Memphis Institute for Biomedical Innovation & Healthcare Solutions: Advanced Biomedical Systems and Solutions

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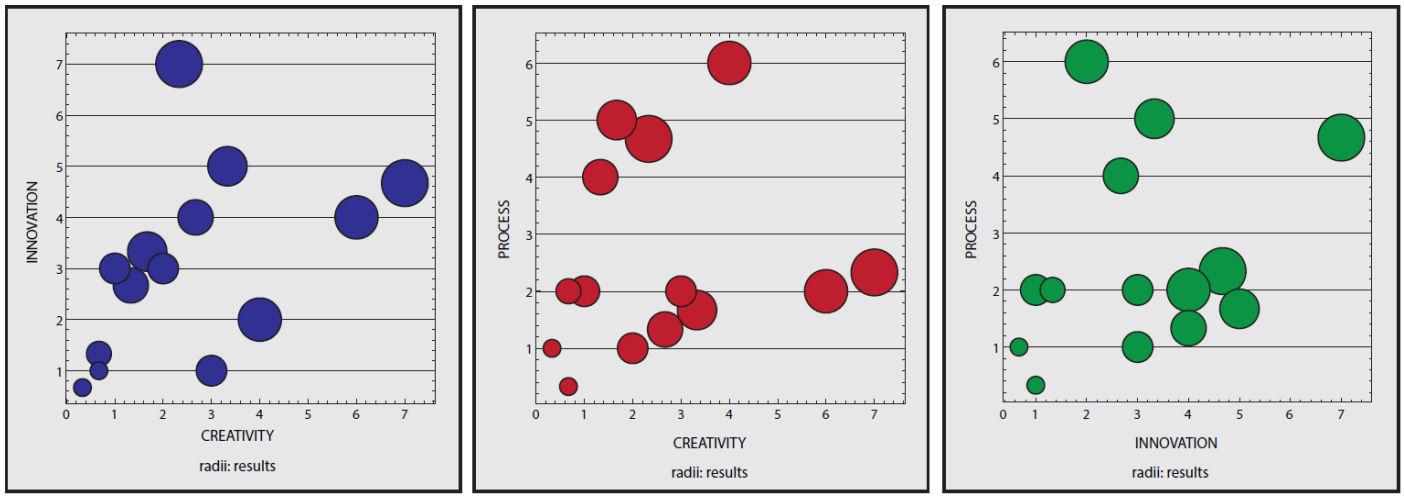


Figure 1: *Our proposed innovation solution uses a quantifiable approach to understanding needs and input used in studying social innovation. The graphs above outline characteristics used to measure innovative potential in participants.*

Abstract

The Memphis Institute for Biomedical Innovation and Healthcare Solutions provides connections between those who need advanced biomedical solutions and those with the passion and talent to create the solutions. We are an international focal point for the development of advanced biomedical systems and solutions for healthcare, leading biomedical companies and universities while in a partnership with IBM. This presentation will cover the formation of this unique Institute of excellence, along with its partnership with IBM, which will provide a technical foundation platform. Lastly, this paper will show the assets created from our novel approaches to innovate product creation.

Keywords:

biomedical, hardware solution, software solution, innovation, collaboration, community, STEM, regulatory, patent, software requirements, applications, regulations, FDA

1 Introduction

Has anyone ever Skyped? How about Face Timed? For companies, one of the greatest cultural achievements today is when a brand becomes a verb (1). So with that, Google the word

innovation. Just the fact that Google the corporation has become a verb in addition to being a service and financial performer is innovation at work, and the business effectively represents the theory of applying new solutions to meet new requirements. Corporate Google encompasses marketing, product, and service innovation. Some might define innovation as reducing lofty ideas to a more focused reality. The more efficient and predictive companies are focusing on innovation, the greater the results. Then, why is not every company a Google (company or verb)?

Innovation is more than just an idea. One could classify innovation as a multi-staged effort to make ideas reality. STEM (science, technology, engineering, and math) professionals, in particular, have been involved in at least one of these phases at some point in their careers. There are those who innovate, but whose ideas are too risky to pursue. Others know of companies that might make a product well, but innovation is incremental. For each employee working on the next big idea, there is another ignored when he or she might have a distinct perspective. This expression of creativity defines the foundation for innovation, but that cannot be its stopping point. Expanding this into a process, one develops these ideas through well-thought out steps. This transforms the ideas into a sequence of steps needed to produce a realistic product (2). Altering any of these phases could have an effect on innovation's outcome, but how would one notice?

However, how does one accurately predict future needs, when he or she does not fully understand those needs? In other words, does one know if he or she is missing potential opportunities when designing, and what factors might be affecting the outcomes? What biases or corporate traditions might limit ideas? Moreover, if an original idea surfaces, how does one understand if it is unique for the business, the market, and for collaborators? Many medical companies fight these seemingly endless battles with some choosing incremental advancements over disruptive solutions for fear of regulatory issues for any number of reasons (e.g. lack of existing products for referencing, scope, funding, or resources). In 2009, the medical device field oversaw over 3,000 filings for medical device products that were similar to an existing product called premarket notifications or 510(k)'s. That same year, only 15 Premarket Approval's (PMA) were filed (3). From a regulatory standpoint, PMA's are the greater risk, because they involve more upfront research, development, and clinical support, due to a lack of historical products, which are similar in nature. 510(k)'s have a shorter path to market due to them referencing existing medical devices similar in nature, and they both must be "substantially equivalent." Even at a perceived lower risk, the regulatory path can be a difficult one. How does new intellectual property infringement affect an FDA submission? How much of the process must be reevaluated and resubmitted? Is this increased perception of risk becoming an epidemic, leaving innovation in fleeting moments of people's minds—instead of becoming reality?

We believe a revolution needs to occur with the way companies and communities think about creating useful products. A better standard for practicing innovation, shortening regulatory paths, ensuring unique patentable designs, and reducing overall misinterpretations must begin. Between

2006 and 2012, more than 80% of existing infringement lawsuits within the United States stemmed from issues originating between reasonable royalty claims (4). Our outlined prescriptions for an innovative solution will align a formal structure for social opportunities with IBM Rational software-controlled metrics and processes necessary not only to ensure business unit acceptance, but also to navigate through patent landscapes and define a more acceptable and optimized regulatory path.

2 Previous Work

Portions of this paper are relevant across multiple disciplines (e.g. innovation); however, we are focusing on biomedical engineering and medical device product development. Within the medical device field, there are areas within the life cycle of products we would like to highlight.

Promoting Ideas. Historically, it has been difficult to separate each concrete process, environment, or program that aids in improving innovation from the ambiguity associated with determining a value for the ideas generated within a business unit. An abundance of techniques and tricks, methods and processes, and consulting services exist, which focus on establishing a creative work environment (e.g. brainstorming methods, mind mapping, speed thinking, and physical think tanks (5)). How can contributors know during these brainstorming sessions if the ideas generated or even the collaborators themselves are maximizing the potential for creativity? To measure these ideas we need to examine the metrics used. How does one account for other possibly unperceived deficiencies that may compromise decisions, such as biased environments, risk aversion, limited initial inputs, or lack of experience with producing or supporting ideas (6).

Traditionally, widening the pool of talent and improving social and environmental factors for innovating within a standard business community has been limited, due to upfront costs, intellectual property fears, or perception of no short-term financial gains (7). However, over the past few decades, efforts including brainstorming and think tank spaces have been growing, and these are becoming a more practiced and accepted method for product development. Social input is on the rise with leaders such as InnoCentive and One Billion Minds making collaboration readily accessible. Sites like these are seen as monumental successes for this type of collaborative environment. Recently, the Harvard Medical School formed an open innovation event around solving Type 1 diabetes through social research (8). Practices such as these show great potential; however, incorporating these techniques into a traditional office model may prove difficult to implement when compared with a business community supported by on-the-spot meetings or the tactile advantages associated with face-to-face collaboration.

Additionally, how does one's creative process use quantifiable data when weighing outcomes and aligning outputs for risk reduction within business models? A recent example of efforts taken to quantify innovation includes Vijay Govindarajan and Chris Trimble's 2010 publication "The Other Side of Innovation: Solving the Execution Challenge (9)". They highlight innovation

as the product of combining a creative phase with an execution phase.

Braden Kelley, author of "*A Guide to Open Innovation and Crowdsourcing*" (Published March 15, 2011, Kogan Page Publishing) built upon this theory by representing it with the following equation:

Innovation = Creation of Value x Reduction in Friction x Translation of Value.

Creating value involves identifying and utilizing insight from customers. Reducing friction comprises the easing of business interactions and improving communications between clients. Communicating these new findings through educating customers on unique advantages between the current and proposed solutions is how value is translated (10).

Kelley's equation still leaves the process in subjective territory. Even with a defined set of variables, how does one quantify the task of "creating value" without introducing subjectivity? Additionally, how does this terminology translate equally from business to business, and how do socially diverse innovators even fit into this equation?

Intellectual Property. Each designed project may have its own unique intellectual property (IP) or patent landscape. This has become the standard metric used not only to protect and license ideas, but also to enforce regional and national laws when infringed. As infringements and subsequent litigations have increased dramatically (11), this phase is becoming even more important as an insurance policy representing one's technology. Within the medical device community, this process may be more sensitive to IP changes, especially when taking into account the higher cost associated with testing and validating.

If one's patent/technology search does not include enough previously developed designs, it increases the risk of infringement. In a "first to file" landscape, does an application decelerate by months or years because of design issues, process changes, or regulation concerns? What if competitors file first and others are unaware of it?

Historically, the IP process has become antiquated and limited in reach because the sheer volume of possible patents and existing technological offerings versus the limited resources available to process these findings is too great. These processes are manual in nature, with legal representatives combing through literally mounds of paperwork. Added to this is an overabundance of subjectivity between reviewers and writers—each with his or her own opinions of how each existing claim might be interpreted or circumvented.

Regulatory Environment. The current regulatory path may vary, depending on a number of factors (e.g. differences between companies and resources, internal processes, history of communication between the FDA, the experience reviewer bring regarding the submission). At

times, companies may submit too little data for fear of regulatory delays or due to inexperienced corporate resources. Since the FDA is the receiver in this process, it mainly works with submitted material and historical filings. With these possible communication concerns, one can see how under-representation or a misinterpretation of submissions might occur.

In the United States, one stage during the regulatory submission process involves supporting the safety and efficacy of the proposed submission through predicate data from existing journal articles. Depending on the scale of the submission, a preparer might sort and evaluate massive amounts of existing information (possibly in multiple languages). When determining if an article is relevant, it is good practice to ensure that the data and relevant cited information is not misrepresented. Similar to issues outlined with *intellectual property* one can quickly understand how each of these areas may be sensitive to misinterpretations or inaccurate data.

Development timelines in the United States for the medical device field can be a lengthy process, depending on the path of sale. The industry commonly calls these separate paths as United States (US) versus Outside United States (OUS). Table 1 shows the average medical device timeframe from submission to clearance for products within the United States and Europe (3).

Description	US (months)	Europe (months)
average 510(k)	10	not available
average 510(k) + clinical	31	7
average PMA	54	11

Table 1: *United States (US) and Europe timelines for medical devices.*

The publication "FDA Impact on U.S. Medical Technology Innovation, A Survey of Over 200 Medical Technology Companies" published the data above. It highlights major concerns with medical device manufacturers because of their ability to *"make their products available to patients faster and at a significantly lower cost in markets such as Europe,"* (3) where the reported average US price tag for 510(k) was $31 million and PMA was $94 million. The publication did state any specific cost associated with filing in OUS markets such as Europe.

3 Requirements

Community input is the backbone of our innovative programs, and the diversity of our participants creates active solutions. When initiating projects within the Institute, it is mandatory that:

- Stages are comprehensive and encompassing to each participant if possible.
- Effort includes validated metrics at all stages.

- Software-solution provides management, traceability, validation, and requirements tracking.

For our pilot project requirements, we are focusing on the three areas above: promoting ideas, intellectual property, and regulatory environment. The process stages developed take into account following guidelines:

- Stages must be collaborative, comprehensive, and measurable. Formal procedures and software requirements exist to ensure objectivity, full comprehension of the processes, and a well-defined goal to align the needs and ideas with the business unit and customer requirements.
- Assumption teams are determined utilizing an innovative metric defined through surveys and other evaluations. This metric takes into account more anthropological inputs, one's emotional intelligence, and needs of the individual before team building.
- Stages dealing with IP will incorporate technical and patent research metrics.
- Regulatory design stages will incorporate needed tools (e.g. quality, testing, journal evaluation) to improve reliability of the data, traceability of each process, and compliance with IEC 62304 – the international standard for medical device software and life cycle processes (12).
- All software requirements are verified and validated through the IBM Rational software.
- System Requirements include flexibility through IBM Rational software.

4 Theoretical Foundation

Mibio is constructing a more quantifiable system, while referencing traditional methods we view to currently have either ambiguity within its process or ambiguity where phases are seen as more "trade art" than a standard defined practice. We take steps to maximize community unity during phases so all participants within the system may play a larger and more impactful role in developing real-world solutions.

Innovation. To establish a more measurable and objective system, the Institute's innovation model will calculate and rank all data collected during the project as inputs (e.g. initial conditions, questions, surveys, problem statements) and outputs (responses from the inputs, brainstorming results). It will allow us to create a record of any input or output at any phase of the process, as well as factors affecting the characteristics outlined below. Essentially, we are treating creativity and innovation as a system similar to a manufacturing process.

As your senses are to the body, the Institute defines innovation as characteristics (senses) and stages (the body). The six characteristics below represent all the senses of innovation (Figure 2). Within each characteristic, there exist stages defining the actions or activities required.

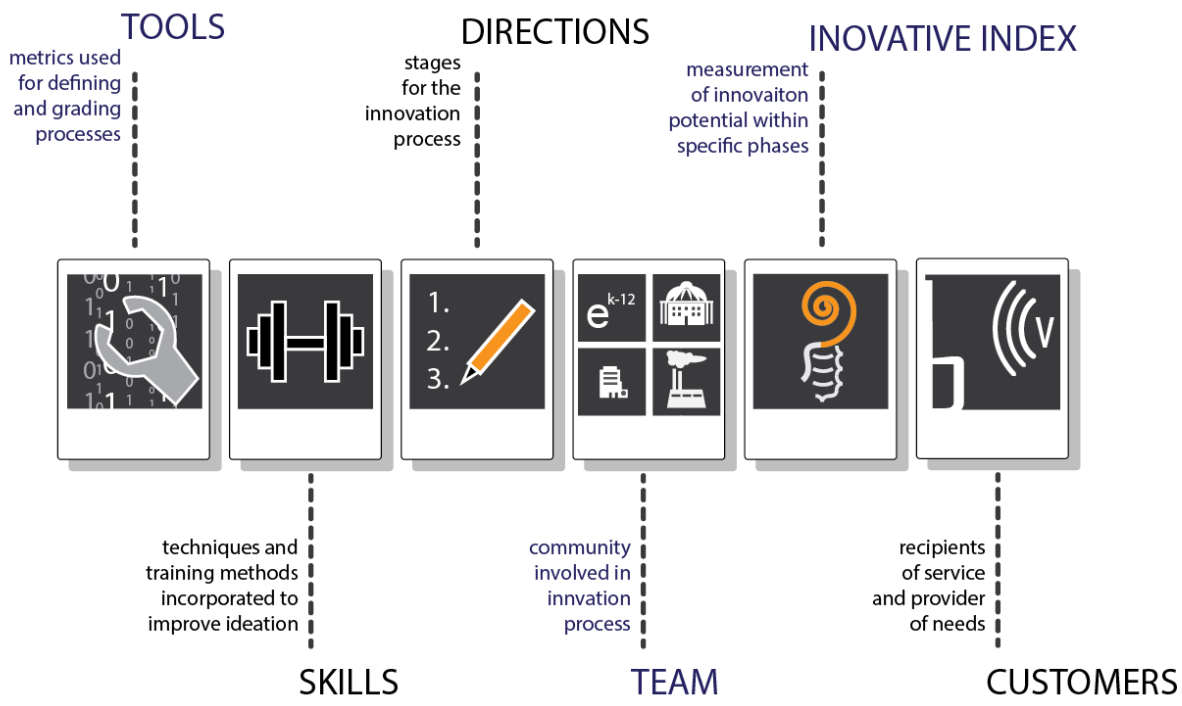


Figure 2: *The characteristics of innovation*

Tools. Many resources exist that are well-established tools for performing analysis of a wide variety of inputs (e.g. analytical hierarchy process, quality function deployment, Pugh matrix). For our project, these methods are sufficient for calculating results with confidence (13).

Skills. Similar to *tools*, many techniques, and methods exist for *skills*. We determined this characteristic would be measured better by its outputs because the inputs were difficult to control (e.g. - technique, language, time, participants, location, how meeting are run). We assume that improving these environmental factors improves possible outcomes, but for this project, these environmental differences were not calculated (e.g. - lower light improves creativity (14)).

Customers. Below, we outline common practices used for information gathering when determining the needs of customers. One traditional method involves engaging customers after a product is developed (which might limit customer feedback at critical development stages). Another popular technique tailors the questions addressed to customers with opinionated business solutions (limits the possibilities of considering solutions outside a business's core competency or risk comfort zone). Scenarios similar to these support the need to filter bias in this section. Although social input is gaining traction, we are focusing on more clearly defining a path for broader input from the internal workforce. For our model, the following stages make up the *customers* characteristic:

- voice of customer - determines external customer emotional intelligence, perceived needs, and defines a possible path for future interaction

- voice of employee - determines internal customer emotional intelligence, perceived needs, defines core capabilities within the business units, ranks the capabilities, and defines a possible path for future interaction
- survey - tool used in ranking the emotional intelligence, habits, and other anthropological inputs
- voice of innovation - determines participants emotional intelligence, risk aversion, perceived needs, and defines a possible path for future contributions

Directions. Building from previous characteristics, we have the tools needed to define software requirements and establish a *direction*. For this project, the innovative *direction* spans from initial needs finding (input) to project submission with the FDA (regulate), and divides into the following stages (Figure 3).

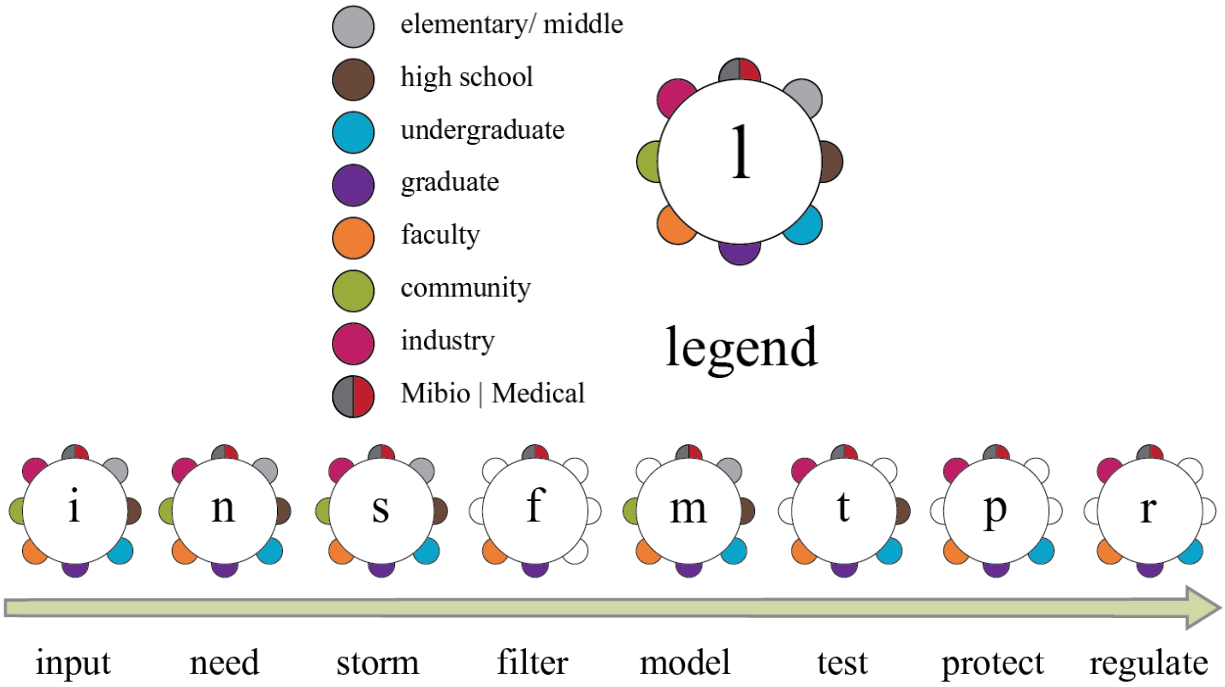


Figure 3: *Our proposed direction stage.*

- **input** - Judges the emotional intelligence, habits, and other anthropological inputs for all participants.
- **need** - Determines true voice of community while reducing bias for future stages.
- storm - Assumption and Brainstorming phases utilize best practices in idea generation.
- **filter** - Evaluation of alignment between ideas and true needs. It is mandatory that this stage filters bias and ensures validated metrics for initial business case.
- **model** - Aligns theoretical ideas with actual competencies: design, research, development, and prototyping.
- **test** - Software and hardware testing to regulated standards. May incorporate verification

and validation.

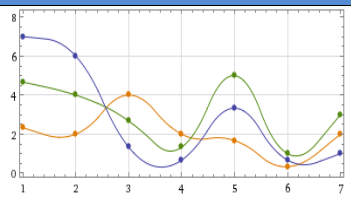
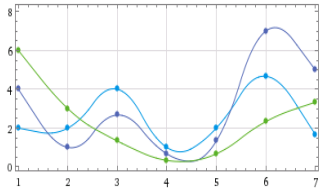
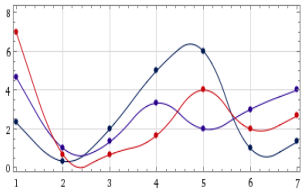
- **protect** - Future software offering will improve possibility for unique product solutions by creating measurable outputs.
- **regulate** - Future software offering will enforce compliance with IEC 62304 and incorporate metrics targeted at improving accuracy and communication of submission process.

Innovative Index. As stated, Govindarajan, Trimble, and later Kelley outlined innovation as variables supporting a business and customer need (e.g. reducing friction x translating ones values), but unsuccessfully refined the subjective characteristics. Mibio outlines the *innovation* characteristic into three stages:

- Creation - capacity to form new purposeful ideas
- Development - creativity inputs are matured across a broader social base
- Implementation - processes and drives ideas to usefulness in alignment with the business unit, customers, and needs.

In ensuring reliably objective results, we measured participants' innovative scores at the initial *input* stage through surveys. The surveys established a baseline before training creative techniques or performing idea-generating activities. This theoretical approach creates a guide for understanding how innovative potential is measured. It allows participants to have relevant and beneficial access to contribute within the innovation process, and it allows bias filtering when assembling teams. With these tools, innovation develops into a teachable and repeatable process.

In quantifying this, relationships and predictable modeling values between the three stages for *innovative index*, survey outputs, and customer needs are determined by the Institute to define a mathematical model. The relationships are proprietary and based on relational algorithms for calculating a predictable model. This predictability allows us to benchmark progress and refine the model for future projects. Table 2 outlines each model for the three stages.

Creation	Development	Implementation
		
P-value: 0.0047	P-value: 0.0196	P-value: 0.0101

Note: Shapiro-Wilk = 99%

Table 2: *Computational models defining innovation as a quantifiable product.*

Team. The *customers*, *innovative index*, and *direction* segments define the software requirements used in developing the *team*. Outputs from the surveys provide a better guideline

for determining the innovative score, as well as defining possible needs. Future stages will incorporate these baseline results in defining predictive modeling studies through the Institute into future modules in the form of comprehensive software.

5 Procedure

Although multiple pilots were completed, this proposed innovation model presents results from two projects: *initial pilot* and *biomedical*. The *initial pilot* began prior to the *biomedical*, and ran within a single company. The larger scale *biomedical* project is an ongoing project, currently in the *input* stage. For this project, the Institute defined the community as industry, university, faculty, STEM programs, and schools. The *initial pilot* was successful when implemented, and we see it as directly relevant and scalable (both industries have equally stringent industry regulations).

Needs. To begin the *input* stage, the Institute performed a needs assessment, creating the voice of the business and community. For the needs assessment, we used a more traditional approach for determining these concerns/opinions. Metrics were omitted for the *initial pilot* and *biomedical* models.

Customers/Innovative Index. The Institute had designed *customer* surveys with industry relevance in mind. The relevant areas defined below have been determined through publication needs gathering (e.g. journals), and industry relevant data mining. The table below (Table 3) highlights details between the *initial pilot* and *biomedical* models. Within each survey, questions cover five relevant areas:

Initial Pilot	Biomedical
change	disruptive
waste	process efficiency
work environment	surgeon
product	innovation
end user	patient
manufacture	device manufacturer

Table 3: *Defined trends within each industry space.*

Each question lists three to five possible choices for answers. All choices are weighed against the five following criteria (Table 4) determined, in part, from the *needs*, which will be listed in the results portion.

Initial Pilot	Biomedical
time	reduce time
money	money
environmental	broad population
technology	technology
safety	health improvement

Table 4: *Criteria used to weigh survey results. Terms are industry specific and weighed against the needs of the business/community.*

Direction/Team. Referencing the stages defined earlier in the paper (see Theoretical Foundation on page 8), Figure 4 aligns each stage with all possible contributors at every stage, while highlighting each level of possible participation.

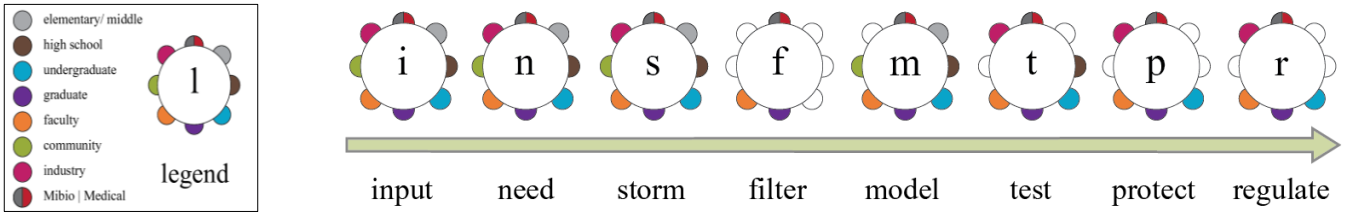


Figure 4: *Mapping the possible collaborative interactions between each participant and stage.*

For this model, we can specifically tailor each stage to address an individual voice from the business or community needs. The process, metrics, and all other requirements will be tracked through an IBM software solution. IBM tools planned for future use include integration of DOORS NextGen, Rational Team Concert, and Rational Rhapsody.

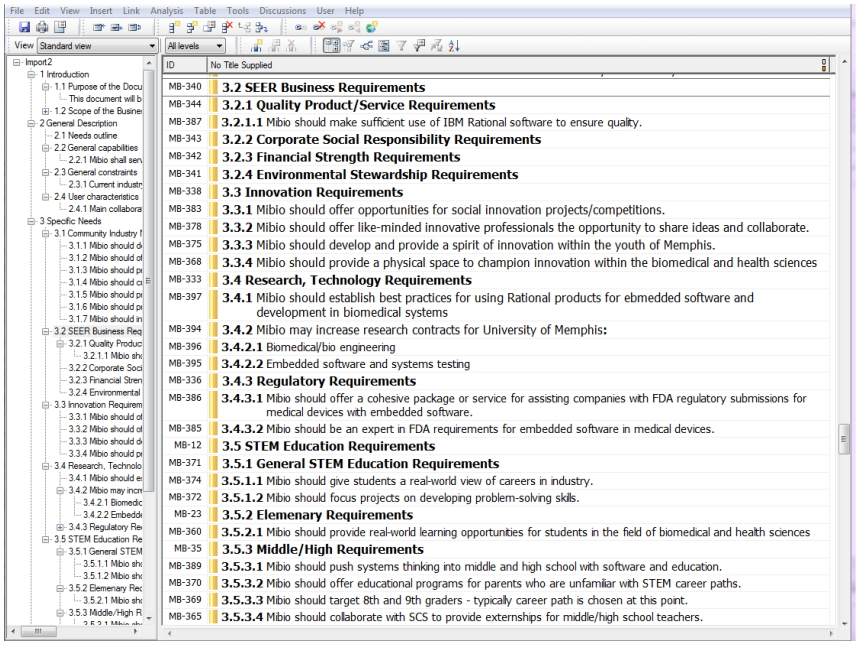


Figure 5: *Defining requirements through IBM Rational DOORS 9.2.*

6 Results

The *biomedical* run is currently underway at the initial community needs assessment stage; however, the *initial pilot* project is at its manufacturing stage. For this paper, we will highlight process results through the filtering stage, in part to keep technological developments protected for the existing customer and proprietary manufacturing processes from being revealed during the *model* stage.

Needs. For the *initial pilot* project, 47 participants out of a possible 65 (72.31%) took part. The table below (Table 5) summarizes the needs assessments from both projects.

Initial Pilot (voice of business)	Biomedical (voice of community)
technological push (45.0%)	innovate - unique products (21.6%)
financial benefit (8.8%)	regulatory challenges (12.2%)
green/ environmental push (33.5%)	specific software (8.6%)
shorten customer times (8.3%)	community involvement (41.7%)
safety (4.3%)	product development methods (15.8%)

Table 5: *Needs comparison: Concerns within the industry.*

Customer/Innovative Index. Table 6 outlines the results from the 47 employees who took part in the survey for the *initial pilot*. Once all information was gathered for the *input* stage, a score

could be determined comparing the input back to the mathematical model of Table 2. Of the 47, 35 were males and 12 females with the lowest survey score being 13 and the highest 54 out of a possible 54 points. Males scored an average of 30.4 ± 10.51 SD, while females scored 35.5 ± 6.22 SD.

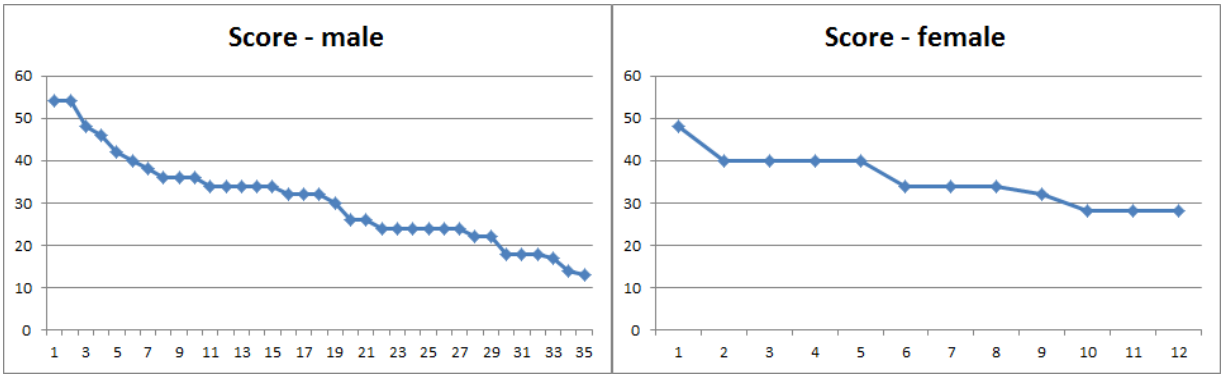


Table 6: *Comparison between male and female participants for rating innovative index.*

Direction/Team. Not all of the top scoring members (average of 47.43 ± 5.38 SD) could participate in the *storm* stage, because of logistical reasons (four participants had travel obligations, and two live in another city). Instead, a team of eight participated whose scores were similar to both the male and female groups for benchmarking an average score and classify the group more by performance than gender. This team was the *assumption* group (36 ± 11.08 SD).

We created three separate groups for comparison: the *traditional*, the *voice of business*, and the *assumption* groups. The first group was the *traditional* team, and it was formed to be the control group. The members had access to all the data they needed and had direct influence of forecasting, current market research, and were directly involved in project management. On the other hand, they were isolated from any of the surveys, mathematical models, or creative sessions. This group consisted of six participants whose product experience ranged between 8 and 25 years.

The second of these groups consisted of the 47 original survey participants, and none of the six above participated in this group. They were formed to be the voice of the business group, which represented survey questions regarding potential of product knowledge, risk, and what each participant thought the vision of the company should entail. Their company experience ranged between 1 month and 20 years and represented 13 different departments (human resources, manufacturing, marketing, engineering, tech service, administration, analyst, legal, product managers, regulations, testing, machinist, drafting). We only used the needs assessments from the 47 participants to define the *voice of the business*.

The last group consisted of the *assumption* participants from the main 47 coworkers, and they

were formed to be the novice group. This comparison would allow us to evaluate the performance of an experienced, yet traditional group versus an unseasoned group given direction. Their experience with the project challenge was untested versus the traditional teams falling between 3 months and 3 years of very basic product line knowledge. This team had neither forecasting, external customer needs, nor marketing research during the entire process.

Table 7 shows the outcomes from the brainstorming phases only, and one should note the *assumption* team was able to brainstorm all of the *traditional* team's ideas as well as 32 others:

Traditional	Assumption	Business
6	38	n/a

Table 7: *Ideas generated for project between each of the three teams.*

For the above table, the business could not participate in the creativity activities for this project. They could, however, rank ideas once they were developed, because of participation in the needs. Each group selected their five best ideas. The criteria for determining weighted value was:

- *Traditional*: did not rank any ideas, so they were ranked by sequential order submitted.
- *Assumption*: determined from *filter* stage.
- *Business*: determined from the *input* stage.

Once it was determined how each group weighed in on individual ideas, they then compared each other's top five ideas by their own independent raking systems (Table8). For this exercise, the same criteria for selecting the five best choices was used, and this was only possible if one completed the *input* stage or independently ranked ideas.

Top Ideas	Traditional - viewpoint	Assumption- viewpoint	Business - viewpoint
Traditional top 5	1,2,3,4,5	2,4,6,10,28	27, 21, 15, 22, 6
Assumption top 5	-	1,2,3,4,5	16,27,26,21,29
Business top 5	-	29,27,16,20,22	1,2,3,4,5

Table 8: *Ranking each groups top ideas and how they viewed other groups (e.g. – the traditional's 5th best idea was number 28th for assumption's and 6th for the business'.)*

Because the *traditional* group did not rank or develop the same ideas as the assumption team, their input was left out when weighing other group's ideas. From the information above, we conclude that each group does not necessarily agree with the other's top choices. This is where the business unit directive and initial needs should align, but more importantly, a defined metric has been calculated.

7 Discussion/ Conclusion

There has been a push toward bringing the communities from high schools (STEM), universities (Tech Transfer Offices), industry (Research Centers within universities), and independent professionals (consulting within industries) closer to develop a system more relevant to real world conditions. Each participant brings specific strengths and opportunities for growth, depending on his or her stage in life. STEM programs engage students to gain interest in science, engineering, technology, and math, while universities receive the participants from these programs as students to help drive ideas and groundbreaking technologies. Another dynamic to consider is the confidence one might possess earlier in life to risk and to be willing to create compared to one or two generational differences (15). Currently, attempts are underway to create a financially sustainable foundation for this hybrid environment. A 2013 report from the Brookings Institution states that policymakers "want universities to be more responsive to market forces, more entrepreneurial, and more attuned to the needs of industry (16)." Technology transfer offices are the business and legal link between creating research and commercialization of ideas through start-up companies or existing businesses. According to Walter Vadivia from Brookings Institution, on average, 87% of universities with technology transfers offices have operated in debt over the past 20 years, which validates their suggestions (16).
On a similar front, it is difficult to disregard the major advancements made within the software, development, and applications communities. Their efforts focus on revolutionizing the World Wide Web and information modeling, and open source programming has commanded the disruptive wave within this cyber environment. There is no foreseeable reason why this integration within technical hardware, software, and open source communities should not continue to mature for the next 10-20 years at an accelerated rate. It is only logical that the communities participating within these electronic walls become part of the system who will be defining them for the future.

Innovation is the cornerstone to true market disruption, and our focus at the Institute is to drive change across the medical device industry. We are in the initial stages of creating programs, metrics, and software to revolutionize the ways cities and communities collaborate, share ideas, and learn from each other by uniting towards real-world biomedical solutions. The *biomedical* pilot runs are underway, and proceeding project participants will be initiating two parallel projects for biomedical and biologistic solutions. Future developments will focus on tackling the needs seen within the regulatory, quality, and patent landscapes. Bringing industry, academic, and STEM experts together adds a level of transparency, community support, and buy-in unique to our model and Memphis.

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References

1. Hoban, Mike. "Google this: What It Means when a Brand Becomes a Verb." *Fast Company*. January 18, 2013. Web. May 31, 2014.
2. Ashby, Matthew W.; Cowan, Kathy Moore; Haralson, Lyn E.; Weekly, Faith. "The Four Key Elements of Innovation: Collaboration, Ideation, Implementation and Value Creation." *Federal Reserve Bank of St. Louis*. Summer, 2009. Web. May 30, 2014.
3. Makeower, Josh; Meer, Aabed; Denend, Lyn. "FDA Impact on U.S. Medical Technology Innovation, A Survey of Over 200 Medical Technology Companies." *Eucomed*. November, 2010. Web. May 30, 2014.
4. Barry, Chris; Arad, Ronen; Ansell, Landan; Clark, Evan. "2013 Patent Litigation Study Big cases make headlines, while patent cases proliferate" PriceaterhouseCoopers LLP, 2013.
5. http://en.wikipedia.org/wiki/Brainstorming
6. Dvorsky, George. "The 12 cognitive biases that prevent you from being rational." *i09*. Newitz, Annalee, January 9, 2013. Web. May 30, 2014.
7. "Measuring outcomes of innovation." *Corporate Innovation Online*. June, 2010. Web. May 30, 2014.
8. Guinan, Eva; Boudreau, Kevin J.; Lakhani, Karim R. "Experiments in Open Innovation at Harvard Medical School." *MIT Sloan Management Review*. March 19, 2013. Web. May 30, 2014.
9. Kelley, Braden. "What is Your Innovation Equation?" *Innovation Excellence*. August 30, 2012. Web. May 30, 2014.
10. Kelley, Braden. "Innovation is All ABout Value." *Innovation Excellence*. August 1, 2011. Web. May 30, 2014.
11. Quinn, Gene. "The Rise of Patent Litigation in America: 1980-2012." *IPWatchdog*. April 9, 2013. Web. May 30, 2014.
12. http://en.wikipedia.org/wiki/IEC_62304
13. http://en.wikipedia.org/wiki/MCDA
14. Pallotta, Dan. "What's the Point of Creativity?" *Harvard Business Review Blog Network*. September 9, 2013. Web. May 30, 2014.
15. Blair, Elizabeth. "Is It Possible to Measure Creativity?" *MindShift*. April 20, 2013. Web. May 30, 2014.
16. Vadivia, Walter. "University Start-Ups: Critical for Improving Technology Transfer." *Brookings*. November 20, 2013. Web. May 30, 2014.