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# Clinical research - Fieldwork perspective on Ramp-up management Studies

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## Abstract

This paper is about the logic of problem solving and the production of scientific knowledge through the utilisation of clinical research perspective. Ramp-up effectiveness, productivity, efficiency and organizational excellence are topics that continue to engage research and will continue doing so for years to come. This paper seeks to provide insights into ramp-up management studies through providing an agenda for conducting collaborative clinical research and extend this area by proposing how clinical research could be designed and executed in the Ramp-up management setting.

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## 1. Introduction and motivation

Social researchers and in particular - management researchers call for alternative and novel methods in studying strategies for organizational effectiveness and thus achieving evidence-based-research. Clinical research method bridges between two disciplines: the applied sciences and the social sciences. The ultimate purpose is to develop knowledge that can maximize the effectiveness of practice.

This research strategy call for different methodology research designs, for instance Cheng and McKinley [1] claim that in prescription-driven research, the independent variables should be applicable and that research should always focus on overall organizational performance as dependent variable[1, p. 98].

This paper provides suggestions that clinical research is an inquiry - while time consuming and requires intensive interactions with the studied organizations and their members - shares many similarities with process consultancy, providing mutual value-added contribution and benefits to both the studied organizations and the researcher alike. The explicit discussion presented in this paper could benefit and encourage

aspiring or even active researchers to make scientific progress in ramp-up studies as a spun-out and recognized management field. The primary aim of this paper is thus to offer insights into and guidelines for conducting clinical research and the second aim is to suggest that ramp-up management studies can be created through a deeper and more robust research process, well embedded in the understanding of how basic scientific discovery is achieved and knowledge is created.

The launching of a third international conference on the topic of ramp-up management says something about the journey of maturity the topic is currently undergoing. It can be said that the conference creates visibility of what the field is and where it is going and this methodological focused paper is strongly suited for this purpose.

### 1.1. Background

To advance ramp-up management studies, a growing number of scholars are engaged in empirical and conceptual studies. (See for instance[2]–[5]). In the previous years some scholars have investigated this area although briefly, most notably Terwiesch with some contributions made in the early

2000 [6]–[8] addressing ramp-up production before changing to healthcare and innovation management. Other noticeable ramp-up management contributions can be found in [9], [10]. Nonetheless, this research topic remains adequately represented throughout conference proceedings, dissertations and working papers [11]–[14]. Whether these sources have strong academic contribution is highly questionable. For instance and to a great surprise to the author, a closer examination of two dissertations [11], [14] reveal that their respective authors use the terms *methodology* and *method* interchangeably or having different meanings. Other studies reveal serious and numerous deep flaws. For instance a working paper [12] on ramp-up performance - cited 3 times according to Google Scholar - presents a time series analysis despite the fact that the paper fails to produce any narrative of leading or lagging effects from the available data. Furthermore, that very same data is treated as normally distributed with constant variance, although some data are truncated and some are binary. This should by no means be seen as a standalone single case but rather a commonly deeply flawed misuse of statistical measures in many scientific disciplines [15]. According to Jeff Leek “*The problem is not that people use P-values poorly it is that the vast majority of data analysis is not performed by people properly trained to perform data analysis*”[16].

There is therefore an essential need to reconsider viable strategies for positioning and advancing ramp-up studies as a solid and recognised management field with robust emphasis on *management* at its extensive level. This focus has numerous potential benefits for contributions through research methodology for ramp-up management, and this paper takes on this task through defining and illustrating particular benefits and challenges of conducting clinical management research.

## 2. Research strategy – Clinical research

The epistemological aspects of any social science researcher are almost infinite in varieties in acquiring knowledge. We are set to ask what the problem is in the management of the Ramp-up process and venture on a study. The formulation of the research question is essential because it is linked to a number of theoretical and methodological choices. The research strategy becomes the methodological connection between the research philosophy and the following strategy in data collection methods and analyses [17].

Clinical research is defined by Cohen & Manion as “*a small-scale intervention in the functioning of the real world and a close examination of the effects of such an intervention*”[18], this research strategy is a choice that - based on research objectives - guides the researcher’s work and determines the approach taken. In the case of clinical research the objectives are directed towards acting, intervening and solving immediate practical problems with functional applications and theory testing which might direct practice [19], [20].

This strategy is in contrast with basic research, where the researcher is directed towards the acquisition of new

knowledge, motivated by intellectual curiosity, with limited or no reference to the potential practical use of the results.

### 2.1. Scientific knowledge production

Academic studies are reflected in two important characteristics or traditions – how we see the nature of the world, i.e. ontology and how knowledge of this nature is acquired, i.e. epistemology. The majority of the management researches – though not always explicitly mentioned in scholarly publications, are imbedded within three perspectives – realism, phenomenology and constructivism:

- The perspective of realism is based on the fundamental assumption that reality exist in a specific and in principal unambiguous manner. Realities are “out there” independently of the researcher’s knowledge of it. From this perspective the intention of the researcher is to capture the phenomenon of interest and to describe them in a settled manner and as accurately, clearly and objectively as possible [21]. One objective might be to identify and explain cause-and-effect relationships between different phenomena which in this context are often defined as variables.
- The other perspective is of phenomenology; which focuses instead of subjective actions, especially with regard to the meaning given to active actions. The researcher’s objective in this perspective is not to identify and explain causal relationships but to interpret, understand and typify subjective universes of meaning.[21]
- The assumption that reality is continuously constructed through social processes and interactions fits within the constructivist approach. Through this perspective the job of the researcher is an attempt to capture the complexity that characterized the phenomena that interest him/her and describe it [21], [22].

Other concepts and philosophies presented in figure 1 include the instrumentalist perspective where the goal appears to be identical with that of the clinical research method; namely helping predict events and solve problems through scientific theories as instruments; though I will argue that not only a research problem but also a practical problem is attempted solved through theory. Thus the instrumentalist’s epistemic stance while still rejecting the scientific realism – tend to merge closer to the truth and move closer to foundationalism concept. This is in line with what Manfred Kets de Vries and Edgar Schein agree on, namely that the clinical approach both scholars use is more empirical than that of the positivist statistical approach; not only is the clinical approach more empirical in getting closer to the data, but the acknowledgement by both scholars that all the activities conducted are an intervention, and thereby data generating [23].

Although foundationalism can be seen as a version of instrumentalism, here science is believed to evolve towards truth and rejecting any statement of reality by unobservable

entities [24]. The research within the foundationalism perspective emphasizes on data-gathering where scientific knowledge is developed inductively.

		Epistemology	
		Science gets closer and closer to the truth?	
		Yes	No
Ontology Scientific theories represent reality?	Yes	Theory progresses by capturing real phenomena <b>REALISM</b>	Theory exploits core assumptions <b>KUHN-ISM</b>
	No	Theories emerge from data <b>FOUNDATIONALISM</b>	Theories compete to solve research problems <b>INSTRUMENTALISM</b>

Figure 1 Matrix of Philosophy of Science Approaches and Associated Logics of Action [25]

2.2. Objectivity and Subjectivity in Clinical research

Whilst on the notion of managing subjectivity, in the traditional sense the realist scientific research concerns itself with minimizing it altogether, as well as any contextual element; the ideal knowledge is therefore objective in the sense that is concerned with reflecting the object of the study as accurately as possible; therefore it can be said that ontology takes superiority over epistemology. This is obviously in strong contrast with both phenomenology and constructivism, both of which contemplate the notion of subjectivity to be the condition of the study process but neither can or should be ignored.

The critical point of the social scientist when applying clinical research approach is being close to the data source, because one cannot understand a social system construct - regardless of the levels be it individual, departmental, or at the overall organizational level - without becoming involved with it, even trying to influence it and change it. According to Schein being able to help people has far more appeal than sitting in a laboratory or massaging numbers.[26]

Oftentimes researchers try to maintain an illusion of objectivity, which in standard practice usually means detachment. Though the moment an epistemic researcher – clinical in particular enters an organization, he/she disturbs the system. According to Kets de Vries, instead of fighting that result, he suggests to use the data that comes with it. *Not taking account of the clinical dimension — the fantasies that people project on you, and your own fantasies in this interpersonal playing field — leads to an impoverishment of the research effort. The natural science model tends to linger on in the social sciences.* [26, p. 17]. Thus it can be perceived that knowledge construction from clinical inquiry is a result of the researcher *not* stepping outside and pretending to see ‘everything from nowhere’ but being an integral part of the study. [27]

2.3. Developing research questions

Different kinds of knowledge emerge when posing ‘how’ and ‘why’ research questions. The ‘how’ questions lead to project description that focus on context, while ‘why’ questions typically seek to identify general causal patterns (realism) that apply to more than just a specific context [21]. The ‘how’ research question is more likely to be answered by the use of more exploratory approach in reaching an understanding of the phenomena (constructivism or phenomenology); this approach involves less structured interviews, focus groups, documents studies or participant observation. In contrast, the ‘why’ research issue can be addressed by analysing valuable data that is generated through the use of structured interview guide or structured observation. (See table 2 for more detailed explanation).

Much of the existing ramp-up management research published in OR journals begins with hypothesis or an outcome assumption which is in line with quantitative inquiry, whereas qualitative research starts with initial question or academic curiosity which Carpenter & Creswell further elaborate on by pointing out that the qualitative questions are ‘evolving’ processes. [28]. Other scholars [29] distinguish research questions with different functions or research outcome: exploratory, explanatory, descriptive, and emancipatory. See table 1 for detailed summery.

Table 1 Matching Research Questions and Purpose [29]

Purpose of the study	General research questions
<b>Exploratory</b> To investigate little-understood phenomena. To identify or discover important categories of meaning. To generate hypotheses for further research	What is happening in this social setting? What are the patterns, meanings of categories for the participants? How are these patterns linked with one another?
<b>Explanatory</b> To explain the patterns related to the phenomenon in question. To identify plausible relationships shaping the phenomenon	What events, beliefs, attitudes, or policies shape this phenomenon? How do these forces interact to result in the phenomenon?
<b>Descriptive</b> To document and describe the phenomenon of interest	What are the relevant actions, events, beliefs, attitudes, and social structures and processes occurring in this phenomenon?
<b>Emancipatory</b> To create opportunities and the will to engage in social action	How do participants problematize their circumstances and take positive social action?

Table 2. Implications of Philosophies of Science for Organizing [25]

Key focus areas	Realist	Foundationalist	Instrumentalist
Characteristic goal and logic of action	Discover fundamental structure of the universe through pure research	Find hidden patterns in data through induction	Truth-independent <i>problem solving</i>
Types of knowledge produced	Scientific breakthroughs, irrespective of commercial implications	Unanticipated discovery of patterns in data from which new theory can be formulated	Pragmatic solutions to theoretically defined problems
Indicators of progress	Causal expression of relationships among theoretical terms; verification of causal relations among terms	Unexpected but replicable correlations indicative of new discoveries; counterintuitive derivations from first principles	Greater number of important problems solved
Characteristic method	Mathematical model building	Data mining	Those that are considered historically and socially legitimate
Illustrative organizing	Self-governing community	Cadre of experts	Cross-field, focused collaboration

### 3. How to conduct clinical research

Conducting clinical research can best be described by Suddaby's grounded theory perspective, which states that it's "most suited to efforts to understand the process by which actors construct meaning out of intersubjective experience" [30, p. 634]. Throughout extended studies of Ramp-up management over a period of two and a half years, the researcher learned most from working with their company colleagues and interacting with their supervisor about the organization. During the first 14-16 months daily involvement are expected and encouraged with the project divisions responsible for conducting the myriad of activities related to the preparation, planning and Ramp-up project management, which makes the researcher realize what initiating production mean in the distinction between theory and organizational realities. It expanded the researcher's skills as an ethnographic investigator and has the potentials of teaching the researcher the ins-and-outs of active listening, understanding, and identification of organizational life themes. It also gives the researcher a microscope through which to observe individual and organizational change process [23].

The clinical researcher has to deal with many levels in the organizational system, each with its own theoretical lenses and explanation model. It is advised that when conducting an intervention, it is paramount to pay close attention to the power network, because any suggestions of process modifications, resulting from some form of organizational analysis must be extended to the key players or a change agent identified in the organization involved. [26], [31].

Researchers attempted occasionally to change organizations starting at the middle- or lower-management levels, though quickly discovered that while it's sometimes possible, it's usually more complicated and time consuming.[23]

Numerous projects are studied during their Ramp-up process development in the organization; this is part of an ongoing effort in trying to distinguish successful from unsuccessful process performances. In doing so, the researcher relates the behavior of the blue collar employee with the behavior of the skilled workers, and that of the manager and suppliers groups, and how those influence the organization. The researcher makes note on their forms of interactions. Some issues appeared during the researcher's presence in formal meetings, GtG, and less formal settings

such as Friday's joint breakfast gatherings, Christmas and annual parties etc.

The given identity of the researcher in the organization is dynamic, in the sense that what the expectations that the various actors had of him/her during their early visits, are not the same 30 months later. The researcher reflects on the manufacturing site and office layouts, the lunch seating preferences different groups had and what the significance of that was? He/she wonders about the major cultural values of the people who had been with the company for 10 or 25 year+. What kind of organizational culture and values were they now experiencing? Questions are asked about employees' hopes for the future, perceptions of recent structural changes, etc. As a result, in a short amount of time, he/she ultimately receives a wealth of insights — a substantial part of it is non-verbal and should be noted during or immediately after it occurred in a log. As the researcher reflects on the impressions he/she has of people and situations, many associations can be triggered. The researcher's task then becomes withdrawing back to the university and conducting some thematic analysis with the goal of identifying the major themes that permeated the Ramp-up organizational units.

### 4. Challenges when conducting clinical research

As clinical researchers we have a systemic view and perceive people in context. We often find ourselves in situations where people in our studied companies approach us with unrealistic expectations. According to Edgar Schein, the hardest part of the clinical researcher's work is 'to see beyond individual dynamics into group and systemic dynamics'. Furthermore, there are two ways the organization perceives an invited clinical researcher and neither of which is attractive:

Fundamentally speaking, one group of people perceives the researcher as the Messiah and expects him/her to have an instantaneous magical problem solving recipe to their lengthy Ramp-up time-span, i.e. 'the problem' you've been invited to unravel.

The other group escape altogether and they appear to be scared, and suspicious of the presence of the researcher, perhaps even look at the researcher's computer screen while passing by and ask into what's being written down on the pad. At some point refuse to talk to the researcher completely, because they inform the resresearcher that they

suspect him/her for being a spy for the senior management team. Why else senior executives take precious time out of their busy calendar to sit with the researcher, show him/her around the production site and join his/her table during lunch breaks. In a way this raises a different yet another problem.

It has been proven that having a broader view is a valuable capability. As researchers, we can come to terms with the situational dictates and pressures put on, expressed and most probably felt by the studied organizational members [32]. It is paramount to always try to take these challenges seriously and demystify our presence in the organization. For instance the author leaves her glasses at home and uses contact-lenses instead, in addition to wearing flat shoes and minimal make-up; it is encouraged to remember as many names as possible and interact with people from different layers in the organization; ask about their day, the jubilee of one of their colleagues or their plans with their families for the holidays.

This strategy is beneficial because it breaks down the barriers; build up trust which helps the researcher gain access to essential data about Ramp-up challenges for sufficient analysis.

### 5. The value of theory in clinical research

The role of theory in conducting clinical research is paramount. In clinical research we use theory to generalize beyond the specific situation and to make predictions about what should happen in other similar situations. The validity of these forecasts can be tested through triangulation.

Depending on how we choose theory in conducting clinical research, it can serve several purposes: it can summarize the knowledge and give meaning to isolated empirical findings, it can provide framework for the phenomena studied and it is also used to explain observable events by showing how variables are related; though *not* according to how well they represent 'actual' causal processes. This allows the researcher to predict what might occur giving a set of specific circumstances. [19], [33]. Schein, however has a different perception of the value of theory: he believes that as clinical researchers, we ought to be able to explore the revealed data without recourse to any particular formal theory or model, to let the data lead the researcher, so to speak [34]. This statement seems to suggest that there are fewer rules and procedures for clinical research to follow, though subsequently more work to be done.

### 6. Dissemination of and contribution of clinical work

The refocus of ramp-up management as a managerial field must have an impact on the research methodologies chosen by new as well as established researchers alike. The field has a strong relationship to the practical world and it is neither identifiable with innovation management nor with operations management, but it should be approached as a single standalone in between these two fields. It cannot be explained and theorized by purely deductive approaches; because the human behavior should not be ignored neither should the social dynamics existing in the organization with direct effects on normative modeling be dismissed.

The studied organization, its participating employees and the academic setting provided basis for this paper and in return the researcher offers deeper and viable understanding of the clinical research approach and more insights into knowledge co-creating within Ramp-up management. For the scholarly community, this paper provides new directions for ramp-up management research, strengthens the clinical research method through providing a comprehensive foundation within the philosophy of science and for empirical work and dissemination.

The scholarly literature has oftentimes sharp, outdated and unproductive separation between methods – being either qualitative or quantitative, and this view is still prevalent [35]. Instead social science should steer away from being a methodology driven and instead focuses on being problem driven in the sense that it employs these methods that's for any given scientific curiosity best help answers the research question at hand. Often times a combination of qualitative and quantitative methods will do the task best.

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