations, which produced problems according to what our interviewee at TR Unit C reported.

The same differences appear also in other domains of organization such as recruiting people. This is a process that was particularly emphasized at Organization A and Organization C as a major task. It is regarded as important to be considered as providing an attractive research environment.

There are also commonalities in organizing TR. One dominant aspect, which is present across all organizations, is the general attitude and role perception of the organization towards facilitating TR: The overarching principle is to serve the researchers and to enable research. "Service" was the most prevalent notion when asked about how to understand their daily work. This does not only apply for the research managers but also for those working in other positions as scientists in positions labeled as "Medical Research Officers". At TR Unit A, to "serve" people has been understood in a very informal and direct way: *"To us they are family"* (A1). Primarily, the aim is to convince researchers to conduct this kind of research and then to assist their individual needs:

> *"Everything starts with a request like - help me build a team and - once they are convened - to provide them with something that their own current organization is not providing." (A1)*

The individual role of the research management is not very clear-cut. Yet, its primary goal is to focus on what each individual can offer to accelerate the process.

The understanding of service at TR Unit B is slightly different. Responsibilities and competences are more clearly defined. The most important role in facilitating TR plays the "research navigator" that helps those researchers with none or little experience in human oriented research to "navigate" through the process:

> *"We bring people through the process who have never done clinical research." (B2)*

The navigator at TR Unit B has no clear-cut tasks but rather assists the researcher in an uncertain environment in everything the researcher might need to successfully conduct research. The navigator therefore has a guiding function and is able to navigate researchers with little experience. The navigator is important since one of his or her tasks is a prevention of wasting research efforts, for example a disregard of safety guidelines and that researchers with little experience are never left alone and can always get advice. The importance of the navigator lies therefore in that research efforts are not wasted because, for instance, they do not keep up with the safety guidelines.

This holistic conception of service also seems to be prevalent in the other organizations although they have not developed a similar model compared to the TR Unit B. At TR Unit C, the idea of service is not only related to the notion not to waste research but also to the demand of not to waste time: The idea is to relieve researchers from any administrative work:

> *"Any regulatory paper that can be written shall be written by the project manager. We don't want our researchers to waste time."* (C1)

For this reason, the TR Unit C has created teams that pair researchers with project managers who do most of the managerial stuff.

Another commonality was that technical infrastructure was mentioned by all of these organizations. Information technology tools particularly are important to connect people, to find out who could work with whom to build teams. At TR Unit C, biobanks play also an important role to attract people to join the TR Unit C. Here again, providing support for researchers is the first goal for all of these organizations. At TR Unit A, such a needs-based approach has been particularly outlined: The design of these infrastructures follows the needs, which have been articulated in meetings and debates. That is why these tools are usually tailored to the respective organizations; they are not ready-made programs. According to our interviewees at TR Unit B, technical infrastructure did also improve the visibility of "control points". Infrastructure makes these important and difficult points of control (e.g. safety studies, IRB requirements) more transparent for a project.

4.4 Evaluation

Another commonality among our interviewees was that among the different organizational practices to pursue TR evaluation does not seem to play an important role. Some of our interviewees did even not understand the background of our question. The idea of *"supporting, providing service and oversight"* does not seem to be very compatible with the idea of control and evaluation. Instead, we find the notion of *"protected space"* for research, which ought to be provided in order to facilitate excellent research.

Table 5: Synopsis of evaluation in TR in the interviews.

ID	Position	Synopsis	Domains
A1	Research Management	Evaluation is not the focus of TR at Unit A. Evaluation criteria by the CTSA (publications) are recognized, yet the focus is more towards application and transfer.	
A2	Researcher	Evaluation is a small component in the TR structure at Organization A. Some type of metrics is currently being developed.	
B1	Research Management	Evaluation is only done internally in a loose fashion.	
B2	Researcher	Quality criteria are not touched by TR, but are part of the domains being integrated. TR has led to an increase in awareness of the relevance of these specific quality management issues.	scientific
C1	Research Management	Evaluation criteria are in place and relate mostly to temporal aspects, i.e. accelerating the process of TR. Other criteria relate to economic returns to internal funding. To a lesser extent, academic achievements are relevant as TR criteria.	economic

This specifically applies to TR Units A and B and to a lesser extent to TR Unit C. At these organizations, information is collected in order to inform funding bodies about the research activities, but this data is not used for measuring and influencing the research process:

"We don't have metrics to answer that question, we are beginning to collect metrics, but I think we cannot answer in a way that is useful to you. Up to now there are no metrics." (A1)

Furthermore, the interviewees do not report that the notion or understandings of research quality at the organization has changed compared to that what has previously been practiced. That continuity has been particularly stressed at Orga-niztaion B by a research manager:

"There are multiple sets of oversights associated to quality. Quality and oversight has always been part of clinical research. There is quality inside the laboratory. There are no specific quality processes since the CTSA has been introduced." (B2)

At Organization C, the situation was slightly different because they orient their strategy strictly to the goals of the CTSA program. Thus, they collect information about publications and third party leverage funding for reporting them to the CTSA. Therefore, publications and research output was more important and so is the effort to find and figure out metrics. However, these metrics do not seem to work when it comes to comparisons between the different domains, which the TR Unit C is expected to serve. Therefore, alternative measures have been introduced of which "velocity" seems to be most important:

"How much time does it take to enroll a first participant in clinical trials." (C1)

Such a metric is consistent with the idea that the primary goal of TR is to increase efficiency, which has been articulated by the research manager of TR Unit C.

Furthermore, there seems to be a connection between diversity in sources of funds and the relevance of evaluation criteria. While at TR Units A and B funding seems to be obtained from diverse sources, the reliance of CTSA grants are very pronounced at TR Unit C. This makes them emphasize CTSA evaluation criteria as very important.

4.5 TR beyond the Organization

In this last section, we wanted to know how the organizations react towards the institutional setting, i.e. different societal stake holders like research councils, governmental agencies or patients, in which they are embedded. Regarding the communication strategies and audiences, which ought to be addressed, much heterogeneity could be found. The different organizations address different audiences to which they want to be held accountable.

Table 6: Synopsis of TR beyond organization in the interviews.

ID	Position	Synopsis	Domains
A1	Research Management	Activities at TR Unit A stress the importance of integration with local communities and policy institutions in healthcare. The work with local communities also feeds back on the research agenda at TR Unit A. Interaction with other local researchers is welcome and deemed beneficial. Measures are being taken to ease the interaction with stakeholders from industry by facilitating contractual agreements. Regulation is an important issue.	scientific, social, ethical, economic, policy
A2	Researcher	Communicating the overall mission is perceived as a complex task. There is a perceived lack of local awareness.	scientific, social
B1	Research Management	The focus beyond the organization is mainly aimed at diffusion towards industry and regulatory bodies.	economic, policy
B2	Researcher	The focus of interaction are mainly other CTSA grant holders.	scientific
C1	Research Management	The most relevant actor group is patients. Other important interaction is geared towards policy makers as recipients of useful knowledge. Further important interaction is focused on requirements by regulatory bodies.	ethical, economic, policy

At TR Unit C, expectations of external actors are very important. TR Unit C particularly concentrates on the NIH and more specifically, on the CTSA. Furthermore, the FDA as a potential stakeholder in TR is important because of the increased focus on human subjects. Regulatory bodies such as the FDA are also oriented towards the expectations of patients because they are considered to become a major force due to the upcoming revolution in health care. They are concerned with how the societal environment will react on findings and research output. These expectations towards patients also relate to their own expectations concerning the attempt to make the health system more efficient by performing TR:

> *"What I really hope is: the expense will go down, efficiency will go up, treatment will become better, and health will become better." (C1)*

Contrary to this strong commitment towards external expectations of governmental and funding agencies, at TR Unit A communication and strategy building is oriented towards the local research network and the university. Therefore, it is not the funding agency to which Organization A wants to be hold accountable, it is much more the local researchers who shall be reached and who shall be encouraged "to build a career in clinical research".

TR Unit A therefore focuses much on the internal organization although their findings and tools have been taken up by many other organizations. Moreover, TR Unit A follows an approach that highlights the importance of promoting and enriching their activities by interaction with other organizations. The diffusion of tools and concepts can be explained by the similarity between the local research network at Organization A and the national ecosystem. The demand-oriented approach at TR Unit A seems to produce ideas and tools such as the KL2 program, which can be easily taken up by other organizations.

CONCLUSION

In this report, we aimed at investigating the organizational context and the organizational practices related to TR. We have analyzed three research organizations in the US, which are considered to be key players in TR. Each of them is unique in that they refer to different institutional histories, relations and contexts, but all of these organizations dedicate themselves to the implementation and fostering of TR. These organizations have been identified by relating their activities to different dimensions of TR that we have developed in the first report. We have conducted interviews with actors in all of these three organizations who presented different perceptions of organizational understandings, practices and processes in TR. We have interviewed research managers and researchers in each organization. At TR Unit C, we were only able to talk to a research manager.

The shared understanding of TR is fuzzy but we could localize three dominant ways of understanding TR: (1) from bench to bedside, (2) from bench to public health and (3) the industrialization of research processes. However, these notions of TR are complemented by very specific notions of TR relating to individual roles and positions within an organization. Differences in these perceptions and expressed views thus probably result from different professional backgrounds. It is striking to see that differences between understandings are particularly strong among the research management positions, which can also be observed in the approaches to organize TR.

TR promotes new roles to organize processes and extends responsibilities of research managers. The interviews reveal strong similarities between the current discourse regarding the role of a **"clinician scientist"** and how this role is generally described by our interview partners. Our interviewee at Organization B perceived his role as providing "medical oversight". The clinicians' importance in providing this oversight was emphasized in that context.

Yet, it seemed as if the clinician scientist was not sufficient for orchestrating the complex process and needs further support. This supportive role was expressed in the role of the research **"navigator"** who ensures that research findings are brought to different stages and whose duty is to help researchers to cope with the diverse "pitfalls" of clinical and translational research in such a way that results are not "wasted". Findings and results thereby find their way through the various clips of human subject research such as safety regulation so that *"the ball doesn't get dropped" (B2).* That view also expresses that TR is an insecure process, which needs persons who provide oversight and mentoring. Similar perceptions have been reported in other case studies on TR, pointing to the expectations that TR is generating in that process precisely because of that uncertainty: This *"is because translational research is chronically uncertain: it is necessarily oriented towards a future prospect of some sort of clinically effective outcome"* (Brosnan und Michael 2014: 683).

TR was therefore understood as a managing activity. Research managers in these organizations report that functions have been put in place to guarantee an adequate TR process. Interviewees from research management report that their most important function is providing service to maintain and navigate the process. If TR is understood as a response to problems in research efficiency, it is the task of the research management to enable research by building teams in which every researcher is accompanied by a project manager. While in the case of the research management at TR Unit C, there was a strong emphasis on increasing efficiency in the research process by fostering TR, the management at Organization A insists on understanding TR primarily as a communicative activity to convince researchers of a new type of research and thereby widening up the organizational landscape. This emphasis on research management and its service and support aims at freeing researchers from administrative burden and at providing opportunities for protected time and space to do research.

There are different ways of identifying goals and gaps in TR. Gaps in exploiting research potential have been particularly emphasized at Organization A. Although all of these organizations are funded by the CTSA funding program, they strategically turned to strengthening clinical and translational research before the funding announcement in 2006. That specifically applies to TR Units A and C although they have had very different processes as to how the organizations needed to react to different organizational „challenges". While at TR Unit C there seems to be a continuous strategic process of identification of key gaps and activities which is steered by the CTSA grant managing institution, there is much more bottom-up capacity building at TR Unit A through frequent interactions between stakeholders from different levels of the organizations' hierarchy. These interactions were a major source of identifying goals towards TR.

There exists no clear-cut concept of how to organize TR. However, TR holds the potential for internal capacity building and is motivated by external challenges. Overall, we found two different conceptions of how to deal with TR organizationally that have been expressed by our interviewees.

The first one is to understand TR as a means of local capacity building. Here, the idea is to enhance possibilities for research and to attract further researchers. The primary addressee of such an organizational strategy is the local research community. The organizational strategy is therefore oriented towards the internal research organization and the specific needs of the researchers. This strategy is mainly followed by TR Unit A.

The second one is to understand TR as an expression of a specific external challenge to which the organizations needs to respond. This framing has been presented at TR Unit B where funding instruments and processes are very much oriented towards the goals of the CTSA funding scheme and so is their communicative strategy. Organizationally, TR is primary understood as a means of increasing efficiency.

TR Unit B seems to be in between these two different conceptions by outlining the transparency of the process while at the same time insisting on the insecurity of the whole process which cannot be fully controlled but maintained by mentoring and helping researchers to navigate, in particular, through regulations of clinical trials.

Nonetheless, **commonly shared predominant aspects of how to organize TR** can be delineated. **Services are the backbone of translational organizations.** All organizations show a strong emphasis on services. Service was the most prevalent notion regarding the general role of organizational units while the understandings of the term were quite different. At TR Unit C, service was meant to increase efficiency and to save time and money, service at TR Unit B was more oriented towards helping people navigate through the research process. At TR Unit A, the primary aim was to connect people and to provide opportunities and space for specific kinds of research.

Matching is an important way of enabling research but also of facilitating the research process. Research management is supposed to help researchers find research partners in order to conduct TR. Furthermore, they match researchers with other actors such as project managers, administrators, research nurses or Ph.D. candidates that are considered to be of help within the research process. Matching therefore also aims at relieving researchers from anything but their own research.

Consequently, the **technical infrastructure** also followed the premise to provide service. In all organizations, the role of technical infrastructure as such has been less emphasized by our interview partners. Yet, we find a strong focus on making technical infrastructure more accessible to researchers and clinicians. Diffusion of knowledge about technical infrastructures is seen to be important. Similar to matching actors to each other, the challenge of matching actors to infrastructure is perceived as a major challenge.

Moreover, new kinds of technical infrastructure are in place to support cooperation activities. At TR Unit A, an important piece of technical infrastructure is a directory of researchers and clinicians. This tool is seen as a major asset in bringing actors together and supporting organizing research activities from the ground up. One example is the technical solution of a directory web service solution of Organization A, which could be accessed by its researchers in order to identify interesting cooperation partners within Organization A, but also actors from outside that are interested in a cooperation.

While at Organization A, the role of technical infrastructure has been primarily seen in ways to connect people, at Organization B, the role of technical infrastructure was perceived to make the clinical research process more transparent to "newcomers".

Guidance is another important service. Processes of guidance are to a large extent connected to new roles within an organization, such as "navigators" in the case of TR Unit B. Navigators are responsible for pointing researchers into the "right directions". Research managers are considered to have the same role and therefore a very holistic knowledge regarding the overall challenges involved in taking a discovery into clinical application. At Organization A, this goal is strongly connected to research management activities.

Another aspect of guidance exists at TR Unit B. Multiple persons act as access points, which would then point researchers, especially Ph.D. students into "the right direction", depending on which actual needs are in place. This results in a needs-driven network of interactions between actors. Regardless of which individual was approached, it would point an individual to the relevant next person to speak to on an individual needs-oriented level.

These activities are largely **self-organized activities** that work as a starting point for TR in these organizations, from which then further activities progress. Self-organization aims at increasing flexibility to address and organize ad-hoc challenges such as specific researcher needs. These flexible instruments are counter-balanced by activities with a long-term focus, namely **socialization through education and process integration.**

Process integration mostly addresses streamlining processes of interaction and transfer, especially between the laboratory and the clinic. These involve diffusion of knowledge about quality management criteria between laboratory and the clinic, in order to arrive at a mutual understanding. Process integration is counter-balanced by increased functional differentiation and division of labor within organizations.

Education towards TR is complex and resource-intensive. Education was considered to be important in all organizations. Two different aspects are relevant in this respect. First, there is a focus on enriching education by scientific and technical knowledge between domains, i.e. deepening the understanding of clinical practice in the laboratory and vice versa. Furthermore, education relates to process knowledge. This aspect focuses on providing a solid knowledge about how to transfer research results into the clinic and in some cases into public health and industry.

Socialization is the second main aspect of education in TR. It aims at long-term goals of establishing a critical mass of young researchers and clinicians that are prepared to operate in TR contexts.

Evaluation is a minor issue for most. Most interviewees argue that evaluation only plays a minor role in their organization. At TR Unit C, we found that evaluation criteria are in place. These relate mostly to optimization of processes, especially regarding timing and velocity of processes. Traditional academic criteria, such as publications and grants are in place, but in terms of evaluation of TR, they seem to be less important. The importance of academic criteria such as publications, are mostly related to signaling competence and capabilities in the light of attracting funding. Although there are different metrics in each of the institutions, there is no differentiated set of measures, which is used to control the research process. Rather it seems that evaluation metrics are mainly used to inform the strategy of the different institutions.

Quality Management is path-dependent and knowledge about it has to be diffused more widely. Quality management in TR seems to be highly path-dependent, i.e. TR is highlighting quality management principles and measures that are already established within the organization and accepted in the field. Yet, it seems that TR led to an increase in mutual awareness of quality management criteria, e.g. researchers in laboratories are more aware of quality management criteria in the clinic and vice versa.

Teaching seems to play a major role in stabilizing the diffusion of knowledge about quality criteria. Some interviewees argue that there is still a lot to be done to facilitate a shared and broad understanding of quality in different contexts. One interviewee was very critical towards the current situation, even though the situation has improved through TR, arguing that the academic system should be more geared towards industry practice.

The impact of the institutional environment on the organization of TR differs. External funding programs can influence topics and evaluation criteria. Internal pilot funding enables high-risk projects. TR Unit B and C both provide pilot funding for research projects with high risk. These pilot funding schemes are made available to all of the researchers in the respective local organizations. Yet, the immediate influence of funding on TR research practices is limited. Some interview partners, however, argue that the CTSA program has led to an improvement in process integration. For others, their local research environment is much more important. Their focus thereby rests on making themselves known among the community for recruiting the best people.

Organizing TR involves incorporating the outside world. Regarding the relevance of external forces and external actors we found differences in approach between the organizations.

While at Organization A our interviewees strongly emphasized the focus on the community orientation in TR, our interviewee at Organization C highlighted the innovation problem, which is related to what we have labeled the economic dimension of TR.

At Organization B, it was the implementation problem, which was highlighted as a specific aspect, which differentiates TR from other debates and previous understandings. In both of these cases, industry participation seemed to be likely to shape TR.

All of these organizational units are deeply embedded in a large local research network. Most of these units have co-operations with the medical faculties and hospitals but also many other different institutions. According to our interviewees, all of these organizations wanted to widen their research network. The primary aim is to reach more and different communities.

Moreover, organizations increasingly focus on regulatory challenges and opportunities of transferring knowledge from research into the clinic and beyond. In the course of putting TR into practice, most organizations have installed dedicated teams to this end.

There are differences in the TR debate between US and Germany. The results of our study can be related to the current debate about TR in Germany and to the discussion about the establishment of the Berlin Institute of Health (BIH) in particular. Comparing the debate and the organizational practices in the US we observe differences about which organizational processes are relevant for establishing TR organizations. First, we observed an important aspect that is currently not apparent in Germany but important in the US: That is the aspect of outreach, i.e. the idea that TR does not stop at the boundaries of the organizations but aims at reaching out to increase the awareness and the possibilities for community medicine and public health. That aspect has been pursued and pushed by research funding organizations but community care institutions seem to be also important stakeholders to which the TR organizations want to be held accountable. This aspect of community medicine and public health is not apparent neither in the policy debate nor in debates about the establishment of new organizations in Germany. Furthermore, in the German debate, TR is primarily considered to be an inherent problem of particular organizations which ought to be overcome by cooperation between university and extra university research (Blümel u. a. 2015: 28). Insufficient translation of knowledge was hence framed to be a systemic problem of the German science system (ibid.). Therefore, the foundation of the Health Research Centers financed by the Federal State was set up to address these problems (Abbott 2010; BMBF 2010; Loos u. a. 2014). Contrary to that, organizational practices in the US case studies indicate that TR is treated as a problem of the profession. Therefore, TR is merely oriented towards attracting people to a specific kind of research. Careers in TR shall be strengthened. These differences also account to the role of technical service infrastructure. While in the German debate, technical infrastructure is primarily understood to address organizational problems and to integrate the different organizational practices (Loos u. a. 2014), the role of technical infrastructure plays a limited role in the presented cases. Its most important role is to help researchers across the campuses finding each other (Organization A) or to make different passages in the research process more transparent (Organization B).

We could neither find that evaluation was highlighted in these organizational processes related to TR nor were such processes communicated in the official documents we analyzed for this study. These statements differ from positions we found in the German debate, where problems in clinical research and lack of quality are understood as requiring a stronger emphasis on evaluation and quality management which should be integrated into organizational processes (Deutsche Forschungsgemeinschaft 1999). This focus on quality management has also been emphasized in reforms about university medicine in Germany (Wissenschaftsrat 2004).

6 OUTLOOK

The second report raises a set of questions which could be addressed by further research: Against that background of differences between the political debate in Germany and organizational practices in the US, it would be interesting to investigate organizational practices at key research organizations in Germany, particularly, at newly established organizations such as the Berlin Institute of Health (BIH). Given the organizational heterogeneity in Germany, it is to be expected that organizational profiles also follow different conceptions and expectations as to how to implement TR.

For the BIH, this report might help to address questions of process optimization and evaluation regarding the organization of TR processes. The presented foci on organizational structures and practices at leading US organizations in TR might provide an insightful perspective on how process management of TR could be discussed.

7 BIBLIOGRAPHY

Abbott, A. (2010): Germany plans for a healthy future: National health-research centres take shape. In: *Nature* 468, S. 358–359.

Blümel, C., Gauch, S., Hendriks, B., Krüger, A. K. und Reinhart, M. (2015): In Search of Translational Research: Report on the Development and Current Understanding of a New Terminology in Medical Research and Practice. In: *iFQ-Berichte* (54).

BIH (2015a): Berlin Institute of Health - core-facilities. Available at: *www.bihealth.org/en/research/core-facilities/* (Zugegriffen März 26, 2015).

BIH (2015b): Berlin Institute of Health - funding-programs. Available at: *https://www.bihealth.org/en/academy/programs/* (Zugegriffen März 26, 2015).

BIH (2015c): Berlin Institute of Health - institute. Available at: *www.bihealth.org/en/institute/* (Zugegriffen März 18, 2015).

Blumenberg, H. (1979): *Schiffbruch mit Zuschauer,* Frankfurt am Main: Suhrkamp.

BMBF (2010): Health Research Framework Programme of the Federal Government.

Brosnan, C. und Michael, M. (2014): Enacting the „neuro" in practice: Translational research, adhesion and the promise of porosity. In: *Social Studies of Science* 44 (5), S. 680–700.

Deeke, A. (1995): Experteninterviews – ein methodologisches und forschungspraktisches Problem. In *Experteninterviews in der Arbeitsmarktforschung.Diskussionsbeiträge zu methodischen Fragen und Erfahrungen.* Nürnberg: Institut für Arbeitsmarkt- und Berufsforschung, S 7–22.

Deutsche Forschungsgemeinschaft (1999): *Klinische Forschung: Denkschrift,* Weinheim: Wiley-VCH.

Flick, U. (2010): *Qualitative Sozialforschung – Eine Einführung.,* Hamburg: Rowohlt.

Heller, C. und Melo-Martín, I. (2009): Clinical and Translational Science Awards: Can they increase the efficiency and speed of clinical and translational research? In: *Academic Medicine* 84 (4), S. 424–432.

Loos, S., Albrecht, M., Sander, M. und Schliwen, A. (2014): Forschung und Innovation in der Universitätsmedizin Expertenkommission Forschung und Innovation, hrsg. In: *Studien zum deutschen Innovationssystem* (7-2014), S. 210.

Makropoulos, M. (1998): Modernität als Kontingenzkultur. In G. von Graevenitz und O. Marquard, hrsg *Kontingenz.* Poetik und Hermeneutik. München: Fink, S 55–79.

Vignola-Gagné, E. (2014): Argumentative practices in science, technology and innovation policy: The case of clinician-scientists and translational research. In: *Science and Public Policy* 41 (1), S. 94–106.

Wainwright, S.P., Michael, M. und Williams, C. (2008): Shifting paradigms? Reflections on regenerative medicine, embryonic stem cells and pharmaceuticals. In: *Sociology of Health & Illness* 30 (6), S. 959–974.

Wainwright, S.P., Williams, C., Michael, M., Farsides, B. und Cribb, A. (2006): From bench to bedside? Biomedical scientists' expectations of stem cell science as a future therapy for diabetes. In: *Social Science & Medicine* 63, S. 2052–2064.

Wissenschaftsrat (2004): *Empfehlungen zu forschungs- und lehrförderlichen Strukturen in der Universitätsmedizin,* Berlin: Wissenschaftsrat. Available at: *http://www.wissenschaftsrat.de/download/archiv/5913-04.pdf.*

8 APPENDIX: INTERVIEW FIELD MANUAL

A   Understanding of TR:

- What are your "understandings" of TR? What does TR mean according your experience?
- What is your conception of the future of TR? Which goals does your organization derive from these understandings?
- Do we need a different conception of quality? / What is your conception of quality, does it play a role in TR?

B   Organization setting and key figures: Organizational history?

- How did your specific Translational Research organization evolve? /
  Can you tell us something about the organizational history of XXX?
- What were the rationales in the organizational development?
- Current figures (only if not detected by preliminary analysis)
    – According to your knowledge, how many employees does your organization have?
    – How many are affected – either financially or organizationally by TR activities?
    – How are these activities embedded in the larger organizational structure?
      Is there a specific role of the managing body?
    – Which units are integrated? (not collaborators)
    – How many projects are funded or affected by your organization?

Internal Organization (Resources, processes and practices)

- Which organizational goals guide the management of TR in your institution?
- What processes have been established to maintain and manage these goals?
- What processes have been employed to enhance or stimulate TR related research?
    – Are there any funding instruments?
    – Which criteria guide the selection of projects if any?
- What processes have been employed to monitor and or evaluate TR?
- Are their specific positions and obligations/Responsibilities?
- Are their certain characteristics for the profile of these positions?
- What resources does your organization provide and manage?
    – Which data can be used?
    – What technical resources does your organization provide?
- What role does the technical research infrastructure play for your organization?
    – In what ways was the introduction of these instruments justified?
    – Which organizational processes are addressed?
    – How are these infrastructures embedded in the wider organizational landscape if any?
    – Who uses these instruments and infrastructures?
    – How do researchers and/or practitioners access these infrastructure?
    – How are data maintained and handled by these infrastructures?
- Summarizing the organizational key characteristics, what barriers and enablers for TR
  do you perceive in your organization?

Organizational Environment

- According to your position: Which actors and/or organizations are relevant in TR?
    – Why are cooperations relevant?
    – Which of these institutions are relevant for your organization? What role does the policy environment play?
    – What are the challenges /risks in TR for your organization? Which problems are to be overcome?
    – How do you respond to these challenges organizationally?
    – Are their specific expectations towards your organization?
    – How do you communicate your research and activities in TR accordingly?