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EXPERT OPINION

Exploring open innovation with a patient focus in drug discovery: an evolving paradigm of patient engagement

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It is suggested in this article that patient engagement should occur further upstream during the drug discovery stage. 'Lead patients', namely those patients who are proactive with respect to their health, possess knowledge of their disease and resulting symptoms. They are also well informed about the conventional as well as non-conventional treatments for disease management; and so can provide a nuanced perspective to drug design. Understanding how patients view the management of their diseases and how they view the use of conventional versus non-conventional interventions is of imperative importance to researchers. Indeed, this can provide insight into how conventional treatments might be designed from the outset to encourage compliance and positive health outcomes. Consequently, a continuum of lead patient engagement is employed that focuses on drug discovery processes ranging from participative, informative to collaborative engagement. This article looks at a variety of open innovation models that are currently employed across this engagement spectrum. It is no longer sufficient for industry stakeholders to consider conventional therapies as the only mechanisms being sought after by patients. Without patient engagement, the industry risks being re-prioritized in terms of its role in the patient journey towards not only recovery of health, but also sustained health and wellness before disease onset.

Keywords: lead patient, open innovation, patient centricity, patient engagement

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1. Introduction

Mulley *et al.* discuss that medical practitioners cannot recommend the most effective treatment without a consideration of how a patient values the risks, benefits and side effects associated with the treatment [1]. The authors expand on the notion of preference diagnosis as a means of patient engagement. Preference diagnosis involves the provision of information, joint discussion, evaluation of options and an analysis of how preferences change once the patient is more informed of the condition and the options available. Preference diagnosis is deemed to be important for the management of chronic conditions [2]. Decision making and patient preferences can change over time as a variety of therapies are used, the results monitored and the health of the patient evolves. Studies have shown that patients who are engaged in decision making are more motivated and that their clinical outcomes are better [2]. While medical practitioners can gather information relevant to a preference diagnosis through patient interaction, by presenting the risks, benefits and side effects of each possible course of action and observing how patients react, it is advocated in this paper that the biopharmaceutical industry and regulatory agencies engage patients earlier in the drug discovery and development process.

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Article highlights.

- Patients can provide vital information as to how conventional treatments, nutrition, other remedies are collectively used to address disease and the associated symptoms.
- Patient engagement can be viewed across a spectrum, with varied points of intervention, mechanisms of engagement and varied levels of engagement.
- It is suggested in this paper that patient engagement needs to move further upstream during the drug discovery stage.
- 'Lead patients' can provide a nuanced perspective to drug discovery as well as development.
- A variety of open innovation models are currently being employed to engage patients – permitting the transition of patients from the role of simple participant to the mid-level informative role, and at the highest level of engagement – the collaborative role.

This box summarizes key points contained in the article.

Imperative is the joint understanding as to how patients view the management of their diseases, view the use of conventional versus non-conventional interventions and how conventional treatments might be designed from the outset to encourage compliance and positive health outcomes.

The biopharmaceutical industry is currently seeking personalized treatments as well as new opportunities through drug repurposing. Patient engagement early in the drug discovery and development process can offer the insight needed to design personalized, more holistic treatment platforms in addition to drug repurposing avenues as patients themselves search for these options. While we can contend that engagement may be more suitable for chronic disease where longevity of support is needed for disease management, we can suggest that even in the case of acute diseases the patient voice in terms of clinical trial design as relevant and treatment option availability (with implications for compliance and impact) should be recognized.

2. Engaging patients across the discovery spectrum

Carman *et al.* discuss that patient engagement can be viewed across a spectrum, with varied points of intervention and varied levels of engagement [3]. These authors discuss the levels at which patient engagement can occur across the healthcare system, from the direct care setting to incorporating patient engagement into organizational design, governance and policy making. Patients can be engaged at the lower end of the spectrum through a consultative process, whereby patients might receive information about a diagnosis; further along the continuum, patients may be asked about their preferences regarding a treatment plan; at the higher end of the continuum, patients participate in partnership with healthcare providers in terms of treatment choice based on preferences, medical evidence and clinical judgment [3]. I offer that a similar continuum of engagement be devised by the biopharmaceutical industry to engage patients in the drug discovery process, in this case, the engagement of the 'lead patient'.

According to von Hipel, "lead users are users whose present strong needs will become general in a marketplace months or years in the future…Moreover, since lead users often attempt to fill the need they experience, they can provide new product concept and design data as well" [4]. With this definition in mind, *I qualify* 'lead patients' as those patients who:

- are proactive with respect to their health including an awareness of wellness;
- are aware of the role of functional foods in disease prevention and health promotion;
- possess knowledge of their disease and resulting symptoms;
- have an understanding of the link between wellness, functional foods, exercise and disease management and
- are well informed about prescription medications and disease management.

It is these lead patients who can provide a nuanced perspective to drug design. Hence, the opportunity exists to change the patient's role from consumer to participant in self-care and health promotion, and more so to that of value chain partner. Although the traditional notion of value chain partner assumes engagement of the patient and patient advocacy groups during the later stages of drug development, lead patients should be sought to enable patient-centric drug discovery and patient-centric clinical trial design. These lead patients may offer:

- Insight into personal methodologies used to promote health and prevent disease.
- How an awareness of diseases condition(s) will impact personal behavior change(s) such as seeking opportunities to improve health/disease knowledge, engaging other patients through social networks/media, seeking information about treatment options including competitor options.
- Personal health targets such as disease prevention, diseases control or elimination.
- Their perception of prescription medicines, delivery mechanisms and treatment compliance.
- Treatment options sought given the benefits, risks and impact on personal life style.
- Clinical trial designs best suited to personal life style and needs including the role of technology to facilitate patient-driven data collection.

Figure 1 illustrates lead patient engagement, namely that lead patients can participate in health promotion, disease management, drug discovery, treatment analysis and clinical

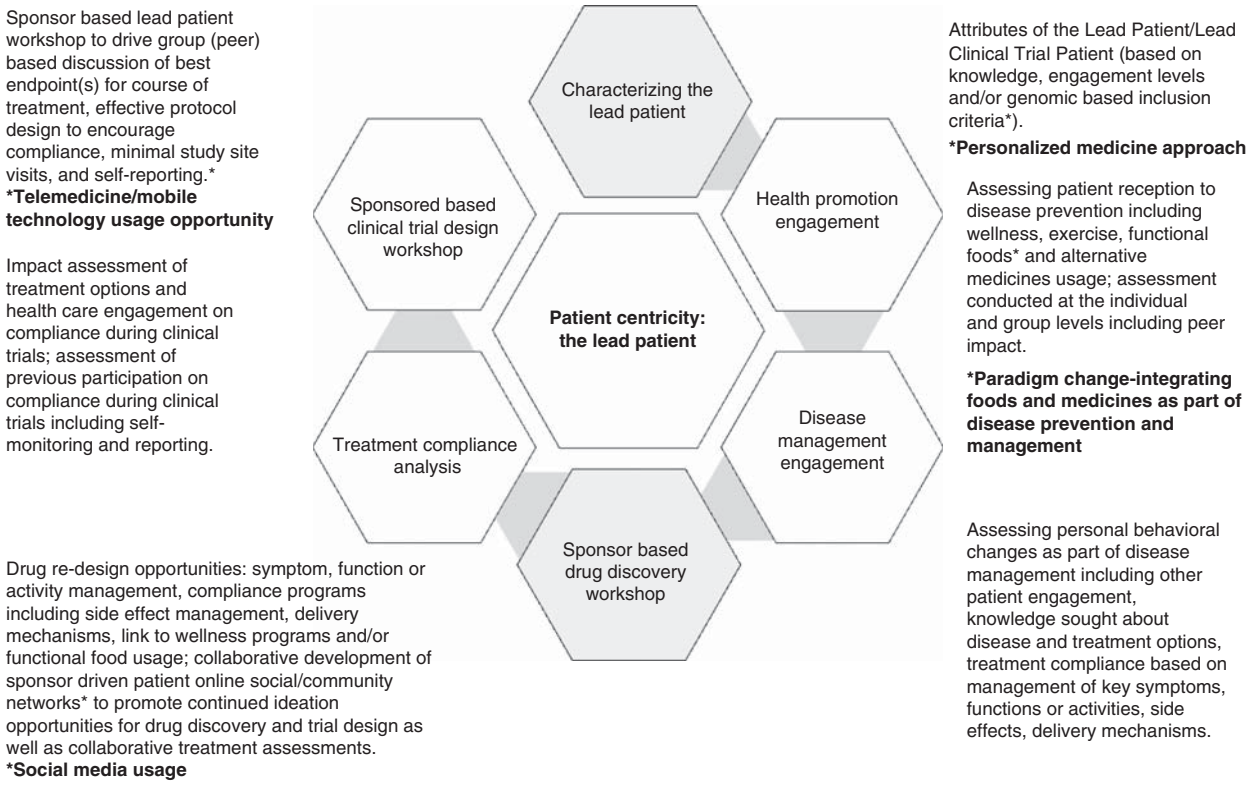

Figure 1. Engaging the lead patient: paradigm changes through personalized, holistic and technology-driven drug discovery and development.

trial design/participation. Opportunities for patient engagement specifically during the drug discovery phase include: discussions to evaluate and prioritize research questions, patient-evaluated points of intervention and end points, treatment design with a focus on minimizing side effects, ensuring compliance and maximizing the benefits of a patient's holistic health plan, in addition to monitoring off-label drug usage as a means of drug repurposing. Below, I discuss examples of initiatives underway that seek to engage patients in upstream activities.

2.1 Patient-powered research networks: prioritizing research questions

The patient-powered research networks (PPRNs) consist of networks of patient organizations focused on a key health condition with the expressed goals of sharing health information and engaging in research [5]. Some PPRNs provide participants with the opportunity to directly enter their information into online surveys within a patient portal, upload data from remote monitoring devices (and sensors) or enter their health data generated by mobile health applications. The possibility exists to formalize and codify the anecdotal conversations participants have about important health concerns shared online through a variety of vehicles. While the data can be used for clinical research, disease self and physician management, the goal of the PPRN is to collaboratively prioritize research questions. Moving forward, the PPRNs are planning in-person or online discussions of research priorities, including focus groups, and formal methods to rank research topics [5].

2.2 The patient-focused drug development initiative: a context for studies and decisions

Assessment of a product's benefits and risks includes an analysis of the severity of the condition treated and the current treatment options available for the given disease. This information is vital as it provides the context in which regulatory decisions can be made [6]. The US FDA notes that the drug development and FDA's review process could benefit from a more systematic and expansive approach to obtaining the patient perspective on disease severity and available options in a therapeutic area [6]. In September 2012, the FDA announced a preliminary set of disease areas for public assessment as part of its Patient-Focused Drug Development initiative [6]. Approximately 16 diseases were identified to be the focal point of the first set of public meetings to be held over the 2013 – 2015 period. Disease areas selected included those: that are chronic, symptomatic and affect functioning and activities of daily living; disease areas for which important aspects of that disease are not formally captured in clinical

trials and disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patients feels, functions or survives [7]. Patients are engaged through online postings, webinar-based presentations and discussions, through in-person discussions consisting of large group facilitated discussions and small group breakout sessions [7]. While, the data collected are used to inform regulatory practices, with a view of symptoms, conditions, life impact, treatment selection by patients, treatment-symptom alleviation correlations, treatment design and side-effect impact, biopharmaceutical organizations similarly stand to benefit from the initiative.

2.3 Social networks: tracking the patient journey for holistic treatment platform development

PatientsLikeMe members are documenting their medical histories in detail and sharing the information with other patients. The site encourages patients to participate by offering free tools for tracking medications, symptoms, health outcomes and storing the data. The associated search engine allows members to find others whose medical profiles most closely match their own [8]. In turn, several pharmaceutical companies, universities and research labs have purchased data from PatientsLikeMe with personal information removed and consent provided by patients. Comparably, Cure Together provides surveys and enables patients to contribute their own experiences with over 500 conditions such as arthritis, migraine and endometriosis. Members can rate treatments ranging from exercise to drugs [9]. Patients are encouraged to discuss sensitive symptoms and compare which treatments work best for them. The goal here is to engage patients across their medical decisions, namely during disease diagnosis, treatment option analysis, the choice of conventional or non-conventional therapies, the design of wellness and holistic programs that seek to prevent or slow down disease onset or progression, respectively and further assess patients' expectations for disease treatment and therapy outcome. Finally, Smart Patients is moving towards the holistic engagement of patients. Smart Patients is an online community where patients can not only learn from each other about treatments, but can also acquire information regarding clinical trials and the most current science regarding their health conditions. Across these platforms, patients are empowered through self-tracking and/or natural conversations [10]. In terms of leveraging the data, both quantitative analysis and natural language processing can be utilized by stakeholders for insight regarding drug re-design and ultimately holistic treatment platforms development to better meet patients' expectations.

2.4 Engaging patients in drug repurposing: new discovery opportunities

Litterman *et al.* discuss that social network sites enable physicians and patients alike to crowdsource a diagnosis. Through increased connectivity, patients can engage one another as well as physicians as they attempt to identify the source of their symptoms and understand their recent diagnoses [11]. Litterman *et al.* consider that such connected patient networks can lead to key research breakthroughs, such as defining the genetic origin of the disease, understanding the natural history, defining biomarkers, recruiting patients for clinical registries, natural history studies and clinical trials [11]. The opportunity to engage patients for drug repurposing is additionally discussed. Through information provision, collaboration and education, physicians and patients may be engaged to identify molecules approved for human use including pharmaceuticals, nutraceuticals and other products. The monitoring of any off-label usage clearly necessitates discussion with physicians, patients, manufacturers and regulatory agencies ensuring broad knowledge dissemination and adherence to drug safety standards.

3. Models of open innovation

The cases studies presented suggest that a variety of models of open innovation can be exploited to engage patients across the drug discovery spectrum. Interestingly, research supported by the Patient-Centered Outcomes Research Institute seeks to determine the effectiveness of patient engagement techniques for incorporating patient input into research prioritization. The objectives of this recently funded project include the evaluation of how patient engagement methods (mailed questionnaires, focus groups and online crowd-voting) compare in terms of outcomes and costs. The study will additionally determine the impact of patient demographics and disease severity as influencing participation in research activities [12]. Overall, open innovation strategies must permit the transition of patients from the role of simple participant to the mid-level informative role, and at the highest level of engagement the collaborative role. **Table 1** outlines a newly devised continuum of patient engagement across several models of open innovation: crowd research, research partnerships, co-design programs, patient communities and focus groups.

3.1 Crowd research: tapping into the wisdom of patients and physicians

Crowd research, collaborative or networked science while typically used to connect researchers, has been extended in its reach – incorporating physicians in joint diagnosis with merits in engaging such physicians for drug repurposing activities. Patients can participate at the informative level through the provision of genetic profile information, biological samples, knowledge regarding their experiences with diseases and treatments [8]. Noteworthy is that even the public is being tapped for simple analyses of data and biological samples.

Recently, crowdsourced projects gained traction as a means of finding new drugs through soil samples supplied by the public. In one instance, new drugs will be sought through the cultivation of fungi; in another project, the hope is to

Table 1. Transformative patient engagement models.

Engagement model	Participant	Informative	Collaborative
Crowd research		Patient supplies information or samples	Patient collaboratively analyzes information (including scientific information or biological samples) provided by external stakeholders
Research partnerships			Patient may either occupy the role of engagement researcher or lead patient
Co-designing		Patients may share their preferences with respect to drug design and clinical trial protocol development	Patients may participate in the search for promising new indications as part of drug repurposing; patients actively design clinical trial protocols, select end points and determine data collection processes to meet lifestyle needs
Patient communities	Patients engage in self-discovery in patient-driven communities	Patients share their experiences with treatments, symptoms and disease management	Through stakeholder-driven communities, patients may engage in joint discovery, development and management of treatments and conditions
Focus groups		Patients are engaged in the provision of patient-reported outcome measures	Through lead patient workshops, the patient may be engaged collaboratively in early drug discovery and development studies

source new antibiotics by analyzing samples provided by the public from beaches, forests and deserts across five continents [13,14]. Scientists anticipate creating a world map of chemicals produced by microbes (with the expected outcome new medicines) through these publicly driven initiatives [14]. We might suggest from these initiatives that the public and equivalently patients are untapped sources of knowledge of the genetic and biological diversity in our natural environments which can be accessed at the collaborative level of crowd-based engagement.

3.2 Research partnerships: training patients to conduct research

Research partnerships is an initiative between Alberta Health Services (AHS) and the Institute for Public Health at the University of Calgary, hoping to train patients and former patients in formal research methods. Once these patients graduate, they assume the role of patient-engagement researcher and join AHS' Strategic Clinical Networks in order to determine how the health system can deliver high-quality, patient-centered care [15]. To date, there are a number of Strategic Clinical Networks focused on specific areas of health: addiction and mental health, bone and joint health, cancer, cardiovascular health and stroke, obesity, diabetes and nutrition and seniors' health. Each network comprises healthcare professionals, researchers, community leaders, patients and policy-makers [15]. Along the same lines, the lead patient methodology currently under development aims to engage patients in the design of drugs that meet patients' needs for holistic therapy – working alongside other non-conventional therapies; addressing end points deemed important to patients; in consideration of side effects manageable by patients and compliance issues as a function of patient lifestyles. As such, patients will be engaged as design partners through research or 'lead user' type programs.

3.3 Co-designing with patients

Design thinking can provide a relevant framework for new drug discovery collaborations. Transparency Life Sciences is harnessing the advantages of co-designing with stakeholders. The Transparency Life Sciences Indication Finder is a tool supporting crowd research to identify promising new indications for drug candidates with previously halted development studies [16]. Compounds and indications are commented on using this tool. Thereafter, the Protocol Builder crowdsourcing platform is used by patients, physicians and other stakeholders to contribute to the design of the company's clinical trials [16]. Patient participation assists researchers in setting the goals of a clinical study. Patients respond via the Protocol Builder providing researchers with a clearer view of expectations of their medications, end points and protocols that fit their lifestyle needs. Consideration of patient preferences and lifestyle needs (hence compliance management) move patients into the informative and collaborative levels of engagement with respect to clinical trial designs.

3.4 Patient communities: patient-centered sources of information

Patient communities may be initiated by patients or by external stakeholders. In the case of patient-initiated communities, online forums and/or blogs, the patient is involved in a self-discovery process as to how best to manage disease conditions and associated symptoms. With the involvement of stakeholders from across the biopharmaceutical value chain, patients are likewise engaged in a process that extends beyond self-discovery to discovery, development, the management of

treatments and conditions. The patient role transitions from that of informative (knowledge sharing) to collaborative (knowledge generation). Wyrwich and Vernon put forward that patient-centered sources of information including blogs and websites can provide meaningful information regarding end points of interest and treatment benefits that are meaningful to patients [17]. Pfizer Link is one such online community and a patient-centric engagement tool for patients who have completed and graduated from a Pfizer clinical trial. Participants are given access to current information on diseases and conditions of interest, including suggestions and tools for disease management, opportunities to participate in future clinical trials, and registries, as well as the summary results from the trial [18]. Exploiting social media, the Get Healthy, Stay Healthy site, enables patients to connect with Pfizer's medical information group and ask questions about diseases, wellness and prevention [18]. While not directed specifically at the drug discovery phase, these information sharing opportunities can provide a wealth of information on patient valuations of treatments – conventional and non-conventional, provide the means to identify 'those lead patients' who may be engaged more directly in drug discovery workshops, as well as how patients engage a variety of stakeholders as part of disease management. Certainly, biopharmaceutical organizations can actively participate in the development of a holistic model of 'health' management – educating beyond diseases, trials and products.

3.5 Focus groups: encouraging patient story-telling and comparative analysis

Focus groups have been employed as a more direct means of informative engagement. Patients may hear other patients' experiences with treatments and disease management providing for comparative analysis or confirmation of similar experiences. Mullin discusses that focus groups have indeed been used to acquire patient-reported outcome measures [19]. In this case, patients report about the status of their health conditions without interpretation by physicians, for example, regarding how patients feel with respect to their conditions and treatment usage. Focus groups generate a pool of patient outcome-related data, notably with regard to symptoms, functions, the impact of disease on activities that are most important to patients and for which improvements are important criteria used in evaluating the effectiveness of treatments [19].

4. Conclusion

The biopharmaceutical industry must better understand what patients' expectations are with respect to health, disease management, when and how patients seek interventions for health/disease management. With the ability to self-monitor symptoms and disease outcomes and with the increased focus on pharma foods to prevent disease and augment health through nutrition, the industry needs to re-assess its strategy of drug design and development in isolation. Clearly, the time has come that patient self-management and wellness preferences be considered as part of new biopharmaceutical drug program development. The fact that co-innovation programs are underway between pharmaceutical organizations and food companies to leverage the movement to prevent disease through a more holistic approach including nutrition is encouraging. What must be ensured is the early and clear voice for the patient during the design stage. Here, the lead patient can serve as the ideal voice.

5. Expert opinion

Lead patient engagement will allow a closer and higher level of engagement with patients prior to disease onset. One-on-one lead patient interviews can be used to assess perception of disease prevention including wellness activities, usage of functional foods and alternative therapies. Patient assessments may be conducted of personal behavioural changes as part of disease management including physician, pharmacist, patient advocacy group or other patient engagement, knowledge sought about disease and treatment options, treatment compliance based on management of key symptoms, functions or activities, side effects and delivery mechanisms. Sponsor-based lead patient workshops can determine unmet medical needs and the effectiveness of current pharmacological and non-pharmacological treatments based on patient treatment assessment parameters. Drug re-design opportunities include: symptom, function or activity management, compliance programs including side-effect management, drug delivery mechanisms to meet patient lifestyles where possible. Wellness, functional food usage and then disease management should collectively be considered by the biopharmaceutical industry in terms of points of healthcare intervention. In the case of Stanford Medicine X, an annual workshop brings together patients and stakeholders including biopharmaceutical organizations to discuss the clinical re-design process. Design challenges and principles of design thinking are leveraged to encourage discussion and establish the necessary social capital to foster collaboration [20].

There are several challenges ahead which can be viewed as opportunities that require consideration including: regulations surrounding patient engagement; seeking out lead patients; the necessary mindset change associated with holistic medicine; re-designing the discovery and development value chain to create patient points of engagement and incorporating technology into the engagement process. In this highly regulatory industry, stakeholders will need evolving guidelines on patient interaction with a nuanced focus on discovery-based engagement. The differentiator here being patient engagement to understand motivators, product usage and treatment expectations versus discussions surrounding specific product pipelines. The patient-centered view of drug discovery will seek an understanding of what matters most to the patients both in their health and disease journeys. This will not entail a view only of end points and disease management,

but how patients seek to maintain their health status and adopt a self-driven prevention attitude. Lead patients may be sought out in online communities and consortia, through patient advocacy groups, and interestingly even through patient innovation communities (patient-innovation.com), where patients are increasingly being encouraged to share innovative solutions designed to manage health and disease conditions. Re-designing the drug discovery and development value for inclusion of the patient will be driven by knowledge sharing and learning alongside the patient (with knowledge articulated for patient comprehension). Value chain re-design will involve assessing the points of interaction, the insight patients can offer along the value chain – be it drug design, drug delivery, clinical trial protocol design, end point selection, disease management and an evaluation of the knowledge-based assets to be exchanged between patients and stakeholders – such as information, materials and experience. Technology itself will be a game changer in terms of patient participation. While clinical trial data collection has been the focus of attention for technological intervention, one can envision the scenario whereby technology can be used to track the collective impact of wellness strategies, nutrition and the use of non-conventional treatments on conventional drug efficacy. ResearchKit is one signal of the impact of technology on patient empowerment, data collection and ultimately personalized treatment design. ResearchKit is an open source platform that can enable patients to track their own health data and potentially discover correlations between symptoms and daily actions such as diet or exercise [21]. Other extensions can permit for patient-driven data collection during clinical trials and then during treatment – potentially revealing correlations between a variety of interventions used (including conventional medications, non-conventional therapies, food, physical activity) to manage symptoms. The data generated will then have to be accepted and incorporated into drug design and portfolio management.

It is no longer sufficient for industry stakeholders to consider that conventional therapies are the sole mechanisms being sought by the patient. Without patient engagement at the highest level possible, that of collaboration (as offered by the lead patient engagement strategy), the industry risks alienating the patient – noting that increased attention is being placed on sustained health and wellness before disease onset. It is hoped that with the patient's voice increasingly recognized that the industry will not only engage the patient, but also envision the paradigm where joint health and disease management are objectives of the biopharmaceutical industry. Patients themselves are searching for greater control and are moving ahead.

Declaration of interest

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending or royalties.

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