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The PLH - Purpose Launchpad Health - Meta-Methodology to Explore Problems and Evaluate Solutions for Biomedical Engineering Impact Creation

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***Abstract*— Healthcare Innovation ideas originating from biomedical engineering departments are rarely based on a deep understanding of a problem, but are often based on coming up with an engineering solution that does not meet an Unmet Clinical Need, is too complicated, bulky, costly, and does not consider global developments. For an impactful innovation design it is essential however to properly understand the clinical issues, forward project the effect of exponential technologies and other global developments. Health and healthcare are in need of disruptive ideas for preventive, predictive, personalised solutions that engage the individuals to pave the way towards real healthcare. We have adapted a novel meta-methodology for dedicated use with health related applications and have used it validating start-up ideas and also during a semester long lecture/seminar classroom setup with amazing results.**

***Clinical Relevance*— This novel health dedicated meta-methodology is dependent on interdisciplinary team and innovation work and heavily relies on a good understanding of the current clinical processes and needs as well as on a future projection of global health delivery developments. The clinical perspective is essential and meaning- and impactful innovation can only be developed validating desirability feasibility, and viability, which needs clinical-, engineering/technical-, as well as economic expertise.**

I. Introduction

Health related innovation ideas are often initiated in a technical department without a clear understanding of the actual clinical and patient needs. The apparent problems that are addressed by the new idea are rarely validated and also are often just incremental improvements of currently implemented and used systems.

Future healthcare should be more predictive and lead to personalised prevention rather than to only focus on fixing the actual health problems [1]. Development activities should attempt to identify product and process ideas that will lead to a shift from the current sick-care to an actual focus on maintaining personal health and with that avoid or greatly reduce the getting sick part (Fig. 1).

Students in technical departments, like biomedical engineering, learn depth, but lack the abilities to understand and solve problems with an empathetic, economic and global point of view. While it is clear that inventions will only become innovations when *desirability* (does the market need it?), *feasibility* (can it be build?), and *viability* (is anyone willing to spend money for it?) are positively evaluated, the needed questions and validations are not initially asked and validated. It is much more normal that we assume things and then quickly come upon with a perceived solution idea that we then start to build.

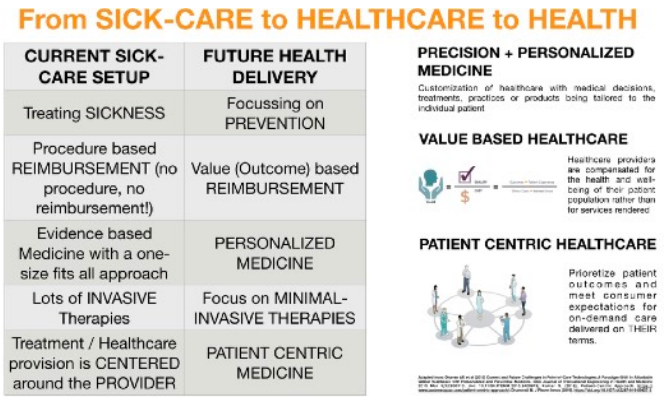

Figure 1: Move from sick care to healthcare including changed business approaches. Future developments need to be in line with these needs.

We do anticipate a significant disruption in for future health developments with the convergence of different technologies. Robotic surgery is currently just a tele-manipulation system controlled by a surgeon, but when this is combined with machine and federated learning, and advanced sensors plus intra-operative imaging a fast move towards semi-autonomous and autonomous control and operation is imaginable. There are several other areas where sensors, machine learning, big data, genetic information, 3D printing could lead to complete new ways of analysing health developments.

Depending on the country you live in healthcare is very different from an offering, quality, and cost perspective and is embedded in different health business model. Some may adapt these new technological abilities much faster than others, because of lack of alternatives and cost issues. This will possibly lead to fast changes in health related delivery offerings and business models.

With that we believe that a dedicated innovation meta-methodology is needed that explores the actual clinical needs and problems, analysis the environment including future technologies, validates assumptions and hypotheses and subsequently evaluates solutions via rudimentary prototype ideas to find a product/market fit that justifies an impact initiative [2-4].

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A good recipe is to find a purpose-product fit in a problem EXPLORATION phase and validate some of the initial hypothesis with many customer and problem oriented experiments. Once that has been achieved, most likely with many iterations and revisions of the initial problem understanding, it is time to build MVP's, minimal viable prototypes (e.g. rudimentary models, sketches) that help to evaluate the product idea towards a product/market fit.

This validation of desirability, viability, and feasibility is often the core initial work of start-ups to define and work on an impactful product and business model. Start-Ups are probably the ones that will focus much more likely on disruptions (making current products and processes obsolete) as existing stakeholders have little interest in such a change.

The three phases of a development process from an idea towards implementation are shown in figure 2.

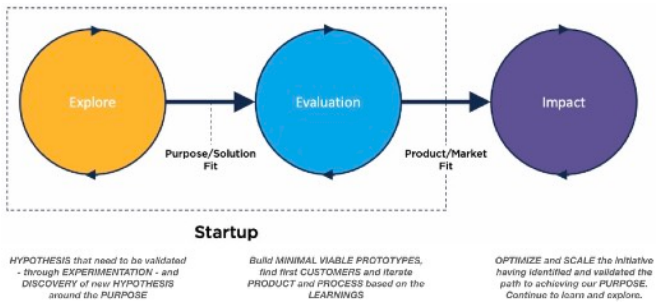

Figure 2: Innovation starts with an exploration of the problem space and a deep understanding of the needs and pains of the potential users / customers. To check that we need to work with lots of hypothesis and related experiments to validate in an EXPLORATION phase a Purpose/Solution fit that justifies to advance to an EVALUATION phase.

The innovation model that we propose is based on the Purpose Launchpad (PL) methodology and adapted to the Health Innovation environment (PLH - Purpose Launchpad Health) that define the interaction of the PEOPLE that are involved in this innovation activity so they understand the needs and desires of the CUSTOMER, are able to define a proper future oriented STRATEGY and a PRODUCT that is attractive and fits the market needs (see Fig. 3) [2, 5].

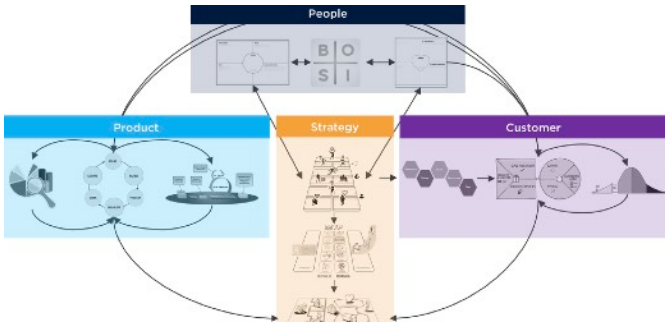

Figure 3: The PURPOSE LAUNCHPAD methodology helps the involved PEOPLE to understand the CUSTOMER needs and desires, to formulate and execute a STRATEGY, and define a PRODUCT that fits the market.

II. PLH METHODOLOGY

A. The eight segments of PL for the different phases

The individual segments have different goals for the different phases. For the e.g. PURPOSE the exploration phase should be used to define the reason for the initiative and your personal role. With more information, insights you will certainly re-iterate and re-define them in an evaluation phase and be more outspoken about it in the impact phase.

TARGETS	Explore	Evaluation
Purpose	Define your identity: why the initiative exists (purpose), what you want to be and how you will do it	Check your identity and iterate it as you learn with real experience
People	Connect with Purpose-oriented communities to find out personas, problems, and solutions. Also, connect with possible team members, and focus on exploration profiles.	Keep engaging with communities to find early adopters and others. Also, keep evaluating the team members with real action and make changes in the team (if needed).
Customer	Start discovering what could be your customer segments.	Start selling to early adopters.
Abundance	Define how to connect and manage abundance.	Start implementing and validating the way we connect with abundance.

TARGETS	Explore	Evaluation
Viability	Define your business model to be financially sustainable.	Evaluate whether your business model can generate revenue and iterate it (if needed).
Processes	Simplify processes to focus on learning.	Start defining and executing operations to deliver value to early adopters, while learning from them and iterating our solution based on it.
Product	Define Value Proposition and learn about it.	Build/iterate MVP to satisfy early adopters.
Metric	Focus on qualitative insights.	Measure value.

Figure 4: PL segments and goals of each segment for the different phases. The IMPACT phase was not listed, as this is typically not a phase reached without growing a Start-Up.

Fig. 4 shows the different goals for the different segments and phases.

Especially for Start-Ups and ideas created in a lab environment it is not always good to start with the PURPOSE as many things first need to fall in place. But a start-up needs to have clear understanding among all involved about the WHY of the operation.

B. The PLH Innovation Tools for Exploration / Evaluation

The Health field is quite special and it is essential to check and analyse the needs of the stakeholders as well as the individual health business models that vary from country to country.

In one the main customer is the hospital in another the individual doctor, and in a third several services are offered in a pharmacy. This is why we defined a small set of tools that

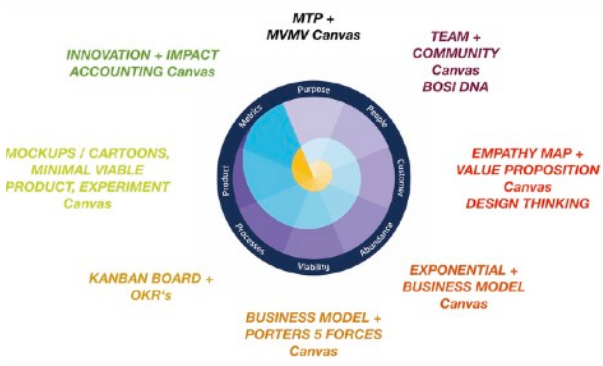

Figure 5: For each of the segments in the EXPLORATION and EVALUATION phase specific innovation tools are proposed. For the PURPOSE for example the MVMV (Massive Transformative Purpose, Vision, Mission, and Values) canvas. Or for the PROCESSES the definition of Objective and Key Results (OKR).

help to understand the problem and help to develop a purpose- and product market fit for health related innovations. All the mentioned tools (see Fig. 5) are publicly available and you also find explanations on their use in the internet. Alternatively they are presented / explained in [5].

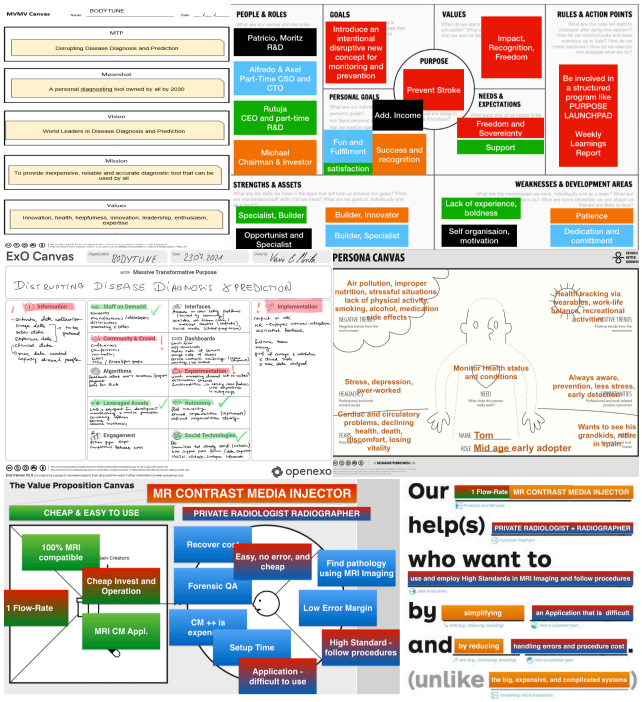

Figure 6: Top right clockwise: MVMV canvas (PURPOSE), Team Canvas (PEOPLE), Persona Empathy Canvas (CUSTOMER), Value Proposition Canvas and Elevator Pitch (CUSTOMER and VIABILITY), Exponential Canvas (ABUNDANCE).

Examples of several of these PLH innovation tools are shown in Figure 6 for a recent biomedical initiative that is currently been developed in the authors research lab and that is also highlighted in Figure 7.

Presented are the MVMV (MTP, Vision, Mission, Values) canvas used for the PURPOSE segment. The MTP, Massive Transformative Purpose, is an organization's higher aspirational purpose and describes the change in the world that a team wants to achieve. The initiatives vision is what we want to become in the future, the mission describes the way on how you will make your vision true, while the values are indicators of the way that the organisation is operated.

The TEAM canvas is centred around the purpose and highlights the capabilities and ambitions of the members. Through an empathetic view on the CUSTOMER (persona canvas) and by evaluating the customers pain and gain it is possible to analyse the problem and define value propositions of a potential PRODUCT and get closer to a purpose- and product-market fit. The connection to ABUNDANCE is best described and visualised using the Exponential canvas.

B. The PLH Innovation process

An experienced PL mentor should guide the team through the process that is in a lot of ways organised like other agile methodologies (e.g. SCRUM).

An independent person or the university professor would be ideal for that role as they are not involved in the day to day process.

A PLH innovation SPRINT (= regular repeating process) can be weekly or biweekly. The team itself should meet daily to discuss the open issues and next things they want to do to gain insights or validate hypotheses. In a weekly planning meeting with the mentor the progress will be presented and a new activities list defined, called the project BACKLOG. The mentor will also discuss the learning and the new insights with the team and inquire about the mood of the team. This is quite important as it may show problems with the team and process early on.

B. Innovation Accounting - Learning as essential Measure

What has the team actually learned during the PLH sprint process is the essential measure of progress. And it is also essential to embrace failure and invalidated hypothesis with learning. The process is iterative and follows the lean startup principle of BUILD something, MEASURE the outcome and LEARN from it.

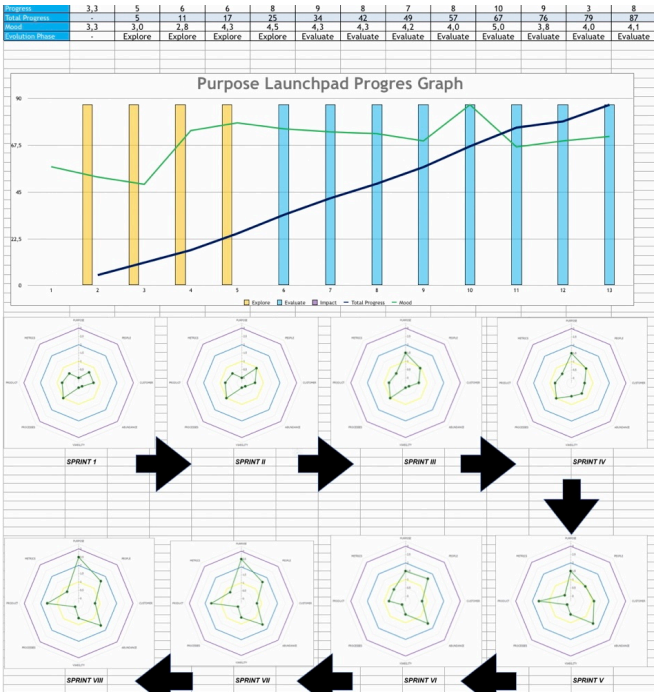

Figure 7: shows the learning progress (points - blue line), mood graph of the team (green line) and the progress radar of a PLH initiative over many sprints / months. It took 5 SPRINTS to advance from the EXLORATION to the EVALUATION phase.

III. RESULTS

The PL provides learning points (1 point for a new insight, 2 points for a validation / invalidation of a hypothesis/assumption), measures the weekly team mood on a scale from 1 (poor) to 5 (excellent), and provides a visual feedback presenting the progress from one sprint to the next based on a standard and publicly available questionnaire.

Fig. 7 shows a PLH innovation - the one that was also used for most of innovation tools in Figure 6 - initiative from the authors lab over many months and the associated visual progress. It also shows the learning curve and total learning points (top graph (dark blue line) and the mood variations (green line). There was a mood dip from sprint 1 to 3 that came from frustration and unclear expectations.

Valuable information that was quickly corrected through additional training.

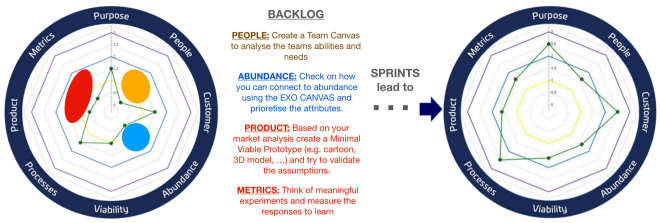

Figure 8: A progress assessment produces a visual progress radar that can be used to define a backlog of items for the next sprint towards an initiative (right) that has progressed towards a product - market fit.

Fig. 8 shows such a progress radar that is used to formulate a backlog of items that should be accomplished in the upcoming sprint. The example shows problem areas (low values) for an evolution from DISCOVERY (yellow) to EVALUATION (blue) phase for the PEOPLE, ABUNDANCE and PRODUCT / MERICS segments and the actions that should be taken to gain progress.

The PLH was also used in a 5 ECTS lecture/seminar (10x5 hour on-site lecture, 3x3 hour online mentor sprint sessions), where undergraduate and graduate biomedical engineering students (n=26, 9 teams) were asked to define, improve, and validate an unmet clinical need (the problem understanding) all the way towards designing initial MVP's.

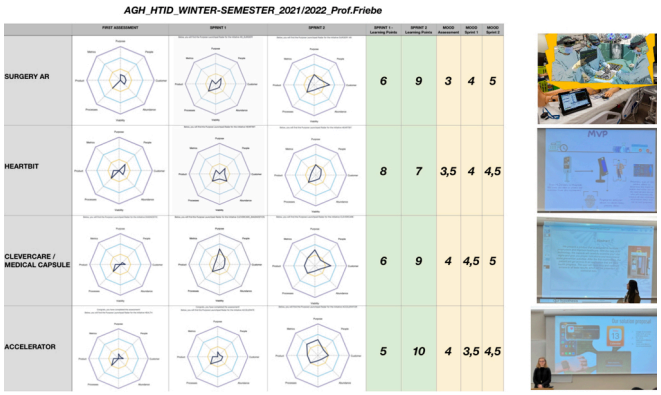

Fig. 9: Biomedical Engineering teams in a PLH lecture / seminar and their progress over 3 sprints including the learning points and the mood changes. GREEN columns = Learning Points after SPRINT 1 / 2, YELLOW columns = MOOD for assessment, SPRINT 1 / 2 (value 0 - 5 best) The pictures on the right show their ideas during the final presentation. Great learnings and happy, motivated students - see radar improvements — all of them were almost completed with their EXPLORATION phase.

Fig. 9 shows visual improvements of 4 of these initiatives, learning progress, and mood changes over 3 sprints. The students all reported that this approach helped them to understand the need for a deep problem understanding and also helped them to see the innovation process as something that does not start with an unvalidated technical solution that is based on assumptions.

V. CONCLUSION

It is important to first understand the problem space that you are trying to address to find a purpose / solution fit for biomedical innovations.

In an exploration phase you gain insights that help you define prototypes that can be evaluated to gain valuable insights for a future product market fit - tested with MVP's.

A validated market with well done customer experiments is also very important when talking to investors in case of a start-up, probably more essential than having a cool technical solution that has not yet found a problem to solve.

ACKNOWLEDGMENT

The PL and PLH artefacts in Figures 3-8 are provided by Purpose Alliance under Creative Commons Attribution-ShareAlike 4.0 license.

Francisco Palao, PhD is recognised as the one that developed the Purpose Launchpad and that stimulated the health innovation related adjustments and the classroom implementation.

All shown canvases and innovation tools are available under Creative Commons Attribution-ShareAlike 3.0 or 4.0 license.

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ETHICAL REVIEW

This research paper did not require or use any experimental procedures involving human subjects or animals and therefore did not require an approval from the Institutional Ethical review Board.

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