Dynamic In-Capabilities: The Paradox of Routines in the Ecology of Complex Innovation[i]

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Abstract

In this chapter we identify the routines enacted in complex innovation processes, specifically during early phase drug development projects. We consider how routines performed locally are nested in, and entwined with, an organizational ecology constituted by multiple stakeholders and an innovation process characterized by 'unknowability'. Drawing from an extensive study of eleven innovation projects in biotechnology firms, we identify strategic routines - protecting, evolving and resourcing the science - that are enacted across organizations in order to develop new therapeutics. These constitute the overarching capabilities that all biotechnology firms must develop if they are to survive in the ecology. We then identify three performative routines enacted within specific projects in these firms as hedging, compressing and reprioritizing. We characterize these routines as 'guesswork' and show how they entail a pragmatic response to the unknowability that has to be 'managed' in this setting. These performative routines reflect the influence and pressures generated by other organizations in the ecology – notably, investors and potential investors, who demand to see swift progress and positive outcomes, and regulatory authorities that prescribe drug development as a linear process. This fosters a regime whereby guesswork routines at the project level simultaneously acquiesce to institutional pressures within the project ecology to demonstrate progress, yet may practically hinder the innovation process.

1. Introduction

A key aspect of organizational knowledge is constituted by routines (Dosi et al., 2008), defined as the 'repetitive, recognizable patterns of interdependent actions, carried out by multiple actors' (Feldman and Pentland, 2003; Cohen et al, 1996). Routines, it is

argued, help to create a 'truce' between conflicting parties and ideas because they establish the implicit rules about how to handle both the social (e.g., governance structures) and the physical (e.g., technological development) worlds (Dosi et al., 2008). Early work on routines suggested that they invoke a degree of rigidity and inertia that seems counterproductive in firms where the focus is on continuous innovation. More recently, however, research on routines, from both dynamic capabilities and practice-theoretical streams (see Parmigiani and Howard-Grenville, 2011, for a review), has emphasized their important role in promoting change as well as stability (Turner and Rindova, 2012). For example, more generative models of 'routine dynamics' (Feldman and Pentland, 2008; Pentland, et al. 2012) highlight the importance of routines for *all* organizations, including those whose main business is innovation. Moreover, even 'routine routines' have been shown to exhibit considerable variation (Howard-Grenville, 2005; Pentland et al., 2011).

This research suggests that routines are important to study in firms whose core capability rests on their ability to innovate. Such firms include, for example, biotechnology firms – our main focus here - whose main (often only) work is to carry out projects that lead, ultimately, to the generation on new products and services. Quite what the relationship is between organizational routines and innovation processes at the level of projects is still not well understood, however. Bessant et al. (2011) argue that the 'trick' for those firms that are in the business of innovation is to develop routines that allow for regular innovative activity. However, they also note a tension in that, the more innovation practices are routinized, the more difficult it is for firms to cope with the unexpected, and capitalize on emergent outcomes (cf. Obstfeld, 2012). Their solution is to suggest that such firms need to simultaneously follow routines, and

acquire the ability to review their routines, and change them as required. However, while this normative idea seems plausible, we know little about what routines actually occur in innovation contexts and with what consequences. In this chapter, then, we address the following research question:

1. What are the routines that are enacted in organizations, in particular biotechnology firms, engaged in innovation processes?

In addition, innovation processes are complex; it is "through local interactions among people and technologies that diverse and novel outcomes emerge" (Garud et al, 2011: 737). Interactions are unpredictable, so organizations engaged in innovation must handle very high degrees of uncertainty. Often they rely on interactions with other organizations as well for knowledge and resources (Swan et al, 2007; Grabher, 2004). As Grabher (2004: 1491) notes; "essential processes of creating and sedimenting knowledge accrue at the interface between projects and the organizations, communities, and networks in and through which projects operate". Most innovation projects unfold, then, within a complex 'ecology' of organizations that generates significant inter-dependencies (Dougherty and Dunne, 2011; Grabher, 2002; Grabher, 2004).

For biotechnology firms, for example, this ecology consists of multiple stakeholders, with different agendas: investors who want to see fast, high returns; clinicians who choose whether or not to enroll patients into trials; regulators who set rules to ensure safety, and so forth. Thus organizational routines for developing innovation need to be understood as nested within this wider ecology. In relation to the regulatory approval process, for example, this depicts drug development as if it follows a linear progression through distinct, timed, phases and stage-gates that move drugs in development

through clinical trials to commercialization (see Figure 1). These institutionalized rules are translated at firm-level into a set of processes that organize the firm's portfolio of products in development into a series of discrete projects, each with its own project management schedule and plan laid out according to regulatory approvals milestones. Together these projects constitute the firm's development 'pipeline' (see Figure 2 for an example). However, in this complex innovation ecology, project teams encounter a great many unknowns because they are dealing with science that is still emerging and they have to interact with many potential stakeholders within the ecology (Swan et al, 2010; Dougherty and Dunne, 2012). Development processes 'on the ground' are therefore far from linear and predictable (Sthyre et al, 2010; Newell et al, 2008). How do those engaged in these projects practically cope with all of these unknowns and develop routines that can progress development while, at the same time, responding to institutionalized regulations that track a linear path to commercialization?

INSERT FIGURES 1 and 2 NEAR HERE

To answer such questions, and to better understand the dynamics through which routines operate in relation to complex innovation processes, requires an ecological approach that shows how being embedded in an ecology of interacting organizations shapes the enactment of routines at lower levels of project work. Previous theory on routines recognizes that they rely for their development on existing knowledge and repetition across contexts (Eisenhardt and Martin, 2000) and are therefore embedded in, and may even change, wider institutionalised practices. However, historically routines have been treated as a more or less coherent 'entities' that act as 'building blocks' of organizations capabilities. Such a view "has slowed efforts to bridge micro and macro understandings of routines and capabilities" (Salvato and Rerup, 2011: 469).

More recently, the process/practice theoretical stream on routines has made great inroads into better understanding their dynamics, evolution and generative effects (e.g. Feldman and Orlikowski, 2011; Dionysiou and Tsoukas, 2013). However, usually empirical work in this stream studies single, or occasionally multiple, routines in *single* organizations. In contrast, the 'ecology of routines' – the way they are intertwined, both within organizations, and with broader communities of organizations - is rarely examined (Salvato and Rerup, 2011). Hence, following from our first research question we ask:

2. How does the organizational ecology shape these routines and how do these routines shape the innovation process?

Our analysis identifies the performative routines at the project level that enable the team to cope with the unknowns that they face when innovating whilst adhering to institutional orders and the demands placed by other stakeholders in the project ecology, importantly, investor and potential-investor expectations. Our findings show that these performative routines can be characterized as hedging, compressing or re-prioritizing and, more generally, that they are all enacted as forms of, what we refer to as, 'guesswork' in the face of unknowability. Paradoxically, the guesswork routines, which are targeted at making progress while sustaining the order set by the wider ecology (the pipeline), often compromise the innovation process. Our contribution, then, is to show how performative routines, enacted locally in projects to deal with constant change and uncertainty reinforce, rather than challenge the institutionalized order and encourage practical actions that appear counterproductive to innovation processes. Thus, understanding the role of performative routines in generating both

change and stability in complex innovation settings is not only important but also requires an understanding of the nested nature of the project and the firm within a wider, highly regulated and market-sensitive, ecology of organizations. Next we discuss critical facets of complex innovation contexts, and follow this with an overview of a practice based view of routines, which we followed in our analysis.

2. Complex Innovation Within a Project Ecology

Recently, Dougherty and Dunne (2011; 2012) have contrasted *complicated* with *complex* innovation, suggesting that, whilst similar, the latter needs to be theorized as a distinctive form of innovation and poses particular management challenges (Dougherty and Dunne, 2011; Snowden and Boone, 2007). Both forms of innovation entail a highly interactive process comprising multiple actors and organizations drawing together distributed specialist knowledge through a fairly lengthy development process. A good example of complicated innovation is the development of an aircraft, which typically takes several years, involves multiple organizations and stakeholders, including standards-setting bodies, and is accomplished by dividing the work into parts (e.g. parts of the aircraft) and then assembling the parts together. In these settings innovation is complicated but problem parameters are more or less known. In complex innovation processes, by contrast (e.g. new drug development), problem parameters and cause-effect relationships (e.g. the underlying science) are largely unknown or still being discovered (Dougherty and Dunne, 2011, Styhre, 2006). Dougherty and Dunne (2012: 1467) summarize the characteristics of complex innovation as: "nonlinearity, unpredictable interdependencies and the emergence of knowledge over long periods of time as innovators search the 'unknown unknowns". This means that complexity is

epistemic (how do we know what we don't yet know?) not just computational (how do we calculate solutions to known problems?). Moreover, as a result of 'unpredictable interdependencies', unanticipated changes can occur at any step and can have significant and immediate effects on the development process. Complex innovation processes typically span many years and require significant financial investment, without any guarantee that a new idea will eventually turn into a commercial product or service, which is different to complicated innovation projects where costs may well overrun but a final product/service will be developed. Managers must therefore cope with paths to innovation that are not smooth and linear but uneven, iterative and often unpredictable, with a very high risk of failure (Styhre et al, 2010; Obstfeld, 2012; Newell et al, 2008).

Put simply, the development of entirely new drugs requires different scientific specialists, typically spanning public and private sectors, to work closely together in order to identify 'targets' (e.g. proteins) for possible diseases, as well as molecules, or chemical compounds, that might interact with the 'target' for therapeutic effects. This specialist scientific knowledge needs to be brought together with commercial, management and product development expertise if the financial and other resources needed to progress development are to be secured. In the early phases of drug development biotechnology firms are typically where this occurs, with the majority of these being small firms set up by those with specialist scientific knowledge in specific areas deemed to be exploitable (Swan et al, 2007).

In the early phases then, innovation is typically organized around projects led by biotechnology firms, which have been initiated to exploit some new area of science that appears to have commercial potential (Pisano, 2006; Gittelman, 2007). These firms are

located within an ecology comprising multiple stakeholders and high levels of inter-dependencies (Newell et al., 2008). For example, these small firms are usually highly resource constrained and require private investment to resource projects. They often rely on partnering arrangements with larger pharmaceutical firms to take new products to market should the results from early development be promising. Senior managers in biotechnology firms are responsible for developing and overseeing a portfolio of development projects, indicated in their development 'pipeline', which they use to attract investment and collaboration for ongoing and future projects. During development a series of increasingly large human clinical trials are required in order to test safety and efficacy through to commercialization. Given their limited internal resources, biotechnology firms usually work with an array of other organizations and stakeholders (clinical research sites and hospitals, specialist clinical research organizations (CROs) and manufacturing firms) in order to perform such trials. This all occurs within a highly regulated institutional context, which enforces strict requirements and a sequential ordering process for approvals and data reporting (e.g., the FDA in the USA).

The characteristics of the ecology and the challenges this poses for those managing complex innovation processes are well-recognized, but the ways in which these challenges are routinely handled in practice is not at all well understood (Dougherty and Dunne, 2012; Hodgson and Cicmil, 2006). The role of routines in this context has not been much examined, perhaps because the very idea of routines has seemed at odds with the characteristics of complex innovation (Obstfeld, 2012). Nevertheless, as we shall see, routines are important because they make this unpredictable innovation process seems as if it were predictable.

3. Managing Complex Innovation and Routines

Dougherty and Dunne (2011) have begun to theorize the ways in which the ecology of complex innovation processes 'should' be organized. Using a social practice lens, albeit not the language of routines, their propositional model for organizing complex innovation ecologies suggests that certain practices need to be performed repeatedly and on an ongoing basis in order to handle the degree of complexity entailed. Their study thus complements recent work on routines in that they take a 'knowledge as practice' view (cf. Feldman and Orlikowski, 2011; Cook and Brown, 1999). Their model describes three sets of social practices necessary to foster and handle the ongoing collaboration and emergence necessary for innovation in the ecology; orchestrating knowledge capabilities (to support emergence and new product development efforts); enabling ongoing strategizing (to frame and direct new development efforts over time) and; developing public policy (to ensure public welfare and safety). These practices, they argue, should be enacted at the level of the ecology in order to counter the 'natural' tendency to focus on single-firm performance and on short-term, incremental innovations and benefits. From a routines perspective, we might argue that these constitute a capabilities view of routines (Winter, 2000) at the ecology level to explain the influences on sector performance i.e. as 'whole' entities (Rerup and Feldman, 2011).

Dougherty and Dunne's analysis is helpful in sensitizing us to the complex, and differently oriented, range of social practices needed at the level of an ecology to foster and sustain complex innovation. The model also alerts us to the need to understand innovation practices at project-level as nested within (cf. Schatzki et al, 2001), and simultaneously facing, a broader array of social and institutional practices; for example,

around the regulation of science or the control of intellectual property (IP) and financing (Grabher, 2002, 2004). However, what are not explained, or studied, are the routines that are actually practiced within organizations developing innovation projects to handle the ongoing complexity and emergence they face (Feldman, 2000), or the ways in which these routines are intertwined with the broader ecology of organizations (our focal research questions). As Feldman (2000: 622) highlights, "Ostensive routines may be devoid of active thinking, but routines enacted by people in organizations inevitably involve a range of actions, behaviours, thinking, and feeling". It is these repeated thinking/feeling *actions* that constitute the performative routines that allow adaptation to change. This distinction between ostensive and performative alerts us to the role of agency and the messiness of day-to-day organizing, which is likely to be extreme within the context of complex innovation projects, and which underpins practice-based perspectives on routines (Parmigiani and Howard-Grenville, 2011). Here, then, we are interested, in particular, in identifying what performative routines are practiced within organizations developing innovation projects in order to for drug development to progress in the face of ongoing unknowability. Given the nature of complex innovation, we want to develop, moreover, an ecological perspective that is sensitive to the ways in which performative routines are entwined with wider, institutionalised practices in the ecology. In developing this perspective we are in part responding to Dougherty and Dunne (2011: 1221) who note "It is necessary to articulate the actual day-to-day process of complex learning and innovation in particular projects so that the ecologies can be organized to directly support these activities".

Existing literature suggests that, even in complex innovation contexts where it is pretty hard to plan anything, traditional project management tools/artifacts are used nonetheless to organize activities (Sheremata, 2000; Andriopous and Lewis, 2009; Styhre, 2006). For example, within biotechnology firms, it is a well-established practice in the industry as a whole for senior management to produce (typically in a Gantt chart) an overview of the firm's pipeline for the various products in development (as per, Figure 2). This pipeline is routinely drawn upon to internally to plan development work at project level as well as to demonstrate externally to potential investors when they might expect different products to become commercially viable (Styhre et al., 2010). Any firm's pipeline is premised on development moving sequentially through the various stage gates laid out in the regulatory approvals process (e.g. Phase I to IV clinical trials – e.g. Figure 1). Here lies a puzzle. The pipeline, and specific project management plans that follow, prescribe a linear sequencing of activities and knowledge flows, and planning to pre-defined targets, timelines, budgets and outcomes. They are based on an assumption that most activities can be predicted with a fair degree of certainty, so that they can be planned in advance and smoothly executed. Whilst these artifacts are certainly developed and applied by project teams, they do not accommodate the ongoing emergence they actually experience (Hodgson and Cicmil, 2006; Schreyogg and Sydow, 2010; Obstfeld, 2012). They give us little clue, then, about the performative routines actually practiced by project teams managing innovation processes. Given that the pipeline is common parlance and 'currency' in development, however, and that it (and associated project management tools) tracks a regulatory process, they do suggest though that performative routines may be shaped in a very important way by institutionalized, ecology-level practices.

Our empirical study that follows therefore examines how senior management and project teams in biotechnology firms engage in routines to manage (or cope with) the unknowability that characterizes such projects whilst simultaneously following the linear path to innovation inscribed in development pipelines and approvals processes. Considering how routines are enacted at project level can contribute to theory on the organization and management of complex innovation because it allows us to move between more normative accounts of what 'should' be done (e.g. Dougherty and Dunne, 2011; Pisano, 2006) to an analysis of how things are actually done, why and with what possible consequences. It also allows us to consider the ways in which performative routines at the local level of projects are entwined with, the broader ecology of interacting organizations and institutions within which they are nested.

4. Empirical Study

We use data collected from a longitudinal study of eleven projects entailing the early phase development of novel therapeutics in nine different firms (in two firms we followed two distinct projects). Firms were chosen to include both small and medium-sized biotechnology companies, facilitating a multi-case design that allowed us to provide robust insights about how routines are managed in the context of a complex innovation process (Eisenhardt, 1989). From the firms that we gained access to, we selected projects that were in Phase I clinical trials aimed at establishing safety (although basic science on the underlying mechanisms was still being carried out) and planned to begin Phase II safety and efficacy trials within the next twelve months. This is a point where 'epistemic uncertainty' (Grandori, 2010) is very pronounced and where commercial and scientific pressures come together.

A key criterion for selecting projects was that we would be provided with excellent access to key projects and stakeholders, allowing us to conduct detailed longitudinal research (including observation of project meetings and access to documentation) so that we could to capture the dynamics of routines and how these were influencing ongoing innovation processes (Feldman and Pentland, 2008). Access was key because drug development is notoriously secretive (and results can be shareholder sensitive). This meant negotiating legal confidentiality agreements that preclude us from revealing any details of the underlying science or firm identifiers.

We also needed to choose a period of time over which to observe and document practices that would bring 'the everyday activity of organizing' (Feldman and Orlikowski, 2011) into focus and allow us to link this to innovation processes. In drug development, this poses special problems - it takes around eight-to-fifteen years to commercialize drugs and upwards of 85% of projects fail (Hay et al, 2014) so it is practically impossible to do a full live 'tracer' study. Hence we chose development projects that had been 'live' for at least two years and followed these projects over a thirty-month period. This allowed our longitudinal analysis to include both historic and live processes (Pettigrew, 1990).

4.1 Data collection and analysis

Data collection techniques comprised observations, interviews and documentary analyses. Two of the authors visited each case site four-to-five times over a thirty-month period. The first visit to each company involved interviews with senior VPs, often including the CEO, and was focused on becoming familiar with the processes that were used in each company to manage drug development (Turner and Rindova, 2012), as well as to identify specific projects that were currently ongoing and that met our

criteria. During subsequent visits, we focused on the particular projects we had identified, interviewing key actors in these projects, as well as undertaking repeat interviews, where possible, with senior staff. In this phase, our focus was on collecting systematic data on the way those involved in managing projects in this particular industry adapted to changing circumstances (the 'systemization stage' of data collection, as described by Turner and Rindova, 2012). Visits were arranged so that we could observe project-team meetings but during visits we also had the opportunity to observe informal meetings held on an as-needed basis to address project issues. We were provided access to project documents (e.g., company reports, minutes of meetings, trials plans and product development schedules, and drug pipelines) and also conducted repeat interviews with project team members (typically interviewing the same person on two-to-four different occasions). We conducted a minimum of fourteen interviews and observed four formal project team meetings in each case. When interviewing, we used the narrative interview convention (Jovchelovitch and Bauer, 2000), providing a time frame for structuring the interview ('Tell me what has happened in the project, both successes and failures and any unanticipated events, since we last met') and then encouraging uninterrupted storytelling. Each interview was recorded and transcribed verbatim. Detailed notes were taken during (and completed after) observed meetings.

From the first round of familiarization interviews, plus data we had on the process of drug development more broadly (e.g. from the FDA website), we identified the routines (repeated patterns of actions) that were common across our case organizations. To do this we deployed grounded theory analytical techniques used to good effect previously (Gioa et al, 2010). Specifically, we began, using open coding, by identifying across all our first phase interviews and documents actions that were taken to manage the

development process, which related to, for example, the requirements of the regulatory process. We then organized our data to draw together any actions used repeatedly across all eleven cases, grouped as 'first order codes'. From these first-order codes we clustered these recurring activities into three categories (second-order themes) that we refer to as the 'strategic routines' used in the ecology (to distinguish them from routines performed locally within specific projects). These strategic routines are organizational-level practices that had been established to protect, evolve and resource the science that formed the basis of the drugs in development (see Table 1). Although unusual for process/practice studies (which usually prefer to build from micro-analysis of routines in single organizations), we were interested at this stage in identifying common, repeated patterns of actions associated with drug development in the ecology, so this method of identifying routines seems warranted.

INSERT TABLE 1 NEAR HERE

Given the strong regulatory environment, and the importance of intellectual property (IP) protection in this industry, it is perhaps not surprising that we were able to identify common routines across cases and that these were associated with different aspects necessary to develop and progress the science. These routines, in other words, are related to the strategic capabilities that are essential in this industry (hence our labeling 'strategic routines'). This link between routines and capabilities was previously identified by Winter (2000: 991) who states that an organizational capability is "a high level routine (or collection of routines) that, together with its implementing input flows, confers upon an organization's management a set of decision options for producing significant outputs of a particular type".

From the data collected from subsequent visits and observations, we analyzed how these strategic routines were either followed or disrupted during the ongoing development projects that we were specifically focused on. To begin this part of the analysis, all data were entered into NVivo and we wrote detailed descriptions of each drug development case (around 13,000 words). These descriptions provided a rich, chronologically ordered account of key events in each focal project. Once we had these rich descriptions, we used open coding to identify all sections of text that related to actions taken by managers to protect, evolve or approve the science for their focal project (Locke, 2001). During this stage, it became evident that a number of unknowns were regularly encountered in relation to protecting, evolving and resourcing the science (see Table 2). We then organized our data by drawing together similar kinds of statements about how these unknowns were dealt with to form provisional categories (a second set of first-order codes). These broader categories were adjusted periodically throughout the analysis. Finally, we clustered these categories into three higher order, researcher-induced themes in order to produce our emerging framework (Gioa, et al, 2010; Eisenhardt, 1989) of performative routines within projects. Thus, we identified three performative routines – hedging, compromising and re-prioritizing. In order to ensure consistency in our analytical categories (Glaser and Strauss, 1967; Sole and Edmonson, 2002) we then went back to our original data and carefully examined whether any key issues were being ignored in the categories that we had established.

We used different techniques to verify the credibility and trustworthiness of our interpretation of the data (Denzin and Lincoln, 1998). First, while, one author was responsible for conducting the initial analysis and (re)writing the case studies, fieldwork was conducted by two researchers so the second could help to discuss, and

verify the final account. We also presented the individual case narratives to project members who were able to verify (and occasionally correct) our interpretations. Finally, we held five scientific advisory board meetings over the duration of the research. Members of this board had extensive experience of drug development processes and confirmed that the problems and dynamics that we had identified were common in this context. For the remainder of this chapter we use two cases (SkinTech and AntibodyTech) as 'revelatory cases' (Yin, 1994) to present findings. Selecting revelatory cases allows us to provide rich details of local practices and dynamics of routines in this complex innovation ecology.

5. Overview of Cases

5.1 SkinTech.

SkinTech is a regenerative medicine company that was originally formed in the 1980s as a spin out from a university. Shortly after the spin-out the founders commercialized a biological 'Skin' product, short-circuiting a lot of the normal regulatory approvals process because the product was classified as a medical device rather than a drug, for which there was, at the time, far less regulation. The product was marketed as a superior replacement for bandages because it contained biologically active ingredients that could stimulate wound healing, as well as protecting the wound. However, as the founders had very little business expertise, they licensed the product to Pharma who were responsible for sales and marketing. Pharma was interested in the regenerative technology because, at that time, this was seen as having the potential to revolutionize medical treatments, such as eventually being able to grow new organs for

transplantation. However, the licensing agreement was dissolved after only a few years as Pharma found that marketing the product involved actively working alongside medics as they learned how to practically use the product and this was very costly. Coupled with the fading beliefs in the industry about the potential for regenerative treatments, Pharma pulled out of the venture.

SkinTech was making losses and filed for bankruptcy. However, two of SkinTech's founders, decided to resurrect it by investing their own money into it. It emerged from bankruptcy, but as a much smaller company that was based on a business model focused upon outsourcing rather than extensive engagement in in-house research and development. SkinTech began working with a variety of academic researchers and organizations (e.g., CROs, manufacturing companies) to develop and expand its product portfolio based on its original technology in the development of medical therapeutics.

At the time of our study SkinTech had three actual and potential product lines in its portfolio:

1. 'Skin' was the original and main product line aimed at wound repair, which was now profitable. However, SkinTech needed to develop the next generation of this product, which would be easier for medics to use and would not contain animal (bovine) products because of BSE risk.
2. 'Dental Skin' was a potential dental application of the technology (regenerating gum tissue) for which SkinTech were setting up Phase I clinical trials.
3. 'Cosmetic Skin' was a potential skin treatment developed from the waste products of the 'Skin' manufacturing process. This waste contains biological material that it was thought could potentially regenerate skin and so reduce

signs of ageing. During the time of our study the first Phase I clinical trial on this product was conducted.

5.2 AntibodyTech.

AntibodyTech was set up by university researchers who had developed a core technology to develop monoclonal antibodies that could potentially be used in a range of areas, including the treatment of arthritis, allergies and a range of cancers. The IP for the core technology was heavily protected so a range of pharmaceutical firms and other biotechnology firms had licensed the technology from Antibody Tech for their own development projects. This provided AntibodyTech with financial resources to invest in its own in-house projects, which included four cancer projects and a project to 'cure' asthma called 'Allergy'. At the time of the research one of the cancer projects had just failed because the partnering agreement that the firm had entered into with a large pharmaceutical firm in order to conduct larger-scale Phase II and III trials had not progressed. This was because the pharma had shifted priorities and abandoned development in that particular cancer treatment area. This forced AntibodyTech to shift its priorities and focus upon Allergy as the basic science around this potential drug was advanced and the firm had successfully filed an IND (Investigational New Drug) with the regulator so it could commence Phase I trials. Whilst relatively well-financed, AntibodyTech did not have the resources or access to resources (e.g. patients) for large-scale trials and, hurt by their previous failure in later phase trials, looked to partner with a pharma if Phase I trials were successful. At the time we commenced research Antibody Tech had successfully conducted one Phase I safety trial and gained approval for both a further Phase 1 safety trial using different dosages and, surprisingly, a Phase II trial aimed at demonstrating efficacy which involved inducing a severe asthma attack

in mild asthmatics. On this basis Antibody Tech believed it was an appropriate point in development to identify a partner who they could work with to take Allergy forward for future development.

The section that follows presents the way in which performative routines were enacted in projects as they attempted to satisfy the regulator and other institutional requirements (IPR) and how these involved considerable 'guesswork'. In the discussion we consider the reasons why guesswork was so central to the performative routines in this ecology as well as the outcomes and consequences for the innovation process.

6. Routines Enacted in SkinTech and AntibodyTech

Both firms were using development pipelines, which showed, stretching years ahead, when different phases of clinical work would be started and completed on each product. The milestones in these pipelines corresponded to dates (usually expressed as year quarters) indicating when clinical trials would be filed with the regulator for approval and, assuming positive results, when subsequent trial phases would occur (see Figure 2). The product pipeline could be found on each firm's website and was focal to discussions with actual and potential investors as it is the generally accepted way in which firms in this sector communicate in order to forecast when different products will (potentially) be commercially viable.

Project teams used a variety of project management tools and techniques (e.g. Gantt charts) to plan their day-to-day activities needed to protect, evolve and resource the science according to the milestones forecast in their pipeline. However, as time went on, setbacks and unanticipated problems inevitably occurred because of the many

unknowns that were faced and, as more was learned about the scientific properties of the therapeutic itself, multiple adjustments had to be made. This meant project plans were revisited on a regular (i.e. weekly or sometimes daily) basis. As one project manager put it: *"we have this Gantt chart that's a hundred pages long and I'm constantly tearing it up".* At the same time, the timescales forecast in the overall development pipeline, stretching years ahead, were more or less immovable. Any proposed changes that would affect the pipeline projection always required approval from senior management, given that any 'slippages' would be received negatively by investors and potential investors because they would dampen investor confidence.

6.1 Managing unknowns

Our subsequent fieldwork identified how the strategic routines (organizational capabilities, in Winter's terms), when enacted, were regularly disrupted by 'unknowns', which were either partly predictable but ignored or cropped up entirely unexpectedly. In the next part of our analysis, then, we focused on the routines performed within projects when attempting to enact strategic routines in the face of the unknowns. Not all the firms in our sample had to deal with all of these unknowns, but to be included in the analysis each 'unknown' had to have been encountered by the majority, if not all of the projects across the sample of 11 case firms (including the two discussed in detail here).

6.1.1 Unknowns associated with protecting the science.

Unless a biotechnology firm has, or is about to acquire the IP for an IND then there is unlikely to be any investor interest or investment, hence protecting the science is fundamental from the outset and continues to be imperative as new discoveries emerge. Typical unknowns concerned exactly what aspects of the science to protect with IPR

(intellectual property rights), what IPRs needed to be acquired based on existing patents and what IPRs to license out to larger, better resourced firms (typically large pharma) to take development into later stages. Great care was required in order to precisely document IP protection for different aspects of the core technologies and/or therapeutics in development. For example if a biotechnology firm did not follow the specified production process precisely, IP protection would be invalidated so great accuracy was required and what might be missing, as far as the regulator was concerned, was often unknown at the time when IP was being amassed. In addition, IPR needed to be registered in each of the countries that a potential drug was likely to be marketed in, and each country had different requirements in terms of documentation. However, at this early stage, the exact choice of countries they (or, more accurately, the pharmaceutical firm that took the project through later development) would want to market to was unknown. Moreover, the biotechnology firms' managers also had to take decisions about who to partner with (e.g. which large pharmaceutical) and at what point, and for what financial return, they should license their IP out. Deals were being sought with potential partners and investors while, at the same time, the managers in our focal projects did not know how (or if) the science would actually evolve and so what to protect.

6.1.2 Unknowns associated with evolving the science

Typical unknowns here concerned what potential and actual investors wanted or expected to see in terms of scientific results in order to invest, or continue to invest, in the development project. This involved a consideration of what opportunities there might be to expand the scope of existing core technologies or products in development, what clinical trials to perform, when to start a clinical trial, and how to manufacture

quantities of the product needed with the right formula to perform scheduled trials to the dosage and formula anticipated (e.g. concentration of solution, in Antibody, or square versus round 'skin' in SkinTech). Within project work, unknowns frequently occurred when clinical trials did not yield positive results. Until further scientific work was conducted, or further trials were designed and conducted, it would often be unknown as to why a trial had produced negative results. For example, all firms encountered problems in orchestrating their manufacturing effort with their scientific work. This was because manufacturing work, needed to scale-up production for larger clinical trials, had to be scheduled many months in advance and, crucially, in advance of the results of ongoing trials (that would often yield unexpected results about the chemical formula) being available. In the Allergy project, for example, the Phase 2 trial designed to induce a severe asthma attack in patients failed (perhaps unsurprisingly) to recruit patients to the timeline anticipated, but the drug solution, which had a short shelf-life, had already been manufactured, resulting in very costly waste.

6.1.3 Unknowns associated with resourcing the science.

The main issue here was what indication/treatment goal(s) to focus on at any point in time given the inherent resource constraints they faced. If a firm was attempting to license its IPR and partner for future development then the major unknown would be about who to partner with (e.g. knowing who had the capabilities, resources and motivation to take the project into large scale trials). More generally, to conduct trials, firms often had to outsource much of the work required (e.g. patient recruitment) to clinical scientists and/or clinical research organizations (CROs). Often firms had little or no experience of dealing with this so would not know whether particular

firms/clinicians could be relied upon to enroll sufficient patients and conduct trials within the firm's schedules.

6.2 Performative Routines

Our analysis then turned to assessing what performative routines were enacted within projects attempting to deal with the many unknowns and unanticipated outcomes (e.g. negative trials results) that they faced. Whilst project teams clearly needed to largely adhere to their firms' strategic routines because of the institutionalized (regulatory and market) pressures in the ecology, their performative routines varied in three ways as hedging, compressing or re-prioritizing. Our summary analysis of the unknowns and the way performative routines were enacted in SkinTech and AntibodyTech's development projects, with a range of examples from the data, is provided in Table 2.

INSERT TABLE 2 HERE

Performative routines characterized by *hedging* occurred when various options available in relation to an unknown that all seemed relatively feasible, depending upon which external stakeholders would be mostly concerned with the outcome, were all pursued at once. In both firms, for example, in terms of protecting the science, firms had filed for extensive patents, typically covering more science than had been deemed 'essential' for fulfilling IP requirements, and/or they had filed for IPR across multiple countries, even if there was no intention to market in some of them. In another example of hedging, in the Allergy team we observed a discussion during one project meeting over the number of patients to recruit for a trial. It was agreed that 'from a scientific point of view' it could be run with twelve patients. However, after some debate the

clinical trials manager concluded, "*The magic number for subjects to be exposed (to antibodies) needs to be around fifty…you might as well stick your finger in the air as to how many patients you need.... It's our guess against their guess, so let's stick with fourty-two – it's the answer to everything isn't it".* A trial with forty-two patients was designed, not just because it was 'the magic number', but because this was the kind of sample size that the team were guessing that regulators might want to see if approvals of future, larger scale, studies were to be eased and it might would be a *'more convincing number'* to present to a partner, depending on who that partner might actually be. The performative routine of 'hedging' entail actions that were significantly more lengthy and costly compared to the strategic routine that, ostensively, needed to be followed. For example, in SkinTech, a considerable amount of IP often *'languished on the shelf'* and in AntibodyTech it was much more costly to recruit additional patients. This performative routine of hedging had developed for two reasons. Firstly, it was felt that future delays with regulation could be avoided if something unanticipated occurred (e.g. the partner decided they wanted to go to market in a different country) and, perhaps more importantly, investor confidence in the firm would be promoted/generated. However in terms of time and costs this routine often created delays from the outset of the projects because of the work and time involved in holding open several options.

Performative routines characterized by *compressing* were probably most evident in our dataset. The routine evident here involved an under-estimating and squeezing the time needed to progress development built into each firm's pipeline. This meant that in the short-term, when activities were delayed, often because hedging actions had not resolved problems or had actually created new ones, there were frantic attempts to compress or as one project manager put it, *'squish-in',* additional activities that were

now required (e.g. the re-design of a trial because a regulator had rejected the trial design) or to attempt a short-cut in order to make up time that had been lost or actually attempt to be ahead of schedule. For example, in SkinTech's dental project there were attempts to manufacture a square molecular shape of 'Skin', which periodontal experts had insisted was required and more suitable for gum healing. However, attempts to manufacture this had failed (because cells reproduce themselves into a circle rather than a square). Regardless of this fact, the team went ahead with a clinical trial *'on schedule'* using the round, original shape instead, whilst recognising that this was not really workable for dentists. In so doing, it did mean, however, that there was no further slippage to the timeline! This action was therefore opportunistic and, from a scientific perspective, somewhat ad hoc. Moreover, the squeezing in of additional work to an already tight timescale often created new problems, for example, with manufacturers who were unable to supply the product to rescheduled, and often very tight, timescales and/or with project staff, who now had to juggle additional demands. Numerous further examples of routines characterized by compressing are presented in Table 2.

Over time, and typically when compressing was no longer feasible, and it was clear that the pipeline projections were totally unrealistic, then there would be a *re-prioritization* of projects and/or clinical studies. Thus actions would be taken to, either concentrate resources on a product line that, in relative terms, was considered to be more promising at that point in time, or to conduct a different trial that was likely to provide positive results more quickly. For example, in SkinTech, a clinical trial on CosmeticSkin (which was expected to be a 'blockbuster' ageing product if it worked) failed to yield positive results from a clinical trial for reasons that were entirely unclear. At this point the

project was deprioritised and efforts of the project team switched back to a new version of the wound repair product that was, it was thought, more likely to meet its deadline.

Performative routines across all of our projects were, in effect, deviations from attempts to enact the organizations' strategic routines that reflected regulatory and market demands in the ecology, in the face of the inevitable, and ongoing, unknowns that projects were met with. The overarching rationale for these performative routines seemed to be to maintain the timelines predicted in the pipeline and/or promote investor confidence in these projects, as highlighted in Table 2. However, all of these performative routines were characterized by what we refer to as 'guesswork', which we define and discuss next as we consider the implications of our findings for innovation within complex organizational ecologies.

7. Discussion and Conclusions

Project planning and the product development pipeline, built around regulatory approval milestones, make it appear as if innovation in this context is a matter of following a smooth linear path from preclinical work, through phased clinical trials with increasing numbers of patients, and proving safety and efficacy of the drug in development, then eventual commercialization. However, we have seen that in complex innovation projects, where knowledge and outcomes are highly emergent (Dougherty and Dunne, 2012; Newell et al, 2008), the path is far from smooth – performative routines are enacted in ways that cope pragmatically with the many unknowns inevitably faced. Thus, one contribution of our study is to respond to calls to articulate

the ‘actual day-to-day process’ of managing complex innovation in particular project settings (Dougherty and Dunne, 2012; Hodgson and Cicmil, 2006).

The performative routines - hedging, compressing and reprioritizing - identified in our study could be understood as ‘skillful accomplishments’, in so far as they helped actors to behave as if things *were* predictable and, in so doing they were focused on addressing the concerns of other stakeholders in the organizational ecology (e.g. responding to regulatory requirements or promoting investor confidence in the firm/project), even in the face of ongoing unknowns and highly emergent outcomes. These routines, collectively, can be referred to as *guesswork,* since they all entailed actions taken to manage development projects based on ‘best guesses’ in the face of unknowns. We define guesswork as routines enacted, using the collective experience of those involved, to establish and proceed through a course of action most likely to convince external stakeholders in the ecology that projects are progressing as anticipated, cognizant of the institutional requirements that exist. These enabled those involved to be pragmatic and to take action at points where decisions *had* to be made but where the outcomes were very difficult, if not impossible, to predict; hence the notion of ‘guesswork’. We argue, therefore, that performative routines enacted within projects that themselves are embedded within organization and a wider ecology of organizations are significantly shaped by the actions and predicted actions of other stakeholders in the ecology.

One contribution of our study, then, in response to our first research question, has been to identify the locally-improvised performative routines actually manifest in firms and projects developing complex innovation processes. This compliments more normative accounts of what ‘should’ be done to ‘orchestrate’ complex innovation ecologies (e.g.

Dougherty and Dunne, 2011; Pisano, 2006) by providing an exploratory account of how things *are* actually done and why.

A second contribution, in response to our second research questions, is to provide a multi-level account of routines that shows how performative routines at the level of projects develop in response to strategic routines used organizations and reflect concerns of the wider ecology. By developing an empirically-grounded ecological view, that takes account of the heterogeneous, multilayered nature of routines, we hope to have contributed, in a modest way, to organization studies on routines, which, as Salvato and Rerup (2011: 469) observe, "*have long neglected the fine-grained, multilayered nature of routines and capabilities. Instead, they have opted to investigate them as truncated, collective, recurrent entities, or 'black boxes," embedded in firms at micro or macro levels of analysis"*.

In terms of the consequences of these routines for the innovation process, our research suggested that those involved fully recognized the inherent uncertainties of development and the implausibility of following linear plans and predictions. Yet, their routines performed locally sought to sustain, rather than challenge, the timelines embedded in the product pipeline. In our case, then, albeit a very dynamic situation, we saw very little evidence of 'dynamic capabilities' or 'deviation' from established processes (Raman and Bharadqwaj, 2012). The highly linear pipelines and timelines remained rigidly in place. Indeed, the performance of routines was actually geared toward affirming the 'myth' of a manageable and knowable, linear development process. Practically then, and somewhat paradoxically, the undoubtedly skillful accomplishment of these guesswork routines, set in motion in order to be able to *do something* when faced with relentless uncertainty, often significantly constrained those involved from

actually developing new, or alternate, processes that might better support scientific development. For example, in SkinTech, in order to 'keep things on track', trials went ahead with round-shaped dental material not suited to gums even though those involved recognized that any results from a trial designed in this way would be inconclusive.

These, outwardly counter-productive activities, can be understood when we consider the ways in which performative routines enacted within these firms are nested in the ecology of organizations implicated in complex innovation (Dougherty and Dunne, 2011). Thus, in this particular ecology the creation and revision of a development pipeline and detailed project plans were underpinned by a highly prescribed regulatory framework which embodies linearity and stage gates, combined with strong pressures from investors who demand to see progress before committing to investment. Given products are still at the discovery stage, 'progress' can only be demonstrated by showing adherence to project schedules that are aligned with the regulatory framework. For example, it is well-known in the industry that, statistically, projects are much more likely to deliver commercial returns once Phase 2 trials have been approved (Kola and Landis, 2004). There is very little tangible evidence, aside from the results of successful approvals, to indicate progress.

In this context, then, market and regulatory pressures create a highly institutionalized set of norms and prescriptions in the ecology around the ordering of work that assumes linear development. This institutionalized 'social order' is translated at the firm level into an array of processes that involve creating pipeline and project plans that conform to the ideal of a linear development process. The guesswork routines that we identify, therefore, helped practitioners 'fill the gap' between the linear assumptions of

knowledge production imposed by the pipeline and the reality of a much more interactive (in the sense of moving back and forth between basic science and clinical work), messy and emergent innovation process identified in previous work (Swan et al, 2010; Dougherty and Dunne 2011; Styhre et al, 2010). In this way, we argue, the various performative routines enacted locally practically reproduce the institutionalized social order. Even though ultimately these may be counter-productive (in terms of development) and so appear to be not fit-for-purpose, for those involved in drug development, it is the practical way in which they can respond to the pressures to make drug development appear tractable (and so worth investing in). In this way, and following Turner and Rindova (2012) we argue that there is a high degree of consistency in the use of guesswork routines in the face of ongoing uncertainty and emergence across all our case study firms.

Thus, a final contribution of our study is to show how routines, enacted locally in order to handle on-going change and uncertainty, are not only intertwined with, but might play an active role in reinforcing and stabilising (rather than challenging or changing) the dominant social order (reflected in the development pipelines) in a wider organizational ecology. The sustained 'myth' of the pipeline development model, in turn, appears to necessitate the further use of these guesswork routines to work around plans based upon this model that in many cases prove unworkable. These initial findings suggest an important dialectical process linking routines performed locally within firms and projects to wider institutionalised orders across the project ecology. It also suggests likely tensions between the mechanisms prescribed by Dougherty and Dunne (2012) to support complex innovation at the level of the ecology (e.g. developing public policy to ensure public welfare and safety) and those needed locally to manage

emergence. Research from a routines perspective has not yet adopted an approach that recognizes this dialectical process.

Finally, rather than organizations designing processes to meet the demands of the emerging science (as suggested by Bessant et al, 2011, and others), we have demonstrated how the application of routines which are largely driven by regulatory and other (e.g. IPR) requirements to address unknowns can practically constrain innovation. In this sense, our findings build on earlier work that suggests that the biomedical innovation system fosters a technological regime that creates 'lock-in' (Vanloqueren and Baret, 2009) – in this case to a set of routines that, whilst acceding to external regulatory and investment pressures, simultaneously hinder the development of novel therapeutics.

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Figure 1. The New Drug Development Process

Steps from Test Tube to New Drug Application Review. (Adapted from: Centre for Drug Evaluation and Research (CDER) Handbook)

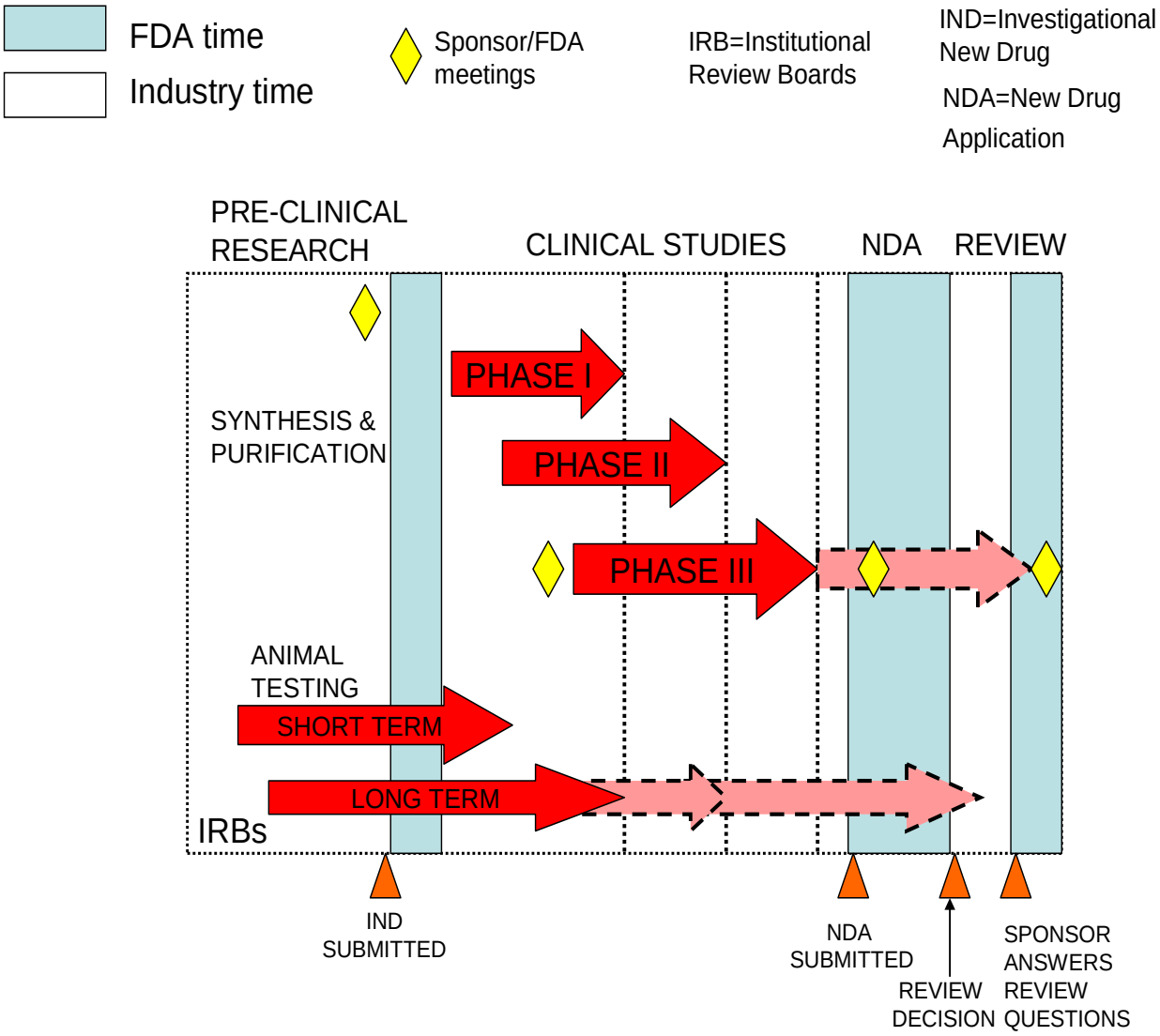
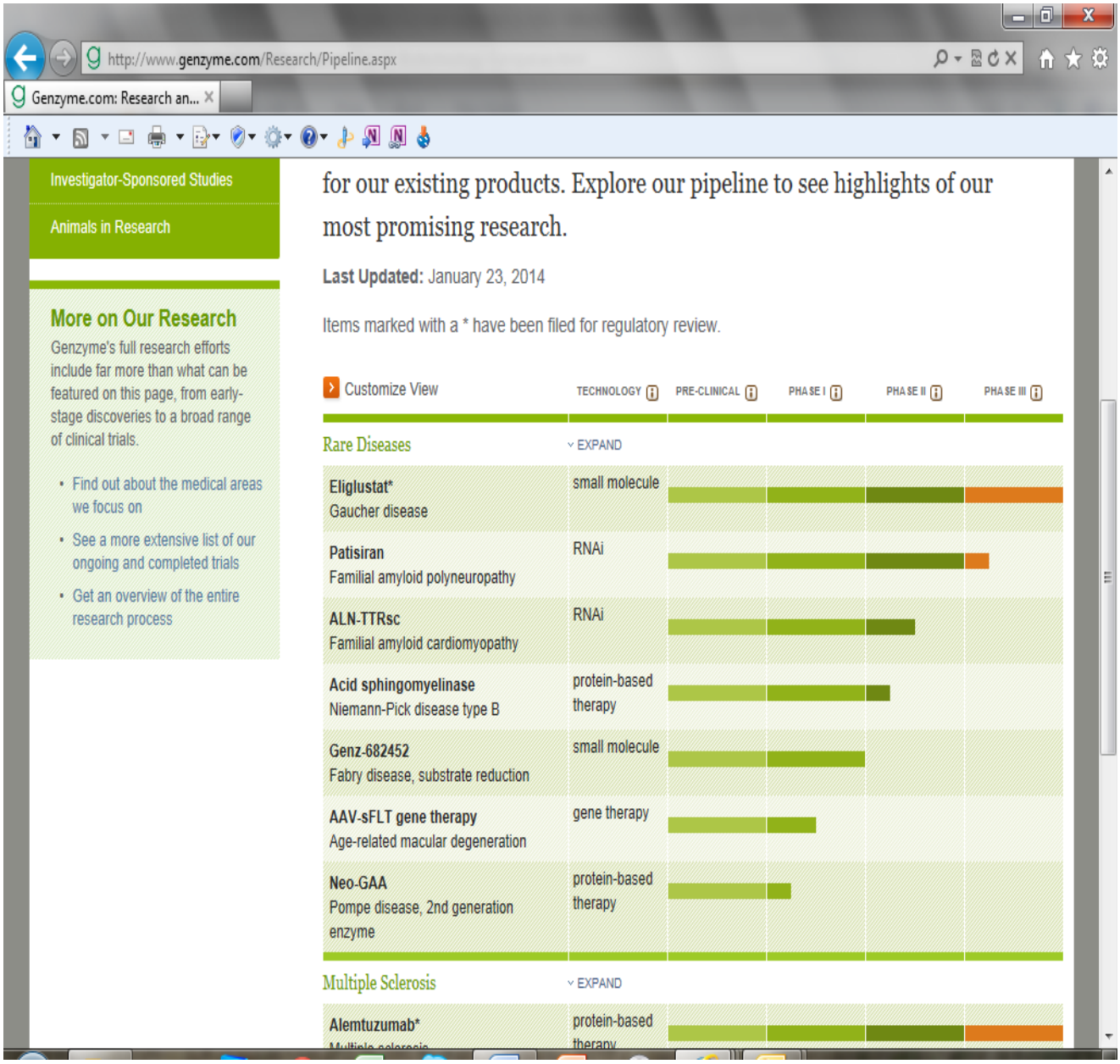

FDA time
Industry time
Sponsor/FDA meetings
IRB=Institutional Review Boards
IND=Investigational New Drug
NDA=New Drug Application
PRE-CLINICAL RESEARCH
CLINICAL STUDIES
NDA REVIEW
SYNTHESIS & PURIFICATION
PHASE I
PHASE II
PHASE III
ANIMAL TESTING
SHORT TERM
LONG TERM
IRBs
IND SUBMITTED
NDA SUBMITTED
REVIEW DECISION
SPONSOR ANSWERS REVIEW QUESTIONS

Figure 2. Example of a Product Development Pipeline from Genzyme Website[1]



[1] This is a typical example taken from publically available information on the web. To protect anonymity we have **not** presented a pipeline from any one of our case studies.

Table 1. Key Recurring Activities Undertaken in all Biotechnology Firms and Strategic Routines

Recurring Activities Common to Biotech Firms	Strategic Routines
Development teams, scientists and IP/regulatory experts research existing and pending patents in one or more countries where drug expected to be marketed	Protecting the Science
File appropriate documentation with various patent offices around the world to protect own science	
Development teams review all scientific data available from their own and other sources associated with different projects to establish whether there is sufficient valid data available to file for an IND and subsequent clinical trial applications; submit applications when sufficient data accumulated or to report trials results	Evolving the Science
Senior management construct pipeline of products in development & upload to website. Meet regularly with development teams to review projects' progress on against pipeline and (re)assess which projects to commit most resources to.	
Development teams (project managers) construct plans/ schedules for their projects using & associated artefacts (e.g. Gantt charts) to ensure progress against overall pipeline	
Clinical teams design trials plan and study protocols (i.e. trials designs, e.g. whether testing for safety and/or efficacy, number of patients, preferred clinical investigators etc.) and determine when and where to run trial. Estimate time/costs to run the trial against pipeline projections	
Development team (chemical manufacturing control scientists) determine and document the raw materials, facilities required and timings for manufacturing batches of product to align with trials	

plans and pipeline projections	
Senior management identify new market opportunities for core technology & determine what resources/expertise are required to support new projects.	Resourcing the Science
Senior/business development teams seek & negotiate deals with potential partners with appropriate expertise to resource development	
Development teams review existing in-house capabilities and establish outsourcing required and review and decide upon external organizations to use	
Development teams conduct due diligence on selected partners for particular projects.	

Table 2: Unknowns Encountered During Project Work and Performative Routines (GUESSWORK)

Typical Unknowns	**Examples of Performative Routines (Guesswork)**
Protecting the Science	
What IP will be needed? What countries to file in?	**Skin Tech & Antibody Tech** 1. Extensive search of existing/pending patents across countries. 2. Prepare and submit enormous amount of documentation in order to comply with patenting requirements across multiple countries and avoid infringing existing /pending patents. 3. Majority of IP languishes on the shelf but considered necessary if projected development plans are to remain on schedule **in order to promote investor confidence** into the future as unsure where trials will be conducted or drug will be registered at this early stage of development. ***Routine characterized as HEDGING***
Evolving the Science	
1. What will be the most likely indication/ treatment goal/trial to focus on to achieve	**Skin Tech:** 1. Review progress across all three projects. 2. Agree that all three face significant and different challenges 3. Decide upon focal project based on opportunity to partner with high status but unfamiliar collaborator **as signal of**

positive results in the near future?	**confidence in the project to existing and potential investors.** 4. Revise (accelerate) product pipeline projections re milestone dates for this project to reflect change. ***Routine characterized as RE-PRIORITIZING*** **Antibody Tech:** 1. Submit trial design documentation to gain approval for extreme/high risk phase II trial testing for efficacy instead of running further phase I safety trial**.** 2. Do not review or assess which sites to approach for patient enrolment as this would generate delays. 3. Revise (i.e. accelerate) product pipeline projections to reflect this proposed trial **to improve investor confidence in project.** ***Routine characterized as RE-PRIORITIZING***
2. What data will be required to satisfy the regulator to register an IND?	**Skin Tech** 1. Multiple teams produce documentation to file for an IND. 2. Senior management propose to file an IND recognizing that there is no possibility of gaining approval. However this ensures that this milestone activity was within the timeframe stipulated in the pipeline projection **to sustain current and possible future investor confidence.** ***Routine characterized as COMPRESSING***
3. When should	**SkinTech:**

we manufacture the product and in what form?	1. Development team **e**stablish that the dental product will require the manufacture of square cells. 2. Inform manufacturing of requirement. 3. Attempt to manufacture a square cell product, but this proves to be much more difficult than anticipated – '*because cells don't grow in such an orderly pattern'*. Recognise that cannot overcome this problem in scheduled timescales for trials. 4. Senior management agree to the manufacture of traditional round cell product instead for proposed trial 5. Trial for dental project goes ahead within stipulated timeframe/plans recognizing that it will fail but ensuring it is on time in order **to sustain investor confidence in focal project.** ***Routine characterized as COMPRESSING.*** **AntibodyTech** 1. Order raw materials for in-house manufacture 2. Manufacture significant quantity of product for high risk trial in-house *before* patients have been enrolled and despite the fact that the product has only a very short shelf life, to align with trial schedule plans **and sustain investor confidence in project.** 3. Trial abandoned because patients cannot be recruited. 4. Dispose of out of date but very costly product ***Routine characterized as COMPRESSING.***
4. What	**Skin Tech:**

science/trials to perform in-house and what to outsource to academics /CRO's?	1. Development team attempt to monitor the work of selected but unfamiliar CRO for dental trial product. 2. Produce documentation for the regulator based on CRO work but lack of understanding of CRO activities. 3.Regulator rejects SkinTech documentation ***Routine characterized as COMPRESSING*** **Antibody Tech:** 1. Contract out high risk trial to unfamiliar CRO based on costs and their availability. 2. CRO fails to recruit patients and trail aborted. 3. Revert back to original plan for CRO to conduct a more conservative trial but only limited time to conduct it because of time lost on abandoned trial. 4. Difficulty in 'encouraging' CRO to prioritize trial. ***Routine characterized as COMPRESSING***
5. What will be the results of trials?	**Skin Tech/Antibody Tech:** 1. Regulator approves some trial designs and not others (based on documentation or trial design) which create delays. 2. Approved trials often delayed (significantly) because of problems with patient recruitment; expertise of external collaborators; competing priorities of collaborators/CROs and negative trial results. 3. Pipeline projections for further trials reviewed

	but timelines typically *not* adjusted so planned future activities (trials, manufacturing etc.) are reviewed and adjusted to 'fit' with original timeline **in order to sustain investor confidence in project.** ***Routine characterized as COMPRESSING***
Resourcing the Science	
1. What will potential investors and/or partners want/expect to see in order to invest resources in the firm?	**Antibody Tech** 1. Design and seek approval for 2 trials simultaneously (i.e. ahead of pipeline projections) (i) a high risk (extreme) trial in hope of demonstrating high levels of efficacy to potential partners more quickly and (ii) a low risk trial to reduce chance of demonstrating problems with science (i.e. negative results) which could influence partnering process. 2. Both trials approved by regulator, including (unexpectedly) high risk trial. 3. Senior management agree to divert resources to the high risk trial **to promote potential partner confidence in project** (with deals now at a late stage), but trial fails to recruit patients and sets back project. 4. Resources diverted back to low risk trial ***Routine characterized as RE-PRIORITIZING*** **Skin Tech** 1. Senior management engage in on-going, ad-hoc and opportunistic networking with strong and weak ties to support future development of core technology e.g. contact head of research at major university Dental School, who used to be on the board of directors of Skin Tech.

	2. Facilitate a meeting with periodontal experts at the Dental School. 3. Members of the school agree to *informally* support a dental project with their expertise in periodontal science. 4. Senior management revise pipeline plan for periodontal project to improve pipeline plan **in order to promote investor confidence,** even though this reduces resources for other projects. ***Routine characterized as RE-PRIORITIZING***
Who might be interested in licensing or partnering arrangement on focal project?	**Antibody Tech** 1. Business Development (BD) team produce a long list of potential partners and begin financial negotiations. 2. Development team request and assess phase II trial plans from long list of anonymous partners and compare to in-house phase II trial plans. 3. Produce short list of potential partners for business development based on their projected development plans but rather speculative as no knowledge of who potential partners might be. 4. BD request and assess all potential partner business plans ***Routine characterized as HEDGING*** **Skin Tech** 1. Informal dinner with the Harvard scientists 2. Produce an outline but nevertheless formal agreement between the parties for a number of preclinical and clinical trials for periodontal application.

	3. Pipeline plan revised to reflect shift in focal project ***Routine characterized as RE-PRIORITIZING***

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