

An analysis of the innovation
management of a technical solution for
medicine reconstitution within healthcare.

From discovering the “pain” to
solution validation.
An innovation management analysis.

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Introduction

The company business activity is the investigation of and development of novel solutions to real world problems, where perceived end-user value is considered created. The problems or challenges are normally presented by the potential client, but occasionally, a new awareness of customer problem or obstacle emerges.

The subject of this analysis is one such 'serendipitous' exposure to a user pain. Pharmaceutical lyophilised actives (LPA) require reconstitution to a liquid state before the medicine is administered to a patient. Some LPAs lack an ideal affinity to the liquids used in their reconstitution. Manual mixing of these LPAs presents the user with several disadvantages.

At the outset we assumed a mitigation (mainly a reduction) of manual processing would be of benefit to the end user and be considered desirable by the end user groups. While the assumption was correct, it did not account for the potential of creating value when developing a system enabled by advanced Industry 4.0 technologies and practices. Harvesting intelligence on the use of the device including geotagging events, types of medicines and the quality control data available on product labelling provided an opportunity to create data pipelines which allowed both real-time and historical data analysis for stakeholder consumption.

The business is a micro in size, does not have manufacturing capabilities beyond inhouse prototyping and historically has not been a sales or distribution network structure. The proposed development was low cost to manufacture and assemble, both attractive attributes, and presented competitors a low bar to bring to market, should they wish to plagiarise the innovation once disclosures had been made. Any commercially sensitive development information shared with stakeholders was subject to NDA. A route to protection was planned and led to a professionally drafted patent specification being filed at the UKIPO, and at the USPTO with request for Track One consideration.

The principal drivers for the innovation.

The initial driver came directly from the NHS end-user in the form of reports of dissatisfaction with current manual standard operating procedures. Given the priority disposed on healthcare at all levels at the then early stages of a rapidly expanding global epidemic, that verbal reporting warranted a little further investigation into both the depth of the problem and the feasibility of a potentially suitable solution. At first sight, the quantum of opportunity was far from clear, nor was the efficacy of the early solution proposals. In essence, intuitively there was a novel solution, but would the end-user need be satisfied and to what extent? and did the market opportunity justify an inhouse project and associated financial and invested time costs? At this stage there was no clear route to third party funding and the solution proposal was still at the idea stage.

"Never waste a good crisis" is the strapline for several trains of thought as the driver, inspiration, or motivation for responsive innovation. The healthcare sector was forced in many circumstances to rely on existing technologies, reinvent creative ways of using those

technologies and generate new tools to overcome the challenges presented in the management of the coronavirus COVID-19. (van et al., 2022) present a table of new innovations and expanded practices adopted by NL and UK maternity care, however one can instantly recognise the applicability of the listed new approaches to almost every sector of healthcare.

Citing COVID-19 as a driver, allowed a leap of faith at the early stages, a question asked was “can the strict and somewhat traditional practices be de-constrained in periods of crisis, and would that expansion persist following successful crisis management?” (Chiu, et al., 2022) in their consideration of changes in pharmacy policies concluded that moving away from strict procedures was justified, and in the context of this report certainly drove innovative approach implementations to overcome the increased demand for their service, simultaneously adapting to accommodating the operational constraints presented pandemic. There was certainly a buzz around rapid development of respiratory support devices, personal protective equipment, and not least innovative approaches to vaccine development. So, where the business felt it had relevant skills and the user “pain” had been articulated, the business set about detailing the theatre in which the proposed development would operate.

“Information is central to the operation of firms. It is the stimulus for knowledge, know-how, skills and expertise and is one of the key drivers of the innovation process.” (Trott, 2021).

[The barriers and risks faced by the company in developing this innovation.](#)

The business at this time had insignificant specialised pharmacy and medicine knowledge. On the other hand, the areas of expertise covered inhouse did encompass electromechanical systems, electronics, embedded systems including firmware and software, and prototyping of small-scale experimental designs.

The barriers were mainly in two spheres.

Firstly, access to resources which could assist in exposing the detail problem experienced by the user. This would necessitate both desk research into pharmacy practice and commercially available solutions and further, access to key specialist resources in the end-user group, namely pharmacists who work at ‘production’ facilities dealing with volume demand for reconstituted LPAs, research pharmacists and research academia in the field.

Secondly, appreciation of the market within which the solution may be optimally placed. Detailed market intelligence was required in respect of size, route to market and profitability, to help justify any early risk when undertaking a sustained development effort.

The key determinants in the process of committing to develop the innovation.

The key determinants were largely considered by early analysis of the problem, the confidence in pertinence of the inhouse engineering skills to materialise a viable solution and a very primitive quantification of the market for the proposed solution.

The business had a history of developing solutions within the technical field the solution may exist in. Arguably, the business was at the early stages of defining the technical problem and the resource needed to address the problem. It was known at an early-stage users had an appetite for a solution to their problem. This was confirmed by interview with a wide range of NHS practitioners ranging from Pharmacy Unit managers, pharmacy technician nurses, operating theatre technicians and medical consultants from several disciplines.

The user need for a solution, an inspiration pointing to how the solution might be implemented, the inhouse appropriate technical resource, and not least goal clarity, all constituted well founded determinants to engage with and commit to a feasibility developmental episode.

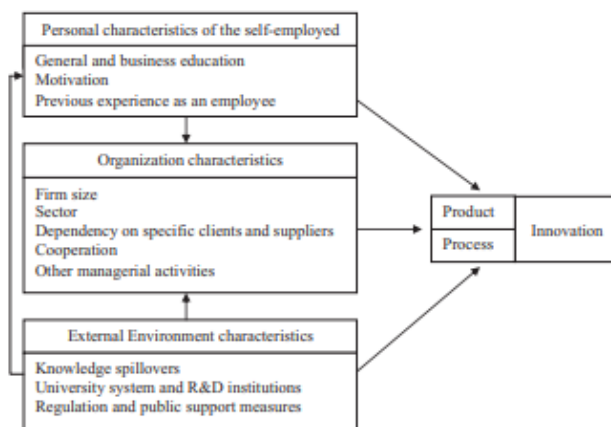


Fig. 1. Factors influencing innovation in SMEs.

from (Romero and MartínezRomán,

2012)

Some consideration is given to the business size and entrepreneurial aspirations as a determinant. A survey (Romero and MartínezRomán, 2012) indicated personal characteristics are pivotal to the innovation process, citing educational background, previous experience, hostility to new technologies, motivation (intrinsic versus extrinsic) and psychological response to perceived risk, as factors in the consideration of the micro business propensity to successful innovation.

The processes and technologies which the company used to carry this development forward.

A range of tools were deployed to manufacture the early prototype. They include resin and filament 3D printers, subtractive machining, 3D CAD, cloud-based services (CAD and AWS algorithms), Labview™ host side software (control dashboard), Python™ and Arduino™ development platforms and embedded processor modules with wireless functionalities.

Basic functional designs were prototyped with the aid of all the tools and the iterative prototype versions was evaluated for functional characteristics only, no attempt was made to move to enclosure or aesthetic design, which did not contribute to product function. To assist in effective functional evaluation a control and measurement dashboard was created. This allowed both programmatic and on-the-fly control of the product key component and recording of the conditions and outcomes of the empirical testing.

Considering the breath of the technologies available to the business, a number could be considered legacy tools. The business operated subtractive machining and additive printers for more than 12 years, host side (PC) software toolchains for more than 20 years. The low cost of adoption and maintenance of technologies introduced in the last five years such as small Arduino/ Python compatible embedded computers has enabled development in previously inaccessible market spaces. Digital technology adoption, which in this case encompass the low or no cost community Integrated Development Environments (IDE), digital cloud-based services and resin and newer generation filament printers, are considered cornerstone to the introduction of new services and supported products into the marketplace (Chester et al., 2018).

The business has not been reluctant to reach out and integrate emerging useful assets into its digital technology portfolio as they become available and relevant. Literature research shows positive performance effects of digital technology adoption on product and service innovation (Blichfeldt and Faullant, 2021). The business' product and associated services could be categorized as existing in multiple technology fields of FIG.2, although the table is focussed mainly on manufacturing as opposed to our analogous case of an automated medicine production technology, the user is the manufacturer with maintenance, scheduling, process, and outcome intelligence needs.

% distribution of degree of usage and utilization of technology potential, process industry cases.

Technologies	No use	Planned	Sum No use	Utilization of technology potential		
				low	med.	high
Industrial robots for manufacturing processes*	73.1	4.1	77.2	2.4	7.5	8.3
Industrial robots for handling processes**	56.4	6.0	62.4	4.4	10.7	17.3
Technologies for safe human-machine interaction	87.6	4.7	92.3	1.2	2.1	1.2
Additive manufacturing technologies for prototyping	82.6	6.4	89.0	2.7	2.3	1.9
Additive manufacturing technologies for mass production	90.0	2.8	92.8	0.8	1.7	1.2
Software for production and scheduling***	28.1	5.8	33.9	4.8	18.9	34.9
Near real-time production control system**	51.9	9.4	61.3	2.3	11.5	19.1
Digital exchange of product/process data in supply chain*	60.6	6.2	66.8	6.3	11.2	9.1
Systems for automation and management of internal logistic*	56.9	10.3	67.2	3.9	13.3	10.2
Product-Lifecycle-Management system or product/process data management	70.1	5.8	75.9	1.6	4.3	3.5

(***; **, *: highly adopted technologies).

FIG. 2 From (Blichfeldt and Faullant, 2021)

As an example, the Industrial Internet of Things (IIoT) has become an important foundation element of many technology products and services and is key to the current NPD. To support the availability of robust evolving IIoT infrastructure, policies to support technological innovation reliant on IIoT are recognised as important at government level and receive substantial attention (Kao et al., 2019)

The extent to which the development relied on resources external to the company and the ways in which the deployment of these resources was managed.

From a technical view, the business had identified a possible methodology to follow in the very early stages of the NPD. When the early testing showed promise, it was considered that further evaluation of the principles was needed before moving to the next stage of design for manufacture (in respect of the active functional element of the product only).

From an end user view, at least two external resource areas were explored.

Intelligence was lacking on the Standard Operation Procedures (SOP) of end user, both at point of delivery (e.g., a nurse or healthcare professional) or at central production facilities, normally pharmacists. Contacts and collaborations were developed in the NHS, at District General Hospitals, Welsh NHS boards and production pharmacy units.

The market size was an unknown, as was the route to that market. A third-party Market Intelligence Report was commissioned with a view to establishing the market did indeed exist, who else had a significant presence in the market area, and the products and technologies commercially available and those under research which may compete with or compliment our proposed product.

Innovation deliberation was not only about the product, but that was also a technical challenge addressed at least to validation of a working prototype. The business considered how to engage with external resources to gain insight into the minimally viable deployment specifications, the financial barriers to early and easy entry to major stakeholders' organisations, and how to capture value from the products in operation by the user.

The external resources necessary were NHS Hospital Boards and Pharmacy departments at senior level. Whilst not open innovation, the approach facilitated collaboration with the user in respect of identifying deployment specifics, what sterilising chemicals may be used, the form factor for siting in a production pharmacy and that for a hospital ward location, what types of LPAs were considered difficult and what was the current SOPs. The intelligence from the user interactions allowed empirical testing and validation of the device, whilst undertaking the reconstitution task across a range of challenges.

This approach could be represented as a *porous innovation funnel*, originally proposed by Chesbrough, albeit with collaborator interaction mainly flowing *into* the funnel as the product developed. The approach can also be largely aligned with *the services value web* (Chesbrough, 2017) and *hybrid StageGate* (Cooper 2014) models.

In time the outward flow of elements developing within funnel will undoubtedly happen, licencing, alternative applications of the innovation to external companies, and external uses of the I4.0 revenue and services cloud model.

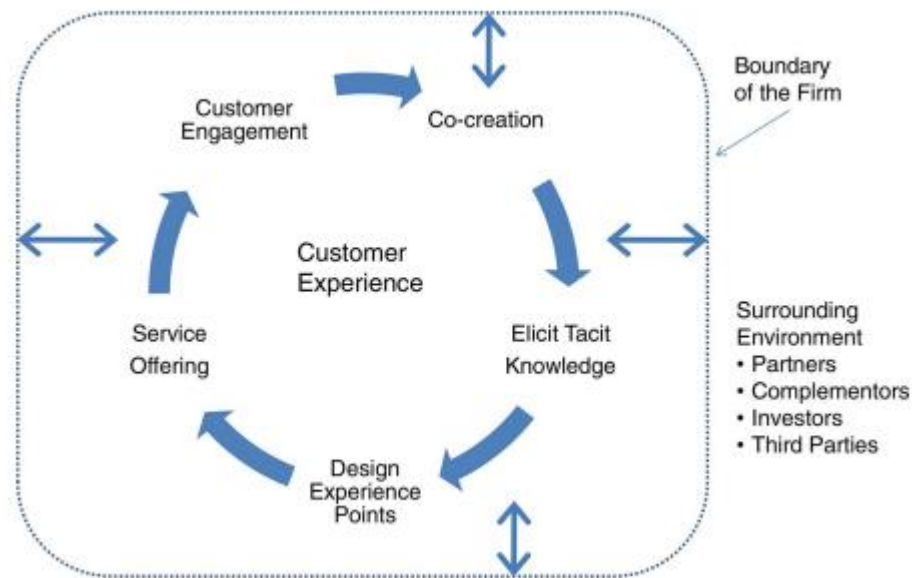


FIG. 3 The services value web from (Chesbrough, 2017)

Chesbrough's Web puts the customer experience at the centre, where each interaction with the customer gives you new knowledge, which is required to advance the value of your product, including related aftersales services, in the eye of your customer. Delivering a better customer experience is what the business should be trying to achieve. By continual engagement or collaborative/ open innovation, not just at NPD stages, a pipeline capturing value is maintained.

How management overview of the development was maintained.

As the project was the subject of a SmartCymru Innovation award, the process of funding application helped, arguably enforced, a structured approach, linking the technical development to the commercialisation end goal with multiple detailed project stages. Project management approaches were applied to plan achievable incremental outcomes, their related milestones, and evaluation of each of the planned stages. Risk analysis charts and mitigation strategies helped ensure a successful outcome (which may not necessarily have been a product that met the need, rather the conclusion of a structured well thought out development plan).

Significantly, a technical report and project progress report were generated as part of the development phase. Beyond a cerebral consideration of how the various elements of the NPD progressed to prototype conclusion, formally committing to a written document helped highlight both successes and failures, along with a critique of their impact on the NPD and forming the basis for reinforcement or change of policy practice in a range of NPD areas.

This approach was largely traditional, without a formal innovation structure and was prescribed and highly linear.

The innovation management decisions are effectively the responsibility of one person. Agility in sole decision-maker management is both an advantage, (think it, do it, no approvals necessary!) and a threat (think it, do it, no oversight!).

The Open Innovation (OI) can be defined as a distributed innovation process that leverages the flow of knowledge crossing company boundaries (Chesbrough et al., 2006), could OI still maintain its effectiveness when combined with lean and agile methods?

The business was inherently agile due to its small size, Agile principles such as individual autonomy, permission for individual experimentation and promoting individual initiative (Cooper, 2014; Cooper & Sommer, 2016) were considered to enhance the implementation of external resources within OI projects. So, can the process be loosely aligned with *emerging idea-to-launch systems*?

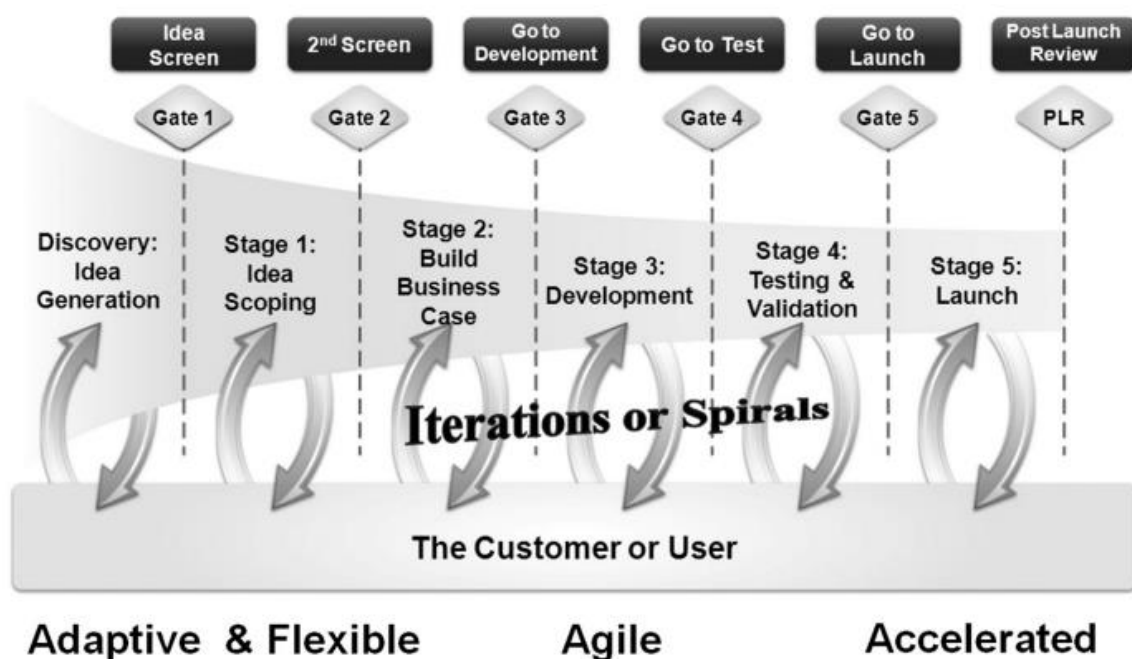


FIG.5 The next-generation idea-to-launch system from (Cooper, 2014)

Considering FIG.5, the project was managed to Stage 2 as proposed by Cooper, however Stage 3 was only lightly touched on, the assumption was quickly reached that the product would have a wide market, which may have been correct, however stage 2 would also at least necessitate evaluation of external investment requirements to and beyond launch (Stage 5), manufacturing collaborations and future sales infrastructure or partnerships. The project plan to deliver the Feasibility Study focussed largely at resolving technical uncertainty and gaining user requirement specification. It can be argued that unknowns in the Stages 3:4 'iterations or spirals' generated a cloud of uncertainty which proved difficult to navigate to achieve much more than an outline viable business justification, which was delivered as part of the study proposal.

The extent to which you feel this innovation process represents best practice.

The innovation process can be measured against several prominent strategies. Many of the OI strategies (as this was not closed innovation by any standard) overlap. Multiple strategies, toolkits and playbooks can be applied to evaluate how best practice is measured, but there is rarely a best route.

With Cooper and Sattel as the best practice yardsticks in this report, a contrast can be made as appropriately reflect either teaching.

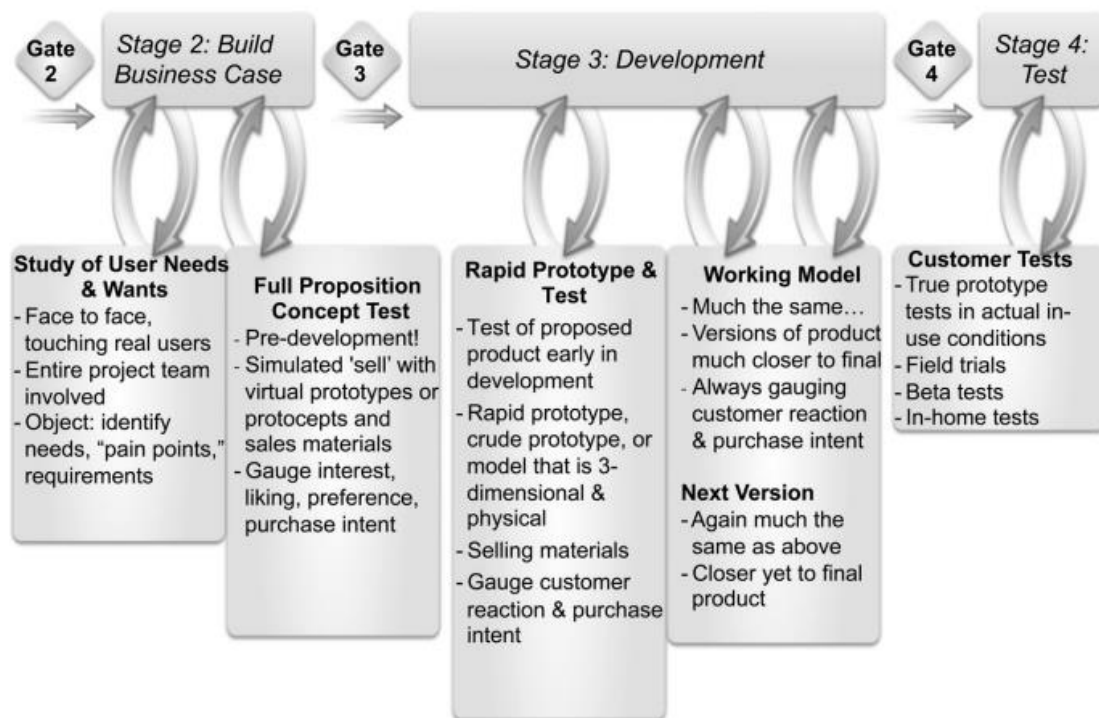


FIG.6 Spiral development built on build-test-feedback-revise iterations from (Cooper, 2014)

Considering the transitions between the gates, the study of user needs and wants was certainly a focus for early engagement and was appropriately attended to, including face-to-face and the pain point definitions. Proposition concept test was not considered with any simulated assets, gauging interest and intent to buy was a subject for discussions with high level potential stakeholders/ customers. Stage 3 was very much in line with Cooper's *idea-to-launch* model and reflected in practice the principle central role of the customer proposed in Chesbrough's *The services value web*.

Passing through gate 4, the device was validated at an NHS central production facility by pharma technicians and production pharmacists with LPAs representative of the most difficult formulations, without any of the 'black art hacks' often employed by users to reduce the level of task difficulty.

Greg Sattel's Innovation Matrix FIG. 7, proposes a forward-looking planning tool, and effectively poses the two questions "how well can we define the problem?", "how well can we define the skill domain(s) needed to solve it?" (Satell, 2017)

4 Types of Innovation

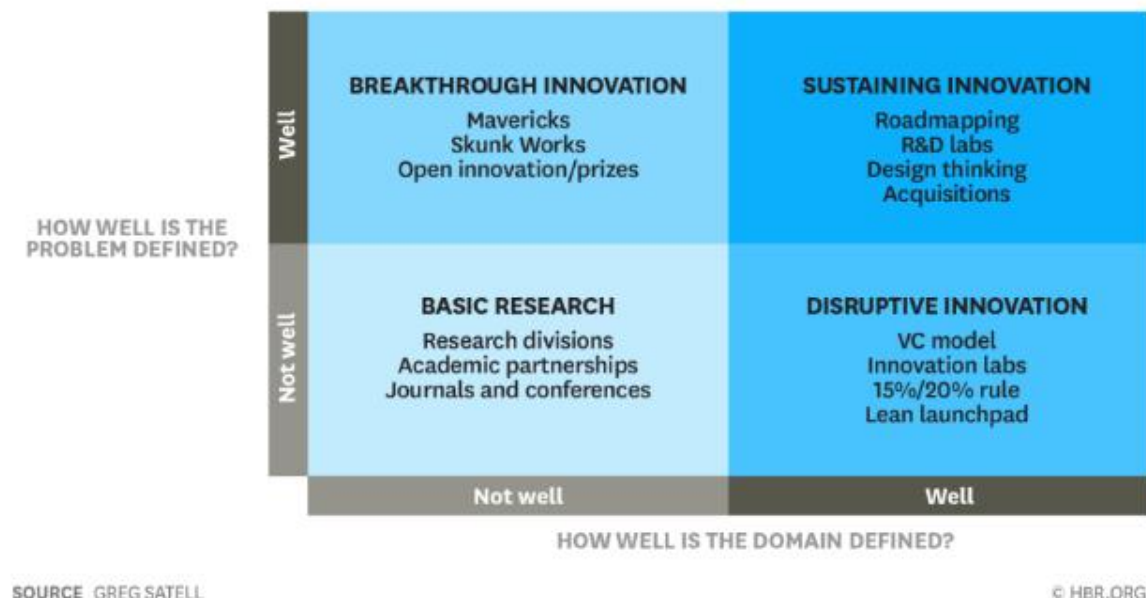


FIG. 7

From (Satell, 2017b)

Reviewing the possible responses to Satell's two questions, with the prior commentary made on Cooper's *idea-to-launch, build-test-feedback-revise*, and Chesbrough's *services value web*.

The problem was well defined to the limit of user requirements and the technical / functional parameters to overcome the challenge presented by 'difficult' LPAs. The wider innovation considerations of manufacturer collaborations, downstream financing and establishing routes to market were only lightly defined. It may be that the fog of uncertainty prevented a more complete quantification, but in the author's view, venture capital funders would expect a more through consideration, a more convincing narrative of prototype to customer highways, before committing to any proposal of support.

The domain definition may also lack the manufacturing, marketing, and supply resource detail. Referring Cooper and Chesbrough models, the technical skills to define the solution, prototype and iteratively test were well established and proven within the business. An experienced senior clinical advisor with NHS recognised prescribing qualifications was employed by the business to close the pharma knowledge gap and provide a skilled individual to liaise with NHS stakeholders. Overall, the domain was considered well defined given the NPD stage achieved.

Within the Innovation Matrix it would appear the project would reside substantially within the Sustaining Innovation quadrant (it is after all what the business normally does), with an overspill into Disruptive Innovation and Breakthrough, given the future plans for a zero-capital expenditure, serverless, cloud-based, device service provision and revenue collection model.

Conclusion

The innovation project has moved beyond the concept and prototype validation stages and has engaged with NHS stakeholders. On reflection, the development phase followed a route broadly aligned with Cooper *Stage-Gate* and Chesbrough's *services value web* models. With reference to Satell' Innovation Matrix, problem and resource (domain) were reasonably well defined.

More attention should have focused on pathways to customer authorised central purchasing bodies and the potential achievable unit sales value. The product and associated services are likely to be fleet commissioned as opposed to singular sales, at least for most of the sales opportunities and require a centralised purchasing strategy.

Fuller consideration of manufacturer collaboration and early decisions on a sales strategy, direct or via a partner or distributor network would also have helped overall goal clarity.

In summary, the project did adhere to many of the best practice principles in open innovation, iteratively considering and involving the customer, developing new solutions to anticipated sales and service challenges (Advanced Industry 4.0 (I4.0) service and revenue serverless solutions).

Opportunities to create, deliver and capture value have been largely exploited in respect of.

- Customer engagement
- Desirable product features,
- Connectivity, design, and implementation compatible with I4.0,
- and very importantly the proposed I4.0 revenue and service cloud-based models.

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