Developing Opportunities in Digital Health: The Case of BioBeats Ltd.

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Abstract

Departing from established research on entrepreneurship, design-based entrepreneurship places an explicit emphasis on the entrepreneurial process as evolutionary and emergent in which knowledge and understanding of an opportunity are acquired incrementally by means of design and evaluation of alternative solutions. This paper develops a use case of BioBeats Ltd., a UK-based university spin-off which has successfully managed to turn an opportunity in digital health into a commercially viable enterprise. Adopting a design-based paradigm, the company under study started by building a technical solution informed by a set of design principles which subsequently allowed the company to convert the socio-technical nature of the opportunity into technological artefacts that were further refined and tested by means of real-world experiments with third parties and citizens.

1. Introduction

Most entrepreneurship research is based on the very basic assumption that there are regularities in the world that underlie phenomena such as new venture creation and that the purpose of theory development is to identify and explain those regularities, preferably in the form of causal mechanisms (Berglund et al. 2018). The two major activities of research in this tradition are generation and testing of theory against observed practical phenomena. This description-driven focus of research in entrepreneurship based on the paradigm of explanatory sciences faces inherent challenges when attempting to capture the details and idiosyncrasies of entrepreneurial judgment and practice in theoretical formulae, and similarly when attempting to apply universal theories in situations that require situated judgment.

This currently dominant description-driven research paradigm resonates with the long-standing rigor-relevance debate in managerial studies usually evolving into an "either/or" argument in which specific studies, researchers, journals, are quickly categorized into "silos" with little interaction among them (Gulati 2007).

As suggested by several scholars the rigor-relevance dilemma can be mitigated by complementing this description-driven paradigm with prescription-driven research based on the paradigm of design sciences (Van Aken 2004, Dimov 2016). In this regard, design-based entrepreneurship builds upon the concept of opportunities as outcomes of entrepreneurial processes informed by design principles and continuous test and evaluation of solutions in real contexts.

This paper contributes to emerging design-based theory of entrepreneurship by providing a use case outlining the design-based entrepreneurial process of BioBeats Ltd., a university spin-off operating in the digital health market which has successfully managed to translate an emergent opportunity into a commercially viable solution backed by several investment funds such as Oxford Sciences Innovation, White Cloud and IQ Capital (BioBeats 2018).

The insights derived from our research on how entrepreneurial processes are conducted in practice reveal the importance of design principles. From an entrepreneur perspective design principles inform and guide the search for a viable solution to the opportunity. From a theoretical standpoint design principles provide valuable concepts, methods and relationships to further build entrepreneurship theory.

The paper is organized as follows: Section 2 situates design-based entrepreneurship, section 3 further develops, by means of a real use case, the entrepreneurial process followed by BioBeats Ltd. a successful spin-off operating in the emerging digital health market. Section 4 provides a commentary on the lessons from the case study, and offers some concluding remarks.

2. Design-Based Entrepreneurial Processes

The opportunity-creation approach proposed by Alvarez et al. (2013) treats opportunities as the result of entrepreneurial action. Opportunities do not exist objectively, ex ante, but are created as entrepreneurs act based on their subjective beliefs. 'Creation opportunities are social constructions that do not exist independent of entrepreneur's perceptions' (Alvarez et al. 2013, p.303). Opportunities, in this sense, are treated as a latent construct that is manifested in entrepreneurial actions such as investment, creating new organizations, bringing products to market, and so on (Klein 2008).

In the context of this paper an opportunity is a socio-technical system emerging from the interaction of agents and technological artefacts. It is the entrepreneur who, by combining and controlling resources, and through the definition and maintenance of boundaries and engagement in exchange relationships, establishes a working set of relationships among previously unconnected actors and artefacts. In this sense, opportunity as a social structure is a design solution that arises at the intersection of entrepreneurial intent and within the constrains of the economic, social and technical context (McMullen and Dimov 2013). Under this design-based paradigm, the entrepreneurial process can be described and explained as an evolutionary and emergent interplay of design principles, a coherent set of normative ideas and propositions, and design solutions as instantiations of an opportunity (Van Burg et al. 2008, Dimov 2016).

A design-based entrepreneurial process is inherently a problem-solving process. The overarching principle being that knowledge and understanding of an opportunity and its instantiation are acquired incrementally by means of design and evaluation of alternative solutions. As a result, entrepreneurs start from a simplified representation of the opportunity and further progress iteratively as the scope of the opportunity is expanded. In such situations the search tries to build a solution that is "good enough" for the opportunity at hand, incrementally solving problems as they are encountered along the way.

Opportunity materialization, the core output of the entrepreneurial process, provides validity by construction thus demonstrating feasibility both of the design process and of the designed solution.

3. Design-Based Entrepreneurial Processes in Digital Health: The Case of BioBeats

Our analysis highlights that design-based entrepreneurial processes are driven by an identified opportunity and articulated through two main processes, build and evaluate, that lead to an opportunity materialization and associated constructs, models and methods, and design principles (Romme 2003, Hevner 2004, Gregor and Hevner 2013). We illustrate the utility of this analysis through its application to BioBeats Ltd.

3.1. Opportunity identification

With regard to digital health, there has been a growing recognition that the use of personal data combined with data analytics is a key factor for the development of novel approaches to healthcare delivery (e.g. personalized medicine, preventive medicine). This can be seen in the focal company under study, BioBeats Ltd. It was initially conceived to address an opportunity in the intersection of health-related data from citizens, artificial intelligence and human insight for the purposes of developing wellbeing products aimed at transforming people's lives for the better. However, to be successful it quickly became clear that this new data-intensive, user-centric, approach to digital health must overcome important challenges such as privacy, interoperability and security among key stakeholders. Digital health will only become a commercial reality if individuals can be persuaded to change their attitudes and allow their medical information to be digitized and processed by third parties (Angst and Agarwal 2009, Kohli and Tan 2016).

The recent Cambridge Analytica scandal is the most recent instance of a series of incidents highlighting the importance of information privacy and the scale of risks involved in the harvesting and further processing of personal data for commercial purposes (Economist 2018). Moreover, it constitutes a case in point of the Personalization-Privacy Paradox: the tension between how digital services exploit users' data to offer them personalized experiences and users' growing concerns about the privacy of that information (Kavassalis et al. 2003, Lee and Benbasat 2003, Sutanto et al. 2013). The Personalization-Privacy Paradox is in itself a wicked problem, it has no definitive formulation, is susceptible to multiple interpretations and is not understood until solutions are formulated (Ritter and Webber 1973). Moreover there is no clear sense of when the problem is solved. As a consequence, their solutions cannot be judged as right or wrong but as good or bad, depending on the results achieved (Dimov 2016).

To address these concerns, BioBeats Ltd. framed the opportunity and sought to overcome the personalization-privacy paradox through 2 interdependent activities:

1. The development of alternative solutions underpinned by theoretically sound principles for design (building phase);
2. Continuous evaluation of the solutions and underlying design principles with third parties and customers (evaluation phase).

3.2 Building phase

Given the socio-technical nature of the opportunity and the strong data privacy implications, BioBeats adopted an action research approach to build the solution coupled with an iterative style of principles development (Markus et al. 2002). Their starting point was a set of requirements derived from Information Privacy (Malhotra et al. 2004), using technology acceptance and trust (Gefen et al. 2003) as a starting kernel theory from which to hypothesize and develop principles for design meeting these requirements.

3.2.1. Development of design principles

Information privacy. Information privacy is defined as "the interest an individual has in controlling, or at least significantly influencing, the handling of data about themselves" (Clarke 1999, Bélanger and Crossler 2011). Individuals' concerns about information privacy play an important role in an individuals' willingness to be profiled (Milberg et al. 2000, Van Slyke et al. 2006), and has influence in their acceptance of technology and intentions to use digital services (Malhotra et al. 2004). Furthermore, the notion of information privacy concern may be conceptualized as the degree to which an individual is concerned about the collection of personal information, her control over the collected information and her awareness of how the collected information is used in the future (Malhotra 2004, Culnan 2009).

Therefore, given the highly sensitive nature of health related data, managing digital health required provision of strong reassurances to prospective participants. This led BioBeats to suggest the following Design Principles:

DP1. Data provenance. End-to-end visibility is required over data ingestion, data transformation, data transfer and insights generation processes.

DP2. Choice and Consent. Digital health service providers must describe the choices available to an individual related to the use and disclosure of their information, and to obtain implicit or explicit consent with respect to the collection, use, and disclosure of personal information.

DP3. Information visibility. Personal information to third parties shall be disclosed only for the purposes identified in the notification of use and only with the implicit or explicit consent of the individual. Individuals gain full access to their personal information for review and correction.

DP4. Security for privacy. Organizations are required to protect personal information against unauthorized access.

Technology acceptance. According to the Technology Acceptance Model (TAM), the intention to voluntarily adopt a digital service is determined by two beliefs dealing with the perceived usefulness (PU) of using digital health and its perceived ease of use (PEOU)

(Gefen et al. 2003, Gefen and Straub 2000, Venkatesh and Davis 2000, Venkatesh et al. 2003). Perceived usefulness is a measure of the individual's subjective assessment of the utility offered by the digital service, while perceived ease of use is an indicator of the cognitive effort needed to learn and to use the digital service. (Gefen et al. 2003).

Paths predicted by TAM also apply to digital health, thus leading BioBeats to formulate the following design principles:

DP5. Recommendation capabilities. Recommendation agents that elicit health-related interests or needs of individuals are required to make recommendations accordingly (Xiao and Benbasat 2007).

DP6. Strong user-orientation. User-oriented concerns must be central to the application of technologies and human computer interfaces.

Trust. Digital health services need not only to be useful and friendly to use but also include trust-building mechanisms. In this regard digital health shares significant similarities with ecommerce, where customers want to engage in economic transactions with the service provider as well as other third parties. Trust becomes crucial in such transactional relationships involving sensitive data. Trust, an expectation that others one chooses to trust will not behave opportunistically by taking advantage of the situation, is a significant antecedent of participation in digital services subject to moral hazard (e.g. service providers behaving in an opportunistic manner and reselling personal data). In this regard, trust reduces the social complexity a consumer faces in deciding whether to use digital health services (Reichheld and Schefter 2000, Gefen et al. 2003).

Additionally, according to Geffen et al. (2003) significant antecedents of trust are (1) calculative-based beliefs (no opportunistic behavior is possible) and (2) structural assurances (safety mechanisms).

Design principles DP1-4 as previously defined contribute to build trust in digital health by providing strong safety mechanisms: choice and consent (DP2) and security for privacy (DP4) give to individuals control over their data and how this data is handled by third parties. Data provenance (DP1) and information visibility (DP3) provides accountability and traceability.

Mitigating opportunistic behavior in the case of digital health requires additional mechanisms, however. In a similar fashion to ecommerce, voluntary exchanges of data and digital services between parties is subject to adverse selection and moral hazard. Imperfections in information can also be actively exploited by market participants to establish market power (Stiglitz and Edlin, 1992; Stiglitz, 2002). Common solutions to these problems involve relying on third-party verification, reputation systems, to force additional disclosures on the seller, to enforce contract clauses designed to generate a separating equilibrium (e.g. warranties), and to perform monitoring (Catalini and Gans 2016).

As far as digital health is concerned, the costs of verification need to be reduced to a minimum as this would allow any participant (individuals, healthcare providers, insurers, etc.) to validate in near real time relevant attributes of specific transactions, and to engage in economic transactions over subsets of information (e.g. one week’s worth of heartrate data) that were previously uneconomical to trade on their own.

This led BioBeats to suggest the following design principle:

DP7. Costless verification. Near zero cost of providing intermediation services is required between participants in digital health.

3.2.2. Solution implementation

These hypothesized design principles guide the development and deployment of a real digital health service which, in collaboration with individuals and healthcare providers (e.g. AXA/PPP, Microsoft, NHS UK), allow BioBeats to validate the solution in terms of validity, utility, quality, and efficacy (Gregor and Hevner 2013). The solution has three main components: Wearable BioSensors (WBS), an Inference Engine, and a Distributed Ledger, as illustrated in Figure 1.

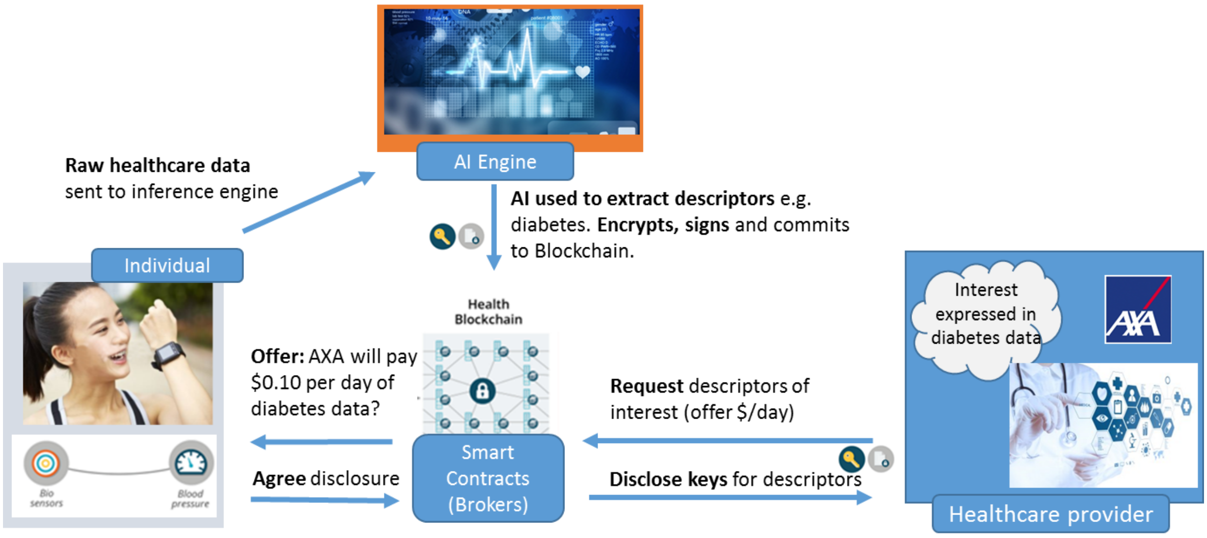

Figure 1. Solution components

Wearable BioSensors. Participating individuals are requested to wear a WBS attached to their wrists on a 24 hour basis for the purposes of monitoring their heartrate and location in near real time. The data is ingested into the inference engine for further processing, encryption and analysis.

Inference Engine. The inference engine is powered by artificial intelligence (AI) technologies to extract signals of clinical relevance from raw data from the Wearable BioSensors. For instance, this engine samples inter-beat information (IBI) from the participant's pulse measured optically by the WBS and creates a digital fingerprint for the users' biometric activity during that period.

Over longitudinal time periods these fingerprints are sampled and passed through bots which have been trained to recognise specific patterns of clinical relevance. For example, acute stress events can be detected with accuracy of approximately 73% as well as detecting more common events such as sleep occurrence with a negligible false positive rate. In addition to classifying events, bots enable an aggregate fingerprint to be computed over days or weeks of user time. These fingerprints can be regressed to multiple baselines of clinical significance such as clinical scales of anxiety and depression.

Distributed Ledger. Through use of distributed ledger technology (DLT), specifically an Ethereum-based permissioned Blockchain, the artefact provides data provenance, brokered access to data, and inexpensive verification. (Iansiti and Lakhani 2017).

In addition to the integrity (immutability) afforded to data due to consensus checking of the Blockchain, provenance of data is further ensured through public key cryptographic signing of the data. Smart contracts implement a commodified exchange for data between data providers (individuals) and data buyers (e.g. insurance company) (Kosba et al. 2016). The smart contract can not only brokerage requests for disclosure but also securely remunerate parties through micropayment transactions in a cryptocurrency using emerging technologies such as IOTA or Lightening (Wood 2014).

3.3. Evaluation phase

The performance of the solution, and its underlying design principles, was evaluated in collaboration with cohorts of individuals, public agencies (NHS) and industrial partners (AXA, BNP Paribas) in the context of two use cases.

Use Case 1: Enabling preventive care via wearable biosensors

An initial version of the solution was deployed in early pilots within the insurance and finance industries (AXA and BNP Paribas) as well as the B2C market (168K users in a 12-month beta). In the B2B deployments, AXA deployed an early version of the technology at BNP Paribas in order to ascertain the mental wellbeing and job autonomy/resilience of their employees in the investment banking department of their organization. This deployment had a number of disruptive outcomes; an initial result indicated that aspects of the psychology constructs measured during the deployment (such as ruminative thinking, or obsessive/repetitive worry) could be linked to profiles of cardiovascular disease. This affected BNP Paribas' own understanding (as well as AXA's) of the risk profiling involved in the provision of benefits from the occupational health perspective. Moreover, later in the study it became clear that the machine intelligence algorithms built as classifiers for mental stress could eventually become automatic referral pathways to occupational health, essentially becoming anonymized referral processes that lead towards being able to offer the right type of mental health care to the individual much earlier than previously possible. Both findings have resulted in cultural and logistic changes at BNP Paribas and AXA reflecting a change towards preventative as opposed to reactive care in their benefits strategy (Cropley et al. 2017).

The results of the first use case provides support for the existence of an entrepreneurial opportunity around the personalization-privacy paradox, the tension between the benefits provided by personalized healthcare and users' growing concerns about the privacy of their information.

The experience of BioBeats-AXA-BNP Paribas partnership reveal the latent propensity of individuals to contribute to digital health services provided that 2 conditions are met:

1. Information systems privacy mechanisms are in place;
2. There is real value for the individuals involved.

In this regard, design principles DP2, DP3 and DP6 emerge as valid principles guiding the development of advanced digital health services.

Use Case 2: Brokering of personal healthcare data to care providers

In a second use case, BioBeats further iterated its solution in collaboration with AXA and University of Surrey researchers. For this iteration two new artefacts were added: a recommender system and a distributed ledger (a.k.a blockchain).

As shown in the Figure 2, healthcare data gathered from a citizen's WBS is encrypted and uploaded to the Inference Engine (1) which periodically collects this raw data, storing it securely within a private data lake, and applying machine learning to distil from the data high level healthcare descriptors (e.g. related to exercise and cardio function) (2). Many citizens may make use the inference engine and their descriptors are encrypted with user-specific keys and committed into the blockchain (3).

A healthcare provider (e.g. AXA) may be interested in cardiac health for the purposes of modelling risk in the users' demographic group (4). AXA requests such data from an identified cohort of participants, causing the platform's broker to issue a contract offer that flashes up on users' mobile devices (e.g. "AXA will pay you £0.10 for each complete day of cardio data") (5) (6). On user acceptance of the proposal, a smart contract is registered into the blockchain which is capable of brokering their encrypted healthcare descriptors to AXA (7). The decryption key for the data is encrypted into smart contract code using AXA's public key, enabling AXA to gather it from the blockchain (8). Throughout this interaction, the user can opt out of sending data at any time by changing their encryption key from that time forward.

This second use case provided further feedback on the technical and commercial scalability of BioBeat's solution, and reinforced the importance of incorporating trust-building mechanisms (DP7), recommender systems (DP5) and strong security for privacy orientation (DP4) into a digital health solution.

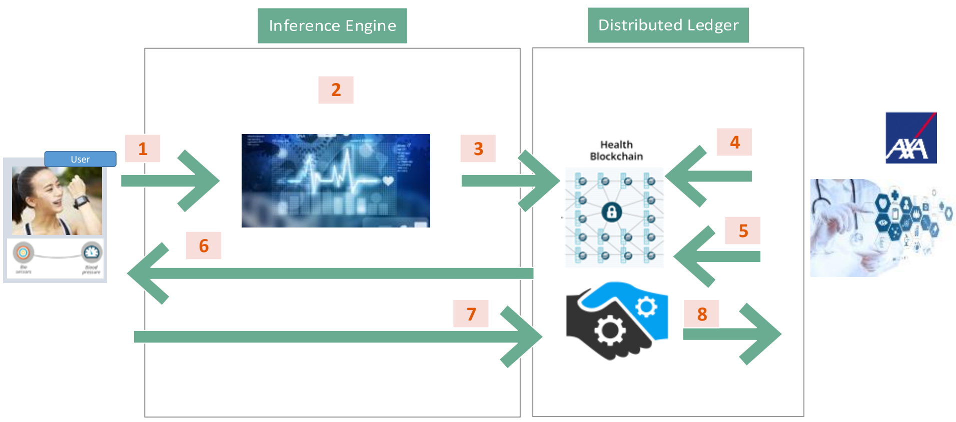

Figure 2. Brokering of Personal Healthcare Data to Care Providers

4. Discussion

The use cases developed in this paper outline the value of design-based entrepreneurship as a theoretical paradigm upon which to better interpret and understand processes of entrepreneurship in technology-intensive contexts. Through application of our analytical framework, the results of our study provide support for entrepreneurship as an evolutionary and emergent set of processes in which knowledge and understanding of an opportunity are acquired incrementally by means of design and evaluation of alternative solutions. Overall, our findings reveal a contingency-based approach to the process of venturing. Far from a “best-practice” approach to entrepreneurship, firms follow a co-evolutionary approach adapting to unforeseen circumstances and establishing a constant dialogue across involved stakeholders including customers.

Our study suggests that in the case of designing innovative solutions around highly tacit, wicked, problems (Rittel and Webber 1973, Simon 1991, Camillus 2008) entrepreneurs need to structure their learning processes around tentative solutions which, informed by design principles, allows continuous testing and validation of value propositions with prospective customers and third parties.

In the specific instance of BioBeats, the entrepreneurial process is predominantly emergent and constructive (Van de Ven and Poole 1995). As illustrated in Figure 3, BioBeats represents a class of university spin-off companies that can be viewed as purposeful and adaptive organizational entities driven by an envisioned opportunity, and whose entrepreneurial journey can be summarized in five stages:

1. Opportunity identification;
2. Development of design principles;
3. Opportunity instantiation;
4. Experimentation;
5. Opportunity materialization.

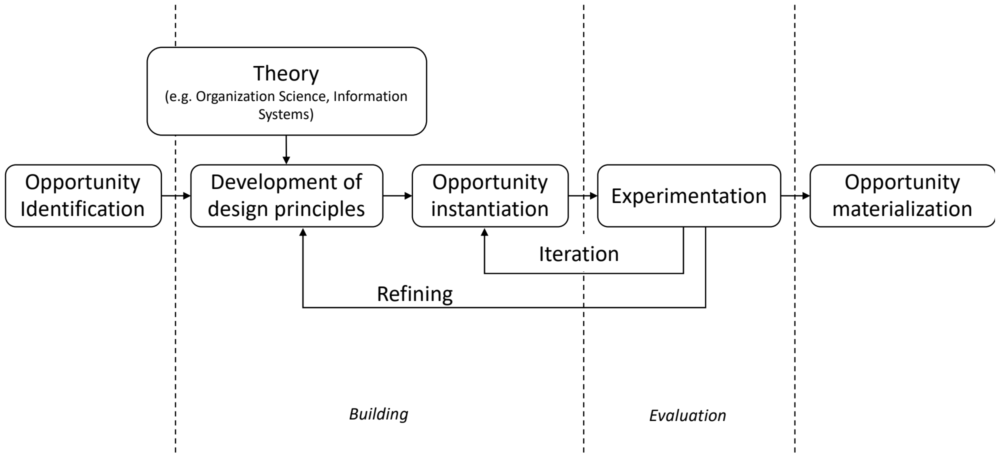

Figure 3. Design-based entrepreneurial process

A key insight from our study is that opportunity instantiations derived from design principles should be extensively tested in practice to uncover their operational effectiveness, and to provide an empirical basis on which to build a deeper understanding of how and why they create value. As such, it is implicitly assumed in this approach to entrepreneurship that design principles are necessarily antecedents to any technological development and further implementation must rely on solid theoretical foundations (Romme and Endenburg 2006).

We also note that design principles emerge as critical components to ensure effective value creation and viable business models (Teece 2010). In the specific context under consideration in our study, digital health, the start-up relies upon well-established principles in the information systems literature: information privacy, technology acceptance and trust. These principles inform the development of technical prototypes that nurture user adoption, ensure regulatory compliance and induce collaboration with relevant external stakeholders (e.g. regulatory bodies, insurance companies, technology providers).

In this regard, along the lines of Hevner et al. (2008), Hevner and Chatterjee (2010), Gregor and Hevner (2013), Pascal et al. (2013) our results reaffirm design principles as dual instruments informing the design of practical solutions and responding to a general class of complex problems (i.e. use of personal data and artificial intelligence to improve healthcare and wellbeing).

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