

Crowdsourcing for Clinical Research – An Evaluation of Maturity

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Abstract

With the growth of the Internet and individuals using the Internet for person health research, crowdsourcing clinical research has the potential to become a powerful tool in surveilling and monitoring health outcomes. This paper evaluates the maturity of the emerging tool of crowdsourcing clinical research using two carefully selected and adapted evaluation models: Project Management Maturity Model (ProMMM) and National Infrastructure Maturity Model (NIMM). Two models were used in conjunction for the evaluation as ProMMM focuses on a professional's ability to utilise crowdsourcing for clinical research, while NIMM focuses on the maturity of crowdsourcing clinical research itself.

To evaluate maturity, the authors reviewed available literature and conducted primary research in the form of interviews at the Melbourne Brain Centre at Royal Melbourne Hospital with Associate Professor Helmut Butzkueven, MS Neurologist and Researcher, and Dr Athina (Tina) Soulis, General Manager of Neuroscience Trials Australia. The tool of crowdsourcing for clinical research and the users and prospective users of the tool were found to be in immaturity. Despite immaturity, the future holds exciting applications for crowdsourcing clinical research with the potential to save costs, time, and recruit wider cohorts into clinical research.

Keywords: crowdsourcing; clinical research; maturity; evaluation.

1. Introduction

Crowdsourcing is a popular method of obtaining services, ideas, designs and even funds by putting out an "open call" for contributions. Swan (2012) defines crowdsourcing as: "the practice of obtaining participants, services, ideas, or content by soliciting contributions from a large group of people, especially via the Internet". This concept is not new; an early example of crowdsourcing is the Longitude Prize, an award offered by the British government in 1714 for the invention of a simple way of determining a ship's longitude (Sobel, 2004). The emergence of web 2.0 has greatly increased the capacity and popularity of crowdsourcing (Swan, 2012). A PEW Research Center study published in 2011 (Fox) found that of the adults surveyed:

- 74% use the Internet;
- 80% of Internet users have looked online for health information;
- 34% of Internet users have read someone else's commentary or experience about health or medical issues; and
- 18% of Internet users have gone online to find others who have health concerns similar to theirs.

This high usage of the Internet for personal health research supports the notion that crowdsourcing for clinical research could be a powerful tool. With the addition of citizen science, there has been a recent rise in coordinated self-experimentation, leading to participant-organised (Roberts, 2011; Roberts, 2010; Martin, Burns, and Doiron, 2011) and researcher initiated (Turner et al., 2011; Wicks et al., 2011a; Wicks et al., 2009; Frost et al., 2011; Wicks et al., 2011b) studies. Researchers are now sourcing entire cohorts and collecting data directly from social media sources.

This evaluation seeks to determine the maturity of crowdsourcing for clinical research by examining published work utilising crowdsourcing for cohort definition or data collection. AB et al. (2013) identifies four main types of crowdsourced research; problem solving; data processing; surveillance/monitoring; and surveying. This paper will predominantly focus on crowdsourced surveillance/monitoring.

The aim of this evaluation is to determine the maturity of the method of crowdsourced clinical research, with focus on evidence for the tool over level of adoption as a primary indicator, with an outcome focus instead of a return on investment model.

2 Background

Crowdsourcing clinical research enables researchers to recruit participants and obtain data from large numbers of patients via the Internet. Crowdsourcing affords researchers a new way to survey diseases "especially given the recent ubiquity of information technology tools that can automate and accelerate the data collection process" over communities in which patients are already volunteering this information (Chunara, 2012), offering a continual pool of participants (Turner, Kirchhoff and Capurro, 2012).

The intended benefits of utilising crowdsourcing for clinical research include cost savings, reduction of geographical limitations and shorter recruitment periods than traditional clinical research. Additional advantages outlined by Freifeld et al. (2010) include scalability, coverage, timeliness, and transparency. Use of crowdsourcing for recruitment substantially reduces the

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costs. A recent study found the cost of such recruitment was \$4.82US per patient, compared with \$86.28US for direct mail and \$195.65US for email enlisted participants (Cascade et al., 2012). Overcoming such costs may enable researchers to increase trial sizes and afford them the ability to enlist participants “in more diverse geographic regions, without incurring the costs of dedicated oversight teams in multiple locations” (Cook, 2011). With many thousands of patients already sharing their health data online, researchers can readily identify suitable candidates for recruitment to specific studies, expediting the entire research process, as recruitment accounts for 45% of study delays (Cascade et al., 2012).

Tepper (2013) quotes Dr Chad Cook, a researcher who has used this technique (his work was reviewed as part of the evaluation), as saying crowdsourcing in this context is “examining the mundane to see if it would affect clinical practice. We can investigate questions with a larger pool of patients and clinicians, and to answer questions we normally couldn’t answer”.

One of the most prominent studies to date utilizing crowdsourcing in an interventional setting is the investigation of the experimental use of lithium carbonate treatment to treat amyotrophic lateral sclerosis (ALS). ALS is a rapidly neurodegenerative disease that causes weakness and atrophy, with a median survival from symptom onset of two (2) to five (5) years (Wijesekera and Leigh, 2009). A small, single blinded study showed that lithium carbonate treatment was potentially efficacious in the treatment of ALS (Fornai et al., 2008). Despite clinician scepticism, patients were enthusiastic to try this treatment, and began taking the medication off-label. Patients used an online spread-sheet to gather data, and PatientsLikeMe[®], an online network that enables people with similar conditions to connect, (PatientsLikeMe[®], 2013) built a lithium-specific data collection tool for the use of their 348 lithium-taking ALS patients. Wicks et al. (2011b) analysed the data collected, and attempted to overcome potential biases created in the absence of randomisation, blinding and placebo control. The researchers used a matching algorithm to match 148 eligible-for-analysis participants to 447 controls using historical data collected on PatientsLikeMe[®]. Lithium carbonate treatment was found to have no effect of ALS disease progression. The researchers acknowledged this study method is not a substitute for double blind randomised control trials (RCT), but the outcome of this study was later replicated in RCTs (Gamez, Salvado and Badia, 2013).

3 Methodology

According to van de Wetering and Batenburg (2009) theories of information systems and IT maturity and adoption are well established, dating back to the early 1970’s. The first known model is the Nolan Model, which was the basis for the evaluation model search. An initial literature search was conducted using Google Scholar and University of Melbourne Discovery. Several articles discussing evaluation frameworks were identified; van de Wetering and Batenburg (2009); Persson and Goldkuhl (2005); O’Neil (2011); and Galliers and Sutherland (1991). From these articles, the frameworks presented in

Table 1 were identified as being potentially appropriate to evaluate crowdsourcing clinical research.

<p>The Nolan Model (Lesleiking and Kraemer, 1984)</p> <ul style="list-style-type: none"> • Initiation • Contagion • Control • Integration 	<p>Project Management Maturity Model (Hillson, 2003)</p> <ul style="list-style-type: none"> • Naïve • Novice • Normalised • Natural
<p>Stages of Project Management (Paulk et al., 1993)</p> <ul style="list-style-type: none"> • Performed • Managed • Defined • Quantitatively Managed • Optimising 	<p>Lee and Layne Model (Layne and Lee, 2001)</p> <ul style="list-style-type: none"> • Catalogue • Transaction • Vertical Integration • Horizontal Integration
<p>Constitutes and the e-diamond Model (Albinsson et al., 2006)</p> <ul style="list-style-type: none"> • Separated • Coordinated • General • Individual • Information • Performative 	<p>e-readiness Categories (van Dyk, Schutte and Fortuin, 2012)</p> <ul style="list-style-type: none"> • Technology / Maintenance • Policy and Legal • Individual Users • Organizational Processes • Planning and Financial Sustainability • Interaction / Community Involvement
<p>Layered Telemedicine Implementation (Broens et al., 2007)</p> <ul style="list-style-type: none"> • Prototype • Small-scale Pilots (Acceptance) • Large Scale Pilots (Financing, Org) • Operational (Policy and Legislation) 	<p>The Seven S’s (Pascale and Athos, 1981)</p> <ul style="list-style-type: none"> • Strategy • Structure • Systems • Staff • Style • Skills • Superordinate goals
<p>The Hirschheim et al. Model (Hirschheim et al., 1988)</p> <ul style="list-style-type: none"> • Delivery • Reorientation • Reorganisation 	<p>National Infrastructure Maturity Model (NHS, 2011)</p> <ul style="list-style-type: none"> • Level 1: Initial, ad hoc, process (basic) • Level 2: Managed, stable process (controlled) • Level 3: Defined, standard (standardized)

	<ul style="list-style-type: none"> • Level 4: Measured Process (optimized) • Level 5: Optimizing (innovative)
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Table 1: Potential Frameworks to Evaluate Crowdsourcing Clinical Research

The authors then reviewed this table and eliminated models that were not relevant in the clinical research methodological space, leaving five (5). These were further examined against the following criteria:

1. Framework evaluates maturity;
2. Framework focuses on evidence for the tool over level of adoption as a primary indicator of maturity; and
3. Framework is outcome focused, not Return on Investment focused.

The results of this analysis are presented in Table 2.

Criteria #	1	2	3
The Nolan Model	✓	✗	✓
Stages of Project Management Maturity	✓	✗	✓
PRoMMM	✓	✓	✓
NIMM	✓	✓	✓
e-readiness categories	✓	✗	✓

Table 2: Analysis of Evaluation Framework Against Criteria

Two evaluation models met all three criteria: Project Management Maturity Model (ProMMM) (Hillson, 2003) and the National Infrastructure Maturity Model (NIMM) (van Dyk, Schutte and Fortuin, 2012). The authors determined the use of both evaluation measures to be appropriate as ProMMM focuses on the ability of professionals to utilise the tool while NIMM focuses on the maturity of the tool itself.

ProMMM (Hillson, 2003) is designed to assess the level of capability of project managers and is often applied to organisations to determine how mature they are. In the context of this paper, stages relate to health care professionals at an individual level. ProMMM has the following levels of maturity:

- Naïve;
- Novice;
- Normalised; and
- Natural.

To assess the maturity of crowdsourcing clinical research using ProMMM, the stage-characteristic model in Table 3 was used, adapted from Hillson (2003).

Level	Characteristics of Stage
Naïve	<ul style="list-style-type: none"> • Potential users unaware of the value of the tool • No structured approach to use • Culture is resistant to change • Need for tool recognised • No experience of use • No application for the tool
Novice	<ul style="list-style-type: none"> • Small number of users have begun to experiment with tool • No formal or structure generic processes
Normalised	<ul style="list-style-type: none"> • Implemented across organisation / industry • Formalised • Recognised value of tool • Understand expected benefits of tool • Users have experience and expertise • Application of tool is routine and consistent
Natural	<ul style="list-style-type: none"> • Accepted culture across organisation / industry • Best-practice usage • All potential users have a degree of experience • Application is widespread and second-nature

Table 3: PRoMMM Maturity Level Characteristics (Hillson, 2003)

The NHS developed a National Infrastructure Maturity Model (NIMM) to assess the IT Infrastructure of the UK National Health Service (van Dyk, Schutte and Fortuin, 2012). In the context of this paper, crowdsourcing clinical research will be assessed against the levels to determine the maturity of the tool. These levels are:

- Level 1: Initial, ad hoc process (Basic);
- Level 2: Managed, stable process (Controlled);
- Level 3: Defined, standard process (Standardised);
- Level 4: Measured process (Optimised); and
- Level 5: Optimizing (Innovative).

To assess the maturity of Crowdsourcing clinical research using NIMM, the stage-characteristic model in Table 4 was used, adapted from Essmann (2009).

Level	Characteristics of Stage
1: Initial, ad hoc process (Basic)	<ul style="list-style-type: none"> • Ad hoc and chaotic usage • Used by individuals only
2: Managed, stable process (Controlled)	<ul style="list-style-type: none"> • Use of tool planned, performed, measured and controlled • Documented use • Requirements, processes of tool are managed • Commitments are established
3: Defined, standard process (Standardised)	<ul style="list-style-type: none"> • The tool is well characterized and understood • Standards, procedures and methods for tool use • Consistent usage • More rigour in use
4: Measured process (Optimised)	<ul style="list-style-type: none"> • Quality and process performance of tool use is understood in statistical terms • Detailed measures of tool performance
5: Optimizing (Innovative)	<ul style="list-style-type: none"> • Usage continually improved based on a quantitative understanding • Focus is on continually improving tool performance • Shared learning

Table 4: NIMM Maturity Level Characteristics (NHS, 2011)

The authors determined the maturity level of crowdsourcing for clinical trials using both models, based on evidence for each stage in available literature and primary interviews conducted at the Melbourne Brain Centre at Royal Melbourne Hospital with Associate Professor Helmut Butzkueven, MS Neurologist and Researcher, and Dr Athina (Tina) Soulis, General Manager of Neuroscience Trials Australia.

4 Results – ProMMM Maturity Model

Initial readings of current crowdsourcing literature indicate it is new to clinical research, and so it is expected that users and prospective users will fall into the Naive or Novice categories.

4.1 Evidence for Naïve Level

4.1.1 Potential Users Unaware of the Value of the Tool – Substantiated, but Reducing Unawareness

Several review and opinion articles have appeared in peer-reviewed journals (AB et al., 2013; Behrend et al., 2011; Cascade et al., 2012; Cheeney, Harskamp and Schupp, 2012; Cook, 2011; Ekins and Williams, 2010; Norman et al., 2011; Swan, 2012; Tepper, 2013) expounding the benefits, limitations and current landscape of crowdsourcing clinical research. The literature predominantly discusses crowdsourcing as a new area, and thus while not all potential users are aware of benefits, there is knowledge transfer growth in this area.

4.1.2 There is no Structured Approach to Use - Substantiated

There are no formal standards for use and application is neither routine nor consistent. AB et al. (2010) found “considerable variability in how the methods of crowdsourcing were reported”. Crowdsourced clinical research is not accepted industry-wide and “do not always conform to generally accepted industry practices of research conduct” (Swan, 2012).

4.1.3 Culture is Resistant to Change – Substantiated

Swan (2012) addresses the belief that some in the medical research field are reported to have, that “citizen science is not really science”. The limiting belief that science is an esoteric exercise to be practiced by a few gifted minds may be overcome through the early successes of crowdsourcing. Results from crowdsourced studies have been published in peer-reviewed journals, but more often in grey literature (Swan, 2012). This may reflect the journal editors’ belief that there is lack of acceptance of the tool in the broader scientific community.

Tepper (2013) states one of the major sources of reluctance in the uptake of crowdsourcing in clinical research is the low quality of data generated and the need to filter information adding to time and cost requirements. Swerlick, James and Minnillo (2011) argue this limitation is actually an advantage that will attract researchers. They describe the physician as a “filter” in the data collection process, which results in missing drug induced adverse events.

4.1.4 Need for Tool is Not Recognised – Unsubstantiated

The need to generate cost savings, reduce geographical limitations of participation and decrease recruitment periods is well established. Crowdsourcing has been found to reduce recruitment costs (Cascade et al., 2012), is immune to geographical restrictions, and has a large pool of potential participants at the ready. Crowdsourcing also offers the advantages of scalability, coverage, timeliness, and transparency (Freifeld et al., 2010).

4.1.5 No Experience of Use - Unsubstantiated

This criterion is not met as there is published experience of use; for example in Wicks et al. (2011b); Turner et al. (2011); Wicks and MacPhee (2009); Frost et al (2011); Cheeney, Harskamp and Schupp (2012); and AB et al. (2013).

4.1.6 No Application for the Tool – Unsubstantiated

The for-profit sector is enthusiastic about possibilities offered by crowdsourcing. Norman et al. (2011) quotes Dr. Paul Chapman, Head of Takeda’s Pharmaceutical Research Division as saying: “In particular I was very excited about the opportunities generated by crowdsourcing clinical research. In neuroscience, for example, we are often faced with very difficult decisions about which of several unmet medical needs to be addressed first, with a good compound for a novel target. Precompetitive crowdsourcing would mean that we could get multiple shots on a competitive compound, we can understand how to align our compound with the most promising unmet medical need”.

A/Prof Butzkueven (2013) raises another application of the tool: “we have trouble in terms of conducting clinical trials in Australia, recruitment is going down and these sorts of communication strategies enable us to reach lots more people at once”. Dr Soulis (2013) adds, “in the 20 years I’ve been involved in clinical trials I think I can count on one hand the number of trials that recruited on time or faster than expected. Recruitment is always an issue. This is a really good tool or vehicle to address this area of recruitment; that would be its biggest advantage”.

4.2 Evidence for Novice Level

4.2.1 Small Number of Users Have Begun to Experiment with Tool – Substantiated

Frost et al. (2011) acknowledge use of “patient-reported outcomes entered via an online community” is a new source of evidence to evaluate off-label medication use. They expound the benefits of crowdsourcing data in their discussion, which is a practice unique to new and experimental research methods. Frost et al. (2011) explain their crowdsourcing method was able to collect previously unrecorded data types from large and increasingly diverse populations. Similarly, Wicks et al. (2011a) describe online communities as “an opportunity” that has not yet been fully explored.

AB et al. (2013) states “crowdsourcing clearly is not used pervasively in health research”. Evidence for more experimentation with crowdsourcing clinical research is presented by Wicks et al. (2011a) displaying an “exponential rise in recent Internet activity in crowdsourced health research” and finding “the term ‘crowdsourcing’ in a PubMed search yielded 16 publications, 13 of which were published in 2011” (Wicks et al, 2011a).

4.2.2 No formal or Structured Generic Processes - Somewhat Substantiated

While the technique of crowdsourcing is yet to be widely

accepted, the ethical principles underpinning the tool are well established. Drug discovery and safety are well-established areas of research requirement. Wicks et al. (2011b) discuss obligations of researchers to collect data regarding the safety of self-experimentation, and of potentially efficacious drugs discovered in crowdsourced data.

Cook (2011) believes that while widespread adoption has not yet occurred, “this is a research model of the future. And as far as having clinicians drive the success of dedicated research projects, I cannot think of a better group to do it”. Tippler (2013) states the implementation of this tool will create economic disruptions, as funding models are not currently adaptive to this tool.

4.3 ProMMM Results Summary

Level	Characteristics of Stage
Naïve	<ul style="list-style-type: none"> ✓ Potential users unaware of the value of the tool ✓ No structured approach to use ✓ Culture is resistant to change ✗ Need for tool recognised ✗ No experience of use ✗ No application for the tool
Novice	<ul style="list-style-type: none"> ✓ Small number of users have begun to experiment with tool ✓ No formal or structure generic processes
Normalised	<ul style="list-style-type: none"> ✗ Implemented across organisation / industry ✗ Formalised ✗ Recognised value of tool ✗ Understanding expected benefits of tool ✗ Users have experience and expertise ✗ Application of tool is routine and consistent
Natural	<ul style="list-style-type: none"> ✗ Accepted culture across organisation / industry

	<ul style="list-style-type: none"> ✘ Best-practice usage ✘ All potential users have a degree of experience ✘ Application is widespread and second-nature
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Table 5: Summary of Results – Evaluation using PRoMMM

Practitioners using crowdsourcing for clinical research fall in the Novice level of maturity according to the ProMMM maturity model. A/Prof Butzkueven (2013) confirms this outcome: “we are just at the starting point”.

5 Results NIMM Maturity Model

As crowdsourcing for clinical research is a new tool it is expected to fall into the Level 1, Basic, or Level 2, Controlled, categories of NIMM.

5.1 Evidence for Level 1 - Basic

5.1.1 Ad Hoc and Chaotic Usage - Substantiated

Crowdsourcing for clinical research is well published, including but not limited to papers by Wicks et al. (2011b); Turner et al. (2011); Wicks and MacPhee (2009); Frost et al. (2011a); Cheeney, Harskamp and Schupp, (2012); and AB et al. (2013). However, usage is currently limited to a few pockets of research interests.

Swerlick, James and Minnillo (2011) describe the crowdsourcing tool as “a green field where the options for what and where to build are wide open” and that this tool could be used in “an almost unlimited number of clinically relevant studies” (Swerlick, James and Minnillo, 2011).

5.1.2 Used by Individuals Only - Substantiated

Swan (2012) states: “thus far the only form of study conducted by professional researchers in crowdsourced cohorts has been retrospective, non-intervention user questionnaires”. The tool needs further research and refinement to be applicable to a wider range of research questions and protocols (Swan, 2012). Once this development has occurred, institutions and companies may adopt the technique more widely, but no evidence was found that the tool is being used across departments, institutions or companies.

5.2 Evidence for Level 2 - Controlled

5.2.1 Use of Tool Planned, Performed, Measured and Controlled - Unsubstantiated

Cheeney, Harskamp and Schupp (2012) note the crowdsourcing technique is currently limited by lack of standardised data collection and validated instruments. Armstrong et al. (2012) echoes the call for validation of measures used in crowdsourced data collection. As does Swan (2012): “crowdsourced health research studies do

not always follow the rigorous protocols”. Cheeney, Harskamp and Schupp (2012) also discuss the lack of convergence in evidence surrounding this tool. For example, some studies have shown that crowdsourcing reaches an older, more ethnically diverse population (Behrend, 2011), while other have shown crowdsourcing populations can be more defined and less representative in demographic makeup.

Armstrong et al. (2012) reports the quality of data obtained through crowdsourcing is unknown, but Behrend (2011) showed data they accumulated through a crowdsourcing effort was as good or better than data collected in a corresponding university sample. Cheeney, Harskamp and Schupp (2012) found dramatic differences in the rates of efficacy of acne treatments. What is unknown is if this is the result of low quality data being collected using crowdsourcing, or a true result that would not otherwise be found due to the difference in cohorts, clinician filtering and research design. A/Prof Butzkueven (2013) provides an example of the insufficient measurement and control of the tool; “for example, you have a disease specific website where people can register and then record their medications, and can report patient reported outcome...you could theoretically use that data for an efficacy study for different medications but you end up with lots of selection biases. People lose interest or become too unwell will stop posting or engaging. They are really just ballooned selection biases that we get in registered studies anyway. So like any other scientific endeavour, the methodologies have to be examined and it has to be peer reviewed”.

Frost et al. (2011), Cheeney, Harskamp and Schupp (2012), Swan (2012), Wicks et al. (2011b) and AB et al. (2013) all address the limitations of crowdsourcing, resultant from a lack of research in to, and refinement, of the tool. The effect of patient motivations in: reporting self-experimentations; the lack of demographic data collection; the temporal habits of online self-report; the lack of diagnosis confirmation; the possible over-reporting of positive outcomes; and, the possibility that people are deliberately misrepresenting themselves have not yet been adequately examined. Dr Soulis (2013) adds to this, saying: “it’s ploughing through the information that would be available... how do you substantiate the validity of the information... how do you work that out? That is a major limitation”.

5.2.2 Documented Use – Substantiated

As previously mentioned, there is documented use of the tool, including but not limited to: Wicks et al. (2011a); Turner et al., (2011); Wicks and MacPhee (2009); Frost, et al. (2011); Cheeney, Harskamp and Schupp (2012); and AB et al. (2013).

5.2.3 Requirements, Processes of Tool Use are Managed – Unsubstantiated

Tepper (2013) discusses that crowdsourcing techniques are “outrunning legal and regulatory protections... we are in the infancy of case law related to the privacy of social network health information”. Swan (2012) elaborates by stating that crowdsourced clinical research do not

conform to standard and accepted industry practices. In fact, studies specifically point out traditional compliance methods are not practicable, and institutional review boards may not approve crowdsourced research for this reason. Dr Soulis (2013) states that “the regularly environment is not ready for it. In the global sense there would need to be guidance from the big regulators like the FDA, EMA in Europe, like our TGA... Regulatory agencies are really keen on proving that you have done your trial in the best faith... making sure they (participants) fully understand what they are signing up for”.

A/Prof Butzkueven (2013) reports that there is a move toward acceptance of these methods: “the ethics committees that regulate research seem to be on board with this in general, but of course there are some ethical limitations”.

5.2.4 Commitments are Established - Substantiated

A commitment to use has been made by the pharmaceutical industry as they recognise the value of crowdsourcing clinical research “to reduce research and development costs” (Ekins and Williams, 2010).

The ethical principles underpinning the tool are well established. Drug discovery and safety are two well-established areas of research need.

5.2.5 NIMM Results Summary

Level	Characteristics of Stage
1:Initial, ad hoc process (Basic)	<ul style="list-style-type: none"> ✓ Ad hoc, chaotic usage ✓ Used by individuals
2: Managed, stable process (Controlled)	<ul style="list-style-type: none"> ✗ Use of tool planned, performed, measured and controlled ✓ Documented use ✗ Requirements and processes of tool are managed ✓ Commitments are established
3:Defined, standard process (Standardised)	<ul style="list-style-type: none"> ✗ Well characterized and understood ✗ Stands, procedures and methods for tool use ✗ Consistent usage ✗ More rigour in use
4:Measured process (Optimised)	<ul style="list-style-type: none"> ✗ Quality and process performance of tool use is understood in statistical terms

	<ul style="list-style-type: none"> ✗ Detailed measures of tool performance
5:Optimizing (Innovative)	<ul style="list-style-type: none"> ✗ Usage continually improved based on a quantitative understanding ✗ Focus is on continually improving tool performance ✗ Shared learning

Table 6: Summary of Results – Evaluation using NIMM

Using the NIMM Maturity Model to look at the maturity of crowdsourcing clinical research as a tool places it at Level 1: Basic, initial, ad hoc process.

6 Conclusions and Recommendations

This evaluation demonstrates crowdsourcing clinical research is a relatively immature tool and is sparsely used by both individuals (ProMMM evaluation), and in the field of health research on a whole (NIMM evaluation).

Low maturity tools are often riskier and harder to operate, as users are unfamiliar with the application. In a highly regulated field, such as health, use of immature tools is especially difficult to justify as focus is on evidence-based methods of research for informing health actions.

With the current limitations of crowdsourcing clinical research: self-selection bias; funding limitations; and, shortcomings in study design (Swan, 2012), crowdsourcing needs further research and refinement for it to be applicable to a wider range of research questions and protocols, and to be competitive with the ‘gold standard’ of RCT’s.

The authors acknowledge further limitations including demographic disparity between groups that do and do not use the Internet or participate in online health communities. For example, "women, non-Hispanic whites, younger adults, and those with higher levels of education and income" are more likely to use the Internet to gather health information than other demographic groups (Fox, 2011). This paper determined the maturity level of crowdsourcing clinical research at the individual professional and industry levels, however the authors identify areas for future research exist to evaluate benefits and limitations of crowdsourcing clinical research, including cost-benefit analysis and validation studies.

Despite such limitations the future holds exciting applications for crowdsourcing clinical research, including: demographic collection (Cheeney, Harskamp and Schupp, 2012); (Armstrong et al., 2012); images for patients to report against (Cheeney, Harskamp and Schupp, 2012)(Armstrong et al., 2012); treatment periods and medication adherence (Cheeney, Harskamp and Schupp, 2012)(Armstrong et al., 2012); and, controls of reporting of new signs and symptoms with clinical review

to prevent duplication (Cheeney, Harskamp and Schupp, 2012)(Armstrong et al., 2012). With more people using the Internet, crowdsourcing clinical research is an exciting tool that can allow clinical researchers the ability to harness currently untapped data, perhaps in conjunction with traditional methods. As Swerlick, James and Minnillo (2011) summarises: “the possibilities are endless”, but at this stage, crowdsourcing is just that, a possibility, and not a proven mechanism.

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