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Seeding and Harvesting the Innovation Gap: Linking Technology to Social and Market Needs*

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The Technology Innovation Mapping (TIM) Tool assists commercialization efforts and students studying product development and technology commercialization by linking the features of a technology to specific social needs (a term in broad perspective that includes technology commercialization used both for profit and not-for-profit applications), thus addressing the innovation gap between laboratory research and business incubators. This paper further develops the methodology; it summarizes the TIM Tool method and expands upon the TIM Tool to better capture the commercialization process for innovative technologies. The paper uses the application of a nano-scale drug delivery technology (advanced by a graduate student team) as a technology commercialization example.

Keywords: technology commercialization; innovation; function mapping

1. INTRODUCTION

PRODUCT DESIGN ENGINEERING TEAMS frequently use function maps to analyze the basic components and relationships within a complex technology or product. Such maps are used to link together inputs and outputs of signals, material and energy [1, 2]. Another type of function map, a "FAST" diagram, is widely used in Value Engineering. Charles Bytheway created this Function Analysis System Technique to illustrate 'how', 'why', and 'when' relationships between functions in a system [3–5]. A variation of "FAST" diagrams, created by Pretium Consulting Services, uses both positive and negative functions, and forms maps with arrows that illustrate how functions contribute to or counteract each other [6, 7].

Innovation and the development of new technologies are driven by market-based needs, or an "opportunity pull" [8]. In technology commercialization where new technologies must be matched to a potential market there may not be a known market to contemplate "pull", a term generally used when the need for the product is clearly understood by the user before the product is defined.† Without "pull," the technology must be initially thoroughly understood, the customer needs must be created, clearly articulated and understood, and an appropriate market must be chosen (or at times created) for the technology. This pattern is often described as "capability push" [9]. With such a "capability push", function mapping using the TIM Tool can be an extremely valuable tool for creating a match between a technology and a market need.

This paper focuses on the concept of a hypothetical or future value chain and uses the TIM Tool to examine the links between a technology and the value chain necessary to deliver a product or service to a customer. Previous papers emphasized the search for customers; while this paper emphasizes the creation of a future value chain, more aptly described as "creating customers" [1, 10, 11].

2. THE TIM TOOL

The TIM Tool (Fig. 1 on the following page) assists in defining, examining and optimizing potential matches between an emerging technology and social needs, and further examines the features (and benefits) offered by the technology [1, 10, 11]. It is (of course) possible that more than one match could be created or that no promising match is found.

The figure depicts the steps (1–4 above the arrows) and results (boxes) of each step in the process of matching emerging technologies with social needs. The technology of interest is on the left. Through a series of four iterative steps using functional mapping, the technology is trans-

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† Commercially successful products must eventually develop market "pull." That is, customers must express their desire for the product/service by purchasing and using the product/service. The term "pull" is generally used when the need for the product is clearly understood by the user before the product is defined.

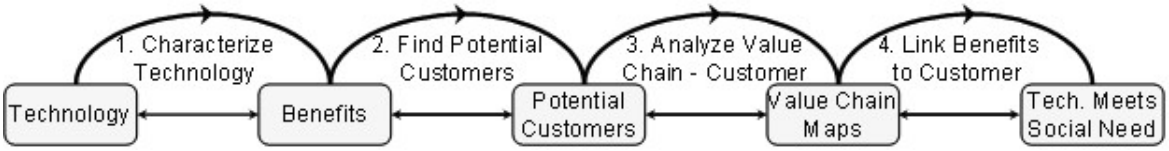

Fig. 1. TIM Tool method for finding potential customers.

formed, understood, and expanded in terms of benefits into multiple potential customers. The customers' corresponding value chain maps help identify a particular benefit or match to a specific customer need on the very right.

The TIM Tool has been used to illustrate the concepts of "Technology Characterization" and "Customer Value Chain" creation [1, 10]. "Technology Characterization" refers to the formation of a clear understanding of the benefits and the unique technology elements of a particular technology (see Step 1 in Fig. 1). With an understanding of the benefits and unique technology elements, the TIM Tool has been successfully applied to the search for and assessment of potential customers (see Step 2 in Fig. 1) [11]. Furthermore, the TIM Tool has been used to introduce how the benefits and unique elements of a technology can be linked to a value chain surrounding a potential customer [10]. A "Customer Value Chain" is defined as a network of value added functions that support and are supported by a potential customer. The term "customer", See Table 1, is used broadly in this discussion to include purchasers, beneficiaries, and users. The following discussion traces an example through Steps 3 and 4 of the TIM tool to illustrate how the tool facilitates developing opportunities based on hypothetical or future value chains that are necessary to deliver a product or service to the customer based on that technology.

The example used in this paper builds upon the TIM tool discussion outlined by Evans et al. [1]. The paper introduced a technology developed at the University of Texas and created a function map of the technology. Technology commercialization research was completed in a graduate course by a research team consisting of Cristal Glangchai, Abiola Ajetunmobi, Jakub Felkl, Adrian Eissler, and Rohin Mukhi [12]. The team compiled information about potential uses of the technology and identified potential customers. This paper examines the technology commercialization evaluation completed by the team. Furthermore, it applies the information gathered by the team, analyzes the data, and communicates conclusions in support of their findings. The example also supports more general conclusions about technology innovation.

This paper uses a collection of terms listed in Table 1.

Note that the discussion below includes a series of function maps. The maps contain functions that are defined to be both useful (value positive) and harmful (value negative). Useful functions are circumscribed by boxes, while harmful functions are circumscribed by hexagons. The functions in those maps are connected by two types of causal relationships; producing and counteracting. Counteracting relationships are represented by lines tipped with a circle. The functions and their causal relationships form networks (or maps) that efficiently represent complex relationships between functions and highlight critical issues [10].

3. A NEW TYPE OF CANCER TREATMENT

A nano-scale drug delivery technology (developed at The University of Texas) allows small therapeutic payloads to be delivered to individual cells [13]. There are three main elements to the technology:

1) a container;
2) targeting ligands;
3) an active lid.

The ligands target only certain types of cells and the lid "opens" in the presence of an over-expression of a cancer specific enzyme. If the containers, ligands, and lid are fabricated to target lung cancer, then the device will target the lung cancer cells, enter the cell, and release a therapeutic agent only in response to an over-expression of enzyme; the technology represents a new weapon against cancer. The technology can be modeled in a

Table 1. Key discussion terms

Benefit	A function describing the overarching purpose of a technology. A benefit is a function that could be valuable to a potential customer. Technologies often have several potential benefits
Technology Elements	Technology elements are a set of functions that define what is unique about a particular technology. For a software technology, the technology elements might include algorithms, data or calculations, but not the computer running the software.
Potential Customer	A potential user, purchaser or benefactor of a product based on a chosen technology.
Value Chain	The network of value-creating activities that would be required to deliver a future product to a potential customer.

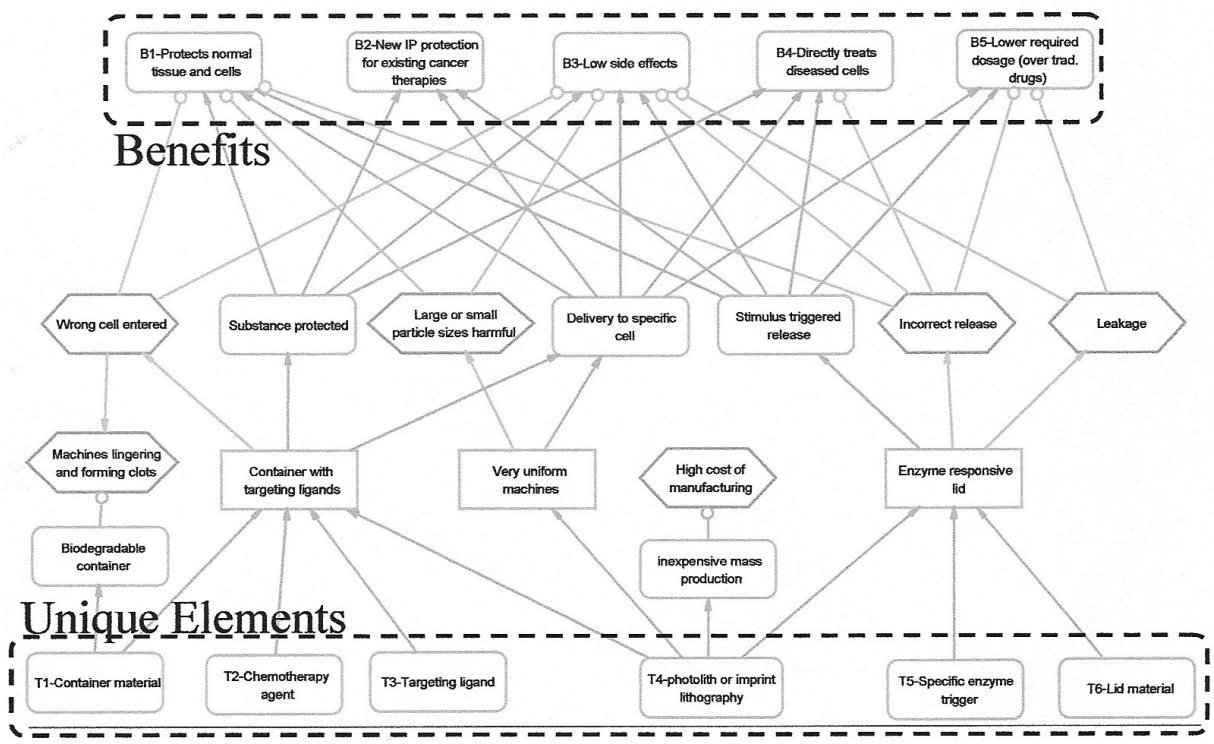

Fig. 2. Key technology elements.

function map as illustrated in Fig. 2 [1]. This map was developed during Step 1 of the TIM Tool process and highlights two critical pieces of information, the benefits of the technology and the unique elements of the technology.

The benefits of the technology may be found in boxes B1 (Benefit 1) through B5 at the top of the figure. The benefits include protecting normal cells and tissues from toxic drugs, lowering side-effects, directly treating cancer cells, lowering the required dosage of drugs, and increasing the IP protection of existing cancer drugs. Currently, chemotherapy treatment exposes all cells to the same toxic cocktail; however, if only chosen cells received the chemotherapy agents, then the dose to those cells could be increased without increasing the dosage to the rest of the body. Thus, a patient would have more efficient treatment and reduced side-effects. Within the oncology community, this would be the "holy grail" of cancer treatment: a delivery device that is lethal to cancer cells, but harmless to healthy cells.

The unique elements of the technology are arranged in Boxes T1 through T6 at the bottom of the figure. These include the scientific understanding of how to fabricate the required materials, fabrication of the delivery device using imprint lithography, development of an enzyme-specific trigger, and the combination of the materials, the drugs, and the targeting ligands. The boxes in the middle of the figure provide the details about how the technology works. Several functions are labeled as harmful in the diagram. These include the possibility of a high cost of manufacturing, the possibility of drug leakage before a target cell is reached, the possibility of not reaching the correct cell, and other possibly harmful effects associated with nanoparticles. The map in Fig. 2 illustrates how the benefits, unique technology elements, and harmful effects help one gain an understanding of the technology, risks which may need to be addressed, and benefits that may be important to a potential customer.

4. CREATING A VALUE ADDED CHAIN

After understanding the benefits and unique elements of the technology, the next step in the TIM tool is to focus on the customer. More specifically, the analysis focused on how the benefits of the technology could be delivered to the customer. However, before performing a complete analysis of any single type of customer, it is important to consider different possible customers and then select the most promising based on a set of criteria [11]. The technology described above is a cellular delivery device. Many alternate applications can be readily considered including antibacterial and pain management applications. Yet, the research that created the technology was focused on the treatment of cancer. This is the main reason for the focus in Fig. 2. In practice, we might choose to perform a broader search for customers, as outlined in a previous paper [11].

With a set of customers in mind, it is easy to focus on how the potential benefits of the technology match with customer needs and not consider

the broader connections required to support commercialization. However, it is important to consider how the benefits of the technology could be delivered to the customer. Because the current lung cancer technology is 10 to 15 years away from reaching the market, the entire body of information currently available to build potential customer needs is relatively sparse and likely to change. It may seem futile to try to determine how the technology will be provided to the market so far into the future. It would be correct to simply say that since there are so many unknowns, a future value chain for this technology cannot accurately be created. However, what is important is not to create the correct future value chain, but rather to consider that an entire chain of activities will need to be setup to actually reach a cancer patient.

Figure 3 illustrates a value added chain for the targeted lung cancer technology. Cancer patients have two primary demands; 1) kill cancer cells and 2) protect healthy cells—a clear match with the benefits of the technology. It is often the case that the benefits of medical technologies match the demands of the patients. Successful medical treatments, however, must also address needs from physicians, insurance companies, regulatory agencies, clinics, and hospitals. Each of these 'customers' participate in the value chain required to actually supply treatments to patients—Box VC3 (Value Chain 3). Some function or functions, then describes how Box VC3 is produced. The question, "how is this function produced?" can be asked at each level to form the value chain.

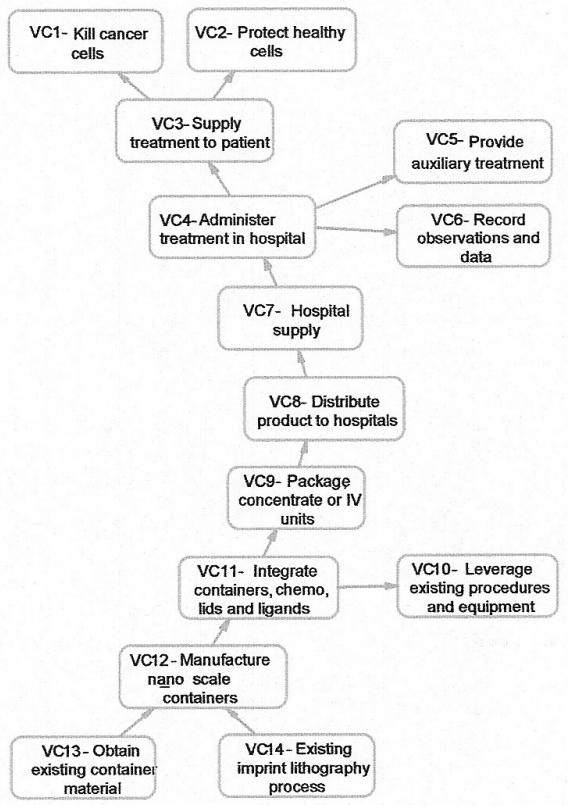

Fig. 3. Value added chain (VC) for targeted lung cancer technology.

The commercialization team needs to understand how a particular function is produced or how that function is produced with respect to the specific technology being assessed. Treatment can be supplied to patients in many ways. Ibuprofen is available over the counter, while other drugs can only be obtained with a prescription. Some drugs are taken orally, some are injected by the patient, and some treatments require administration by specialists. In the case of cancer treatment and chemotherapy specifically, there are auxiliary treatments for the side-effects of the chemotherapy and patients are carefully monitored by medical professionals. Treatments are most often provided in a hospital (Box VC4), which would allow for ease of any additional treatment (Box VC5) and also allow for additional observations and data collection (Box VC6).

The treatment, whether provided as an injection or dispensed as an intravenous drip, would be distributed to a hospital (Box VC8) and stored within the hospital (Box VC7). Before distribution, the treatment would need to be packaged (Box VC9), preferably in a form that matches standard hospital procedures. Before packaging the treatment, the nano-scale drug carriers must be manufactured (Boxes VC11 and VC12) using existing container materials (Box VC13) and currently available nano-lithography processes (Box VC14). The manufacturing process will leverage existing procedures and equipment (Box VC10). The boxes VC3 through VC14 in Fig. 3 illustrate an example of a value chain connecting benefits to a potential customer with a future mass-produced version of the technology.

It is important to recognize that several assumptions have been made during the creation of this map. First, the map is illustrative, and not comprehensive. It provides one example of many possible maps that could describe how the treatment could be supplied to a patient. Although the treatment most likely would be administered in a hospital, many other elements of the diagram could be changed. There could be alternate treatment methods or very alternative strategies for manufacturing the treatment doses. As an example, the containers could be produced by one company and then provided to an existing drug company for the manufacture and distribution of the treatment.

The exercise of building a value chain provides valuable insight into the possible commercialization avenues for the technology. Fig. 3 illustrates that the treatment requires the support of a hospital and will therefore need to be integrated into hospital operations. Other portions of the map could take on many forms, but the act of representing one option serves as a springboard for developing these alternatives. The Tool encourages development and analysis of alternative maps of value chains (and different tasks required to produce the desired results).

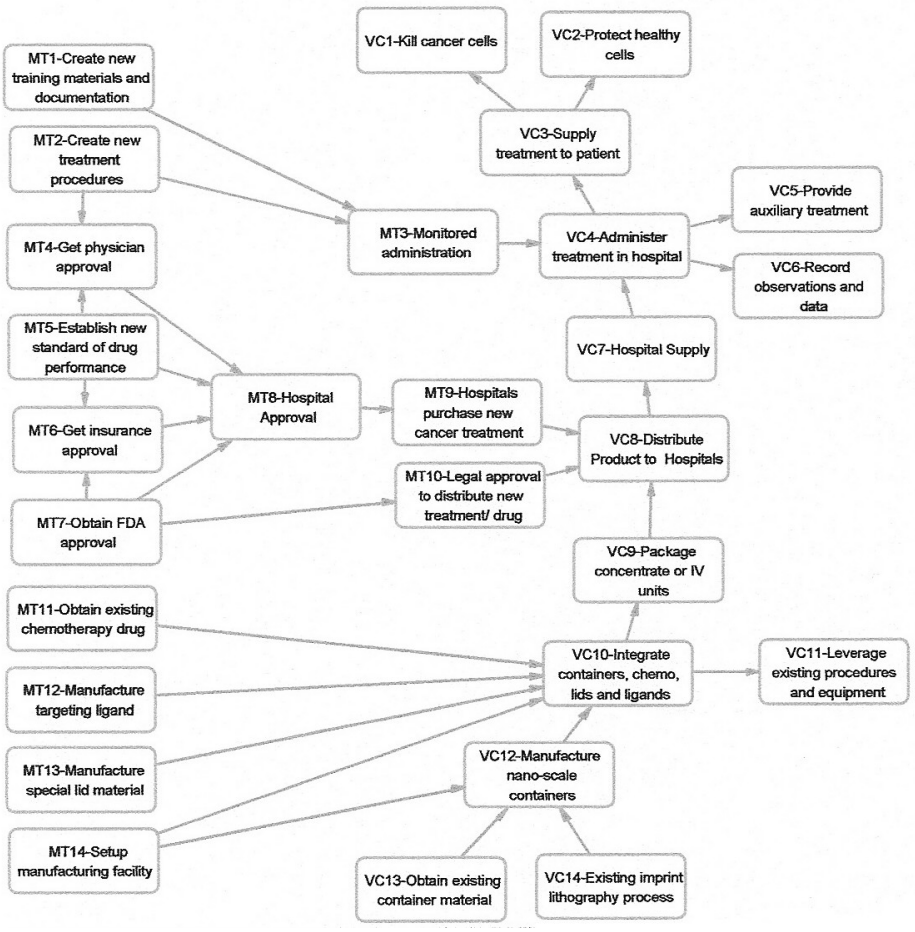

Fig. 4. Main supporting tasks for value added chain.

4.1 Outlining the tasks required to build a value chain

Clearly, many main tasks are required to create the value chain illustrated in Fig. 3 for each function defined within the value chain. These setup tasks can be added to the value chain diagram, as illustrated in Fig. 4. Figure 4 demonstrates that hospital procedures are supported by documentation (Box MT1—Main Task 1) and those procedures must be carefully created (Box MT2) because they are important for supporting physician approval (Box MT4). Furthermore, the procedures and documentation jointly support monitored administration of the treatment (Box MT3).

Hospitals must first purchase the new treatment in order to administer it (Box MT9) and there are regulations that must be followed for any treatment (Box MT10). Purchasing requires approval by the hospital (MT8) and hospital approval consists of several elements. First, a new treatment must be significantly better than previous treatments (Box MT5). This is important in getting physician approval (Box MT4) and the approval of insurance carriers (Box MT6). Furthermore, FDA certification (Box MT 7) is important both for hospital approval and for the regulatory requirements that apply to medical treatments. In addition, before the treatment can be administered the treatment must be manufactured, as illustrated by Boxes VC10–12 in Fig. 4. The fabrication of the treatment further relies upon getting the chemotherapy drug (Box MT11), manufacturing the ligand (Box MT12) and lid material (Box MT13) and setting up some type of facility (Box MT14). The various approvals, their relationships and the fabrication of the treatment were built from research into the process for bringing a new drug to market.

The column of boxes on the left side of Fig. 4 (MT1, MT2, MT4, MT5, MT6, MT7, MT11, MT12, MT13, and MT14) establishes a list of main tasks for bringing the new cancer treatment to the customer. This list could be built without the use of function maps. With the framework provided by the TIM tool, these elements follow naturally from considering how a product is delivered to a customer. Experts in developing new medical products or drugs understand clearly that they have many different 'customers'. A traditional engineering concept of 'customer' might focus on the patient. Starting with the patient, the process of building the simple function map in Figure 4 shows that physicians, hospitals, government agencies and insurance companies are

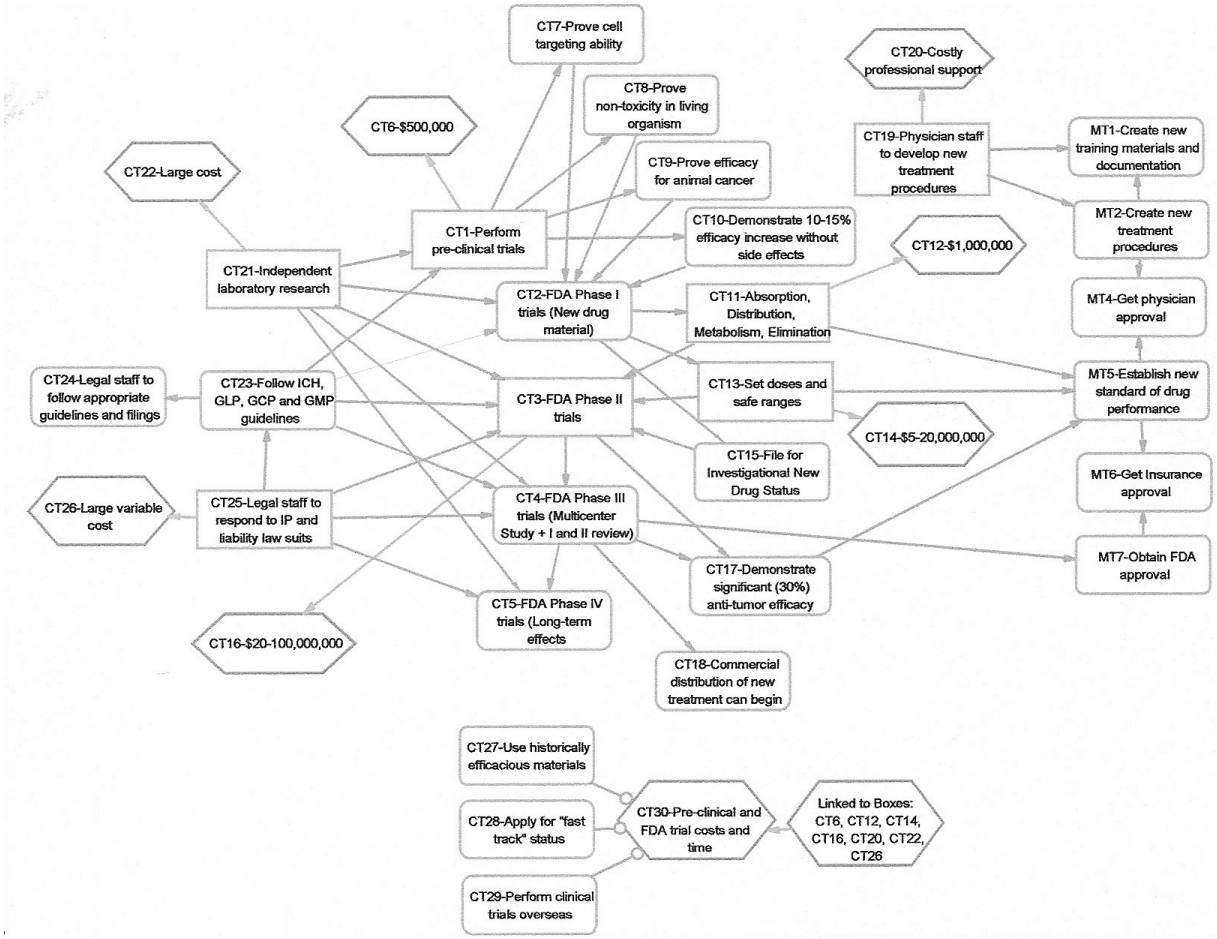

Fig. 5. Clinical trials.

all intermediate customers as well. Building this value chain is an exercise that helps create the needs of the customers identified in the map.

5. CONNECTING THE MAIN TASKS TO THE CURRENT TECHNOLOGY

Step 4 of the TIM Tool, "Create Links," continues from the main tasks listed in Fig. 4. For any new technology, the process of realizing a product includes additional research and development. For new medical treatments, some of this process is organized in the form of clinical and pre-clinical trials. These trials, however, are both costly and complex. There are several distinct phases and each has certain targets and guidelines that must be reached in order to move forward. The phases are somewhat different for each technology and simultaneously address FDA regulations, establish the treatment procedures and guidelines, and facilitate approvals of physicians and insurance carriers. Each phase is also more costly than those preceding it. As with understanding the many customers associated with the medical products industry, expertise is typically required to understand the research and development process (the trials) to bring a new medical technology to those customers.

The function map illustrated in Fig. 5 was created using information gathered during only three 10–15 minute interviews with medical researchers and physicians. It shows the research phases, the key goals associated with them, and how the process supports the main tasks illustrated in Figure 4. The technology, illustrated in Fig. 2 has shown a proof of concept and has been proven to function in a controlled environment, but not within cells or living tissue. The next phase of research for the technology, as identified by the inventors, is pre-clinical trials (Box CT1—Clinical Trials 1). FDA trials would follow this and are shown in Boxes CT2 through CT5. One could draw a direct link from Pre-clinical trials to the FDA Phase 1 trials in Fig. 5 indicating that the successful completion of Pre-clinical trials produces Phase I trials. However, this would miss important details about what the pre-clinical trials are for.

To build this map, it is important to ask why these trials are being performed. Pre-clinical trials would need to demonstrate cell targeting (Box CT7), show low toxicity (Box CT8) and establish the ability to kill live cancer cells (Box CT9).

Ultimately the technology would need to demonstrate both an increased efficacy and lack of side effects (Box CT10). Performing the trials would cost about $500,000 (Box CT6). Each of these goals would need to be successfully completed to move forward to an FDA Phase I trial (Box CT2). The Phase I Trials would first examine some basic behavior of the drug treatment in humans (Box CT11) which would require approximately $1,000,000 (Box CT12). This would also begin to establish the performance of the new treatment (Box MT5), one of the main tasks listed in Fig. 4. The next step, costing between $5,000,000 and $20,000,000 (Box CT14) would be setting dosages and safe ranges for the treatment (Box CT13) which would further characterize the performance and help establish new procedures (Box MT2). At the end of Phase I trials we can file for status as an investigational new drug (Box CT15).

Phase II trials (Box CT3) can have a five-fold increase in cost over Phase I (Box CT16) and have a very challenging task to demonstrate at least a 30% improvement, according to the cancer drug researcher interviewed, over current cancer treatment efficacies (Box CT17). This is perhaps the most critical element of establishing a new standard of performance for the treatment. Following this, Phase III trials are more extensive than Phase II and must support the findings of previous phases. Passing Phase III allows initial distribution of a new treatment to customers (Box CT18). The final phase of FDA trials spans the first several years that a drug is delivered to customers (patients).

The research phases outlined above must be performed by an independent laboratory (Box CT21). There are many regulations and guidelines that must be strictly followed (Box CT22), and liability lawsuits are very common during clinical trials requiring the support of legal staff (Box CT25). Fortunately there are several strategies that can help offset the challenges and costs of these trials: using "historically efficacious materials" (Box CT27), applying for "fast track" status (Box CT28) and performing the trials overseas (Box CT29). "Fast Track" status refers to looser FDA regulations for treatments that are addressing emergency health problems such as AIDS, SARS and certain types of cancer.

Without extensive expertise it is easy to consider FDA trials as one large costly task that must be completed before any new products are sold. Fig. 5, developed from information from three short interviews, illustrates a much more demanding and complex process. It also shows that the purpose of this process is to demonstrate how this new treatment is a significant improvement over existing cancer therapy options. There are many intermediate milestones that must be reached. The most critical of these is perhaps the need to show a 30% increase in anti-tumor efficacy. The costs associated with FDA trials are widely known, but the supporting professionals (physicians and lawyers) and organizations (independent laboratory), shown in Fig. 5 illustrate that the demands extend beyond funding. Thus, building the function map in Fig. 5 has supported a useful understanding of pre-clinical and FDA trials. Instead of a series of tasks, Figure 5 illustrates the causal (How and Why) relationships between each stage of the trials. Ultimately, the purpose of the trials as a whole is more easily understood.

One of the central activities of reaching customers with a new technology is connecting the current technology with some future capability of producing or manufacturing some type of product. With the current example, the phases of the pre-clinical and FDA trials provide some structure for building those connections. Fig. 6 on the following page illustrates the creation of manufacturing capability for the nano-scale drug delivery technology. Boxes CT1, CT2, CT3, and CT4 from Fig. 5 can be found across the top of Fig. 6, and illustrate the clinical trials needed to test the technology. The four main tasks from Fig. 4 (Boxes MT11, MT12, MT 13, and MT14) are found along the right side of Fig. 6 and are related to producing the treatment. The current technology is illustrated by Boxes T1 to T6 along the left side of Fig. 6.

A logical next step in the development of the technology would be to refine both the device and fabrication process (Boxes M2 and M3). This refinement and development effort needs to demonstrate the ability to supply the amount and quality of product required for Pre-clinical trials (Box M5). A better device design (Box M2) in conjunction with improved fabrication (Box M3) would create a laboratory fabrication capability (Box M4) to support both Pre-clinical trials (Box CT1) and Phase I FDA trials (Box CT2). For those two research stages, chemotherapy agent could be purchased (Box M1).

A dedicated nano-lithography setup (Box M7) and the laboratory fabrication would facilitate the creation of a pilot manufacturing facility to support the later stages of FDA trials (Box M6). The larger quantities of treatment during Phases II and III would require more significant amounts of chemotherapy agent (Box M8) and other materials required to create doses of treatment (Box M9). As with the many possible value chains that could be considered, there are also many possible options for producing doses of treatment. Boxes M8 and M9 represent one of these options. Boxes M10, M11 and M12 represent functions that are needed to transition from a pilot manufacturing setup to one capable of mass-production.

There are many new technologies being developed to combat cancer (Boxes M17 to M20) that create the potential for very significant competition (Box M21). Performance (Box CT17), cost (Box M14) and intellectual property protection (Box M15) are all examples of activities that could help address this competition. Furthermore, five core benefits of the technology, illustrated in Fig. 2: "protect healthy cells and tissues," "low side

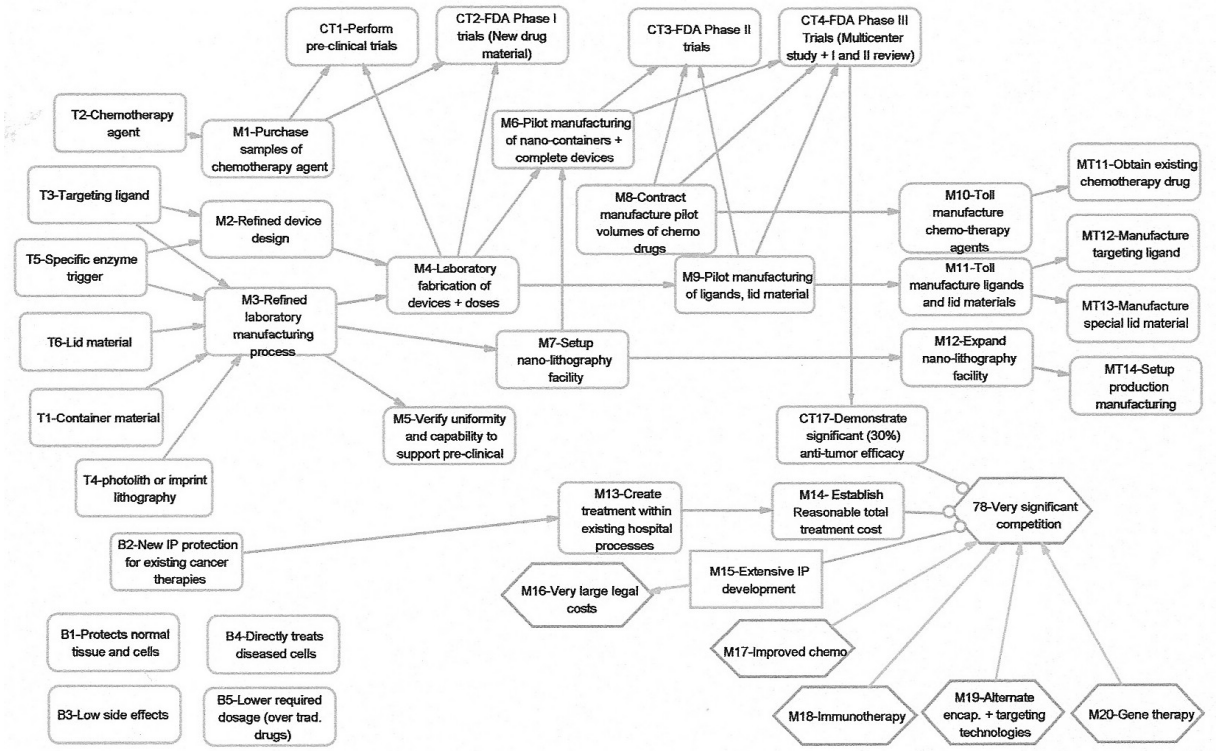

Fig. 6. Creating manufacturing capability.

effects," "directly treats disease," "lower required dosage," and "new IP protection for existing cancer therapies," could further help address competition. Four of the benefits of the technology were associated with the Value Chain illustrated in Fig. 3. The fifth benefit, "new IP protection for existing cancer therapies," (Box B2) is connected to possible lower costs and supports integrating the new treatment into existing hospital procedures (Box M13). This analysis could be carried further to explore strategies for counteracting the specific benefits of competing treatment technologies.

The construction of the map illustrated in Fig. 6 helps establish the causal relationships associated with improving the technology and creating a manufacturing capability to reach customer demands. Further, the path to reaching customers must begin with the current technology and depending on the technology will include technology research, regulatory hurdles, product development, manufacturing and methods of distribution. The key point is that the relatively simple steps to the TIM Tool drive an understanding of all of these areas. Further, with the maps as a framework, additional information about customers or regulatory hurdles can be included and the effects examined readily.

6. CONCLUSIONS

This paper focused on creating a future value chain and examined the necessary links between a technology and a value chain in order to deliver a product to a customer. Links were built from the value chain to the benefits and unique technology elements identified for a nano-scale drug delivery technology previously described by Evans et al. [1].

The example technology used to build the maps in this paper was gathered by a team of students for a graduate course. Several members of the team continued to work on the project for the following year. During that time, the team developed a comprehensive understanding about how the technology could reach customers, and won or placed in several commercialization competitions (including business plan competitions). It is interesting to note that during the graduate course the team had all of the information represented in Fig. 2 through Fig. 6, but were not able to draw several important conclusions. First, the team struggled to understand the specific purpose of each phase of laboratory trials and the milestones for each to be successful. Similarly, their plans did not include a discussion about the interaction of different levels of pilot manufacturing required to support the trials. They also did not include the need for legal and physician staff on the commercialization team. The team understood that FDA trials were necessary and that insurance companies would be involved, but did not include physician or hospital approvals.

Function mapping within the TIM Tool assists activities in technology commercialization by allowing a team to better understand the links between customer needs, the important elements of their IP relative to customer needs, and the course of action necessary to improve the like-

lihood of successful technology commercialization [10]. Furthermore, the links provide a basis for understanding opportunities and risks related to innovation with a particular technology, and promote technology innovation through a deep understanding of the technology and its associated environment.

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