



CHAIRMAN'S SUMMARY OF MESSAGES FROM THE OECD WORKSHOP ON KNOWLEDGE MARKETS IN LIFE SCIENCES - WASHINGTON DC, 16-17 NOVEMBER 2008

What are Knowledge Markets?

- KMs are a catch-all term to describe the formal mechanisms and institutions that facilitate access to and use of a wide variety of types of knowledge within the biomedical community. KMs make knowledge available, accessible, usable and sometimes tradable.
- KMs cover a wide variety of types of data, information and knowledge, including: databases, services, knowhow, materials, compounds, software, methodologies, expertise, as well as any other patentable inventions. What is traded is a combination of combination of explicit know-how, physical materials and methods and tacit knowledge.
- What is new is the ease of communication amongst a very broad scope of distributed, virtual and diverse knowledge resources. The sophisticated use of information technologies enables users to flexibly interconnect these resources and to deliver research efficiencies.
- The elements of knowledge within KMs are sometimes, but not always, individually valued or monetised. While there is often a “pay to play” requirement, the individual assets brought to the table may not be explicitly valued.
- KMs are institutions or structures with formalised rules of engagement amongst diverse parties including traditional competitors (*e.g.*, academia, private research organisations, biotech/pharmaceutical firms, regulatory agencies, individuals), which are designed to leverage multiple sources of external knowledge, and are:
 - Research focussed and translational
 - Not necessarily precompetitive (*e.g.*, Innocentive, brokerages)
 - Reliant on digitisation and a networked IT infrastructure to support access/use of knowledge goods
 - Networked and delocalized
 - Not fully “open” or public
 - Characterised by formal or informal norms
 - Often Pay-to-Play
 - Time & purpose limited
 - Both bottom up and top down – one or the other, but not both – in terms of the aims of research outcomes

- KMs include public private partnerships, consortia, innovation networks, brokerage facilities, prize mechanisms (*e.g.*, Innocentive), data sharing/exchange platforms (*e.g.*, caBIG). [They probably do not include TTOs where each transaction is unique or patient information exchange websites where there is no formalized mechanisms for transferring data, information, knowledge for the purpose of improving innovative process, though exceptions include “patients like me” and EHR databases used in research.]
- KMs have so far typically addressed areas where there are collective action problems, the under-provision of goods and services which might have commercial value or provide a public good if disparate knowledge could be pooled from multiple sources and used. Current examples are found in cancer, infectious diseases and biomarkers.

Are KMs becoming more common, more important in biomedical research?

- Biomedical research system is under enormous pressure as it has become far more diverse, has accommodated many new players globally, has distributed its knowledge intensive resources widely, is awash in information, and has become costly to maintain. Biomedical research institutions are under strain and are looking for new ways of working.
- KMs are on the rise throughout health innovation cycle (from precompetitive R&D through to shared methodologies for meeting regulatory requirements). They may be more common in certain disease or issue areas (Infectious Disease, Biomarkers (personalized meds) and cancer), though it is not clear why this is the case.
- The value of knowledge markets mechanisms as responses to pressures on the biomedical research system seems to be universally acknowledged.
- How big a boom this is or will become, and how radical a departure from past exchange practices, remains unclear. It would be important to start measuring what is indeed happening to get a sense of the extent and impact of knowledge markets. Initial work might include surveys of: *a)* numbers and types of KMs; *b)* number of partners; *c)* funds invested; *d)* citation data; and *e)* resultant products/services. More prospective work on types of indicators that could be developed is necessary.

What are the motivations and incentives for firm and research organisation participation?

Motivations for participation vary by type of actor (firms, PROs, individual researchers, academia) but include:

- Reductions of transaction costs, research costs, duplication
- Risk sharing
- Place to address lacunas and/or unmet needs (*e.g.*, shared novel methodologies, novel datasets such as compound libraries).
- Public Acceptance
- Prestige
- Intellectual challenge
- Norms and peer pressure
- Regulatory approval co-evolution
- Safe haven experimentation with new (more open or networked) research strategies and business models

What are the elements necessary to establish KMs?

- Agreement by all parties to a common set of goals
- Clear public benefit
- Balanced participation agreed at high level
- Articulated goal of being more efficient
- Policies and governance structures set up in advance which address:
 - IPRs
 - Privacy/Confidentiality
 - Human subjects
 - Access

What are the challenges in the establishment of KMs?

- Long term sustainable funding (for establishment and maintenance)
- IPRs
- Privacy/confidentiality, tiered access
- Anti-trust
- Liability
- Logistics and operations
- Infrastructures
- Quality control

Do we understand (and can we begin to measure) the benefits that accrue from KMs?

Experts at the Workshop identified a number of benefits which accrue from participation in Knowledge Markets including for:

a) Scientific advance

- Interdisciplinary collaboration, silo break down: bring new approaches, disciplines and modes of work to bear on particular problems
- Tap into broader, global research community
- Data mining
- Close loop between clinicians and researchers

b) Research efficiency and knowledge management

- Efficiency benefits by getting more use from knowledge and more people involved in research
- Increases collaboration between parties – especially needed to tackle new diseases and treatment paradigms
- Facilitates incremental (and distributed/networked/hived) innovation
- Increases the flow of information (access, flow, management)
- Formalises rules of engagement
- Creates trust
- Creates feedback loops of information with users and clinicians (regarding needs, evaluation)
- Allows learning about how to bring research to market more efficiently

c) Public health benefits

- Increases evidence-based treatment options (predicting therapeutic response population)
- Improves transparency of health information
- Accelerates shift to personalised medicine
- Encourages early adoption of treatments
- Catalyses investment in identified public health need

d) Regulatory – Industry dialogue:

- Tackles challenge of personalised meds and targeted therapies (*i.e.*, how they will be developed and delivered)
- Improves biomarker validation and paves way for regulatory acceptance
- Tackles next generation clinical trial design
- Creates safe haven for new approaches to knowledge sharing and risk sharing (if anti-trust issues are addressed)
- Help establish stable, predictable, transparent regulatory pathways
- There is a good deal of work to be done, however, to document that such benefits actually do accrue. Moreover, there may need to be work on measures of success for individual knowledge markets and on where and how Knowledge Markets work well.

The government interest in KMs

Numerous different reasons for government interest in Knowledge Markets emerged from workshop discussions ranging related to health policy, research policy, industrial policy, and intellectual property rights policy. These included mention of the need to:

- Push biomedical research into 21st Century – toward a more evidence and data based, predictive science
- Ensure research infrastructure development and sustainability
- Disseminate publicly funded research results
- Improve technology transfer
- Plug into international research networks
- Biomedical cluster/industrial policy
- Define acceptable patenting/licensing behaviour of public sector research organisation
- Address health care product productivity slump
- Reduce attrition rates especially in late stage research
- Meet health care needs of population and improve outcomes
- Boost delivery and access to new health products
- Reduce health care costs
- Improve consumer information and health care choice

Impacts on industry and business models for health delivery – where do KMs take us?

- Capitalism is based on an extensive division of labour and increasingly specialized, complex industry organization. However, there is a sense that the division of labour, and the hand-off of knowledge intensive goods and services between the different actors in the value chain, is not working well in the health biotechnology and pharmaceutical sector.
- While there is uncertainty and disagreement about what the ideal industry structure to foster biomedical innovation might be, there is strong evidence that partnerships and networking help address need for risk reduction and cost sharing.

1. Do Knowledge Markets enable new business models to develop?

- Knowledge markets do enable experimentation with new business models and there are numerous examples to date of what these models include.
 - Innocentive, which provides a model of “hive” pharmaceutical development
 - Increased pharmaceutical firm outsourcing of knowledge through virtual networks
 - New approaches to clinical trial design and regulatory approvals which could:
 - Facilitate the emergence of personalised meds
 - Service small markets (orphan drugs, neglected diseases)
- There was some concern, however, that a proliferation of Knowledge Markets might not simply increase the flow of knowledge amongst actors but perversely make coordination amongst such groupings more complicated.

2. Does financial pressure for better valuation impact knowledge management strategies?

- Intellectual Asset reporting is in its infancy, in the long term it could help innovative firms distinguish themselves as good investment opportunities and thus capture more capital.
- In the short term, voluntary intellectual asset reporting helps management understand its own intellectual asset strengths and communicate those externally.
- Investors – both VCs and institutional investors – do not consider long term pay offs from intellectual assets, as their time horizon are short in comparison with the business cycle of the biopharma sector. Moreover, most investors take a portfolio approach which mitigates the need to collect individual data.
- Financial pressures do not yet play a major role in firm decisions to enter into KMs.
- Securitised portfolios of late stage clinical trials from Phase II onwards offer another potential source of capital for biomedical firms. In this model a large number of projects from participating firms are bundled together in a portfolio into which investors inject a one-off large capital investment, raised from fixed income investors (bond holders), and in exchange for guaranteed income over course of a long time period.

3. What elements might encourage a greater use of Knowledge Markets?

- For knowledge markets to become more common than now the case, new infrastructures will likely need to be put in place.
- Part of the solution will be information technology and software based. Interorganizational information systems – or electronic marketplaces – allow buyers and sellers to exchange

information about prices and product offerings. For this to happen, advances are still needed in order to be able to represent knowledge objects in electronic market places so that they can be brokered and traded. The information

- Improved methodologies for the valuation of knowledge intensive intellectual assets – or knowledge objects – would also facilitate the emergence of knowledge markets. Brokerages, prizes and firms that provide outsourced knowledge intensive products and services already exist. They help put a value to knowledge intensive intellectual assets. It is quite possible these sorts of business models will become more common.
- Still in development are the idea of warehouses or safe brokerage services which act as intermediaries between buyers and sellers. Their function would be to be a trusted broker that maintains the confidentiality of their clients' knowledge intensive assets while providing enough information to potential buyers so as to price and trade the assets. Such services would independently value knowledge intensive assets, help potential sellers evaluate the opportunity costs of keeping a knowledge intensive asset in house, and make available select information about these assets to potential buyers so that they can be traded.

Knowledge Markets Policy Issues

Experts and government representatives discussed the role that governments should have in providing a supportive environment for the emergence of Knowledge Markets. They asked what infrastructures – scientific, informational, educational, regulatory, legal – are necessary and what policies or incentives might encourage experimentation with Knowledge Markets?

Infrastructure building and support and science policy

- In the life sciences, governments have a strong policy interest in developing and making accessible data, information, and knowledge, and in maintaining those scientific resources over the long term.
- Governments should support the creation of KMs. They are often key players in the formation of KMs, a source of financial support, as well as knowledge providers themselves.
- In areas where there is a strong public policy interest, governments can play a catalytic role in bringing diverse parties to the table to discuss new knowledge exchange and formation mechanisms. But there is a need to clearly identify the incentives driving participation in knowledge markets.
- Examples of areas which might be amenable to Knowledge Markets included biomarker identification and validation (on larger scale than now), shared compound libraries, and antibiotics R&D.
- A framework to help policymakers involved in the establishment and governance of knowledge markets would be very helpful – it could address the elements necessary for Knowledge Markets to work and some of the challenges that they may encounter. While descriptions of different KMs are useful in establishing a typology, governments expressed the need for practical tools and approaches to issues like: IP management, access rules, data and information sharing, privacy and confidentiality, funding, anti-trust, infrastructures.
- IT infrastructures are the backbone that allow the networking of disparate databases and repositories. Participants noted that it was important for such infrastructures in the life sciences to be sustainably funded and to stay “technology neutral” so that systems are adaptable and don't limit the future scope of research or collaborations.

Intellectual property

- Intellectual property rights play an integral role in knowledge markets. They help structure the rules of engagement and the expectations of different participants. While the management of IPRs is a serious consideration in establishing knowledge markets, it is not an insurmountable barrier.
- There are difficulties inherent in evaluating the worth of intellectual assets. Experts noted that it would be interesting to know if there were systematic barriers to scientific collaborations that emerge from difficulty of evaluating the value of IAs. A better understanding of emerging strategies and models for valuing knowledge intensive assets in the health sector is necessary to grasp the impact Knowledge Markets will have on this sector.
- Publicly funded research organizations are often the least amenable to negotiating broad access to their IPRs. Many of the “problematic” patent access cases were patents that originated in universities. Experts noted the need for government policies *vis-à-vis* research organizations and grantees with regard to how to encourage more sharing and access to publicly funded research outcomes in early stages of research, and suggested this will be helpful for the development of Knowledge Markets.
- In particular, governments were interested in whether general frameworks, models or guidelines for IP management of publicly funded research could help with KM formation.
- There seems to be a shift occurring in the definition of what is deemed precompetitive versus proprietary research results which is affecting the nature of scientific collaborations. Understanding where the line is drawn, what should go into the public domain and any trends was seen as important to elucidate.
- The protection of databases and their impact on access was briefly discussed. One question raised was how can the government influence access when open source models are used, as is often the case in bioinformatics? And how can government identify what intellectual assets it even owns in open source models of collaboration?

Knowledge market models and knowledge management

- Knowledge markets are organizational structures that enable exchange of data, information, knowhow and inventions. The exchange may or may not be monetized. There was some discussion as to what markets are and whether the term “knowledge markets” captures the essence of the mechanisms under consideration and whether “exchanges” would be a more accurate or evocative term.
- The term Knowledge Markets is relatively new, especially as applied to the life sciences. A typology of the different sorts of mechanisms and institutions will be helpful to better disseminate what is meant by this concept. However, work will also be necessary to begin to measure their extent, how work, where they work and eventually their impact on innovation.
- Prizes and matchmaking services like Innocentive are novel ways of accessing external knowledge. Experts were interested in knowing how and where such services could be expanded.
- Knowledge markets are, essentially, mechanisms that enable knowledge management across firms and research organizations. It would be useful to understand how knowledge management strategies are evolving and how knowledge markets fit into those strategies. In short, what is the interrelationship between any new approaches to firm knowledge management and knowledge markets?

Industrial, innovation and regulatory policy

- There was a good deal of interest in the future organizational structure of the health biotechnology and pharmaceutical industry. Some see the rise of outsourcing and services like Innocentive as part of the move away from fully integrated pharmaceutical companies to a more networked pharmaceutical industry ecology. Others thought, on the contrary, that the complexity and difficult capital investment decisions in the health sector portend well for a return to a more vertically integrated structure.
- What are the range of potential business models in the health sector? What are some of the innovation benefits of a more networked or “hive” approach to product development (which, for example, might allow a greater number of innovators to participate and include health care providers in the process). What might drive a return to integration and what will be the impact on innovation in health? What models will deliver incremental innovations? Finally, how do knowledge markets fit with these two business models?
- National competitiveness in science and technology intensive industries remains a central priority for governments, especially given that firms from the emerging economies are beginning to be competitive in the life sciences. What is the scientific or industrial policy rationale for the support of knowledge markets? Are there local returns to participation in the knowledge markets, or are these widely distributed (and if the latter, what is the motivation for government investment in their creation)? Will national competitiveness consideration impact the governance frameworks of KMs?
- Similarly, as Knowledge Markets become more common, it was deemed important to pay attention to broader access and equity issues. Are they indeed open to participants from a wide variety of countries? Do they help or hinder the flow of knowledge across borders? How do lesser developed countries tap into these structures?200
- Regulations can have an impact on the incentives to participate in knowledge markets. There is a need to reduce bureaucracy and red tape, to make sure conflict of interest rules are reasonable.
- Knowledge markets, such as the Biomarker Consortium and the C-Path Institute Predictive Testing Consortium, provide a safe haven for industry-government experimentation with new approaches and methodologies for regulatory approvals. Are there further examples of how knowledge markets are being used to share knowledge and reduce costs and risks of the regulatory process. Do they help create new methods or understanding of how to value technologies? How could KMs be expanded for such purposes?
- Knowledge markets might be helped and hindered by anti-trust legislation. Where does anti-trust legislation impact knowledge market formation and governance? The nature of the impact of anti-trust considerations could be the subject of further study.
- Further work on intellectual capital reporting and developing international standards for such reporting was seen as useful.

Health systems

- How do knowledge markets address global – or local – health challenges, as is done in public private partnerships? How is distributed knowledge harnessed through knowledge markets to address specific public health challenges – for example, AIDS and TB in South Africa? Can this model be expanded?
- Can knowledge markets indeed accelerate the shift to personalized medicines? Do they reduce the costs associated with either research or regulatory approvals and thus make it possible for firms to develop products and services for smaller markets, as in orphan drugs, personalized medicine, or diseases of the developing world?
- Will the networking of health and biological data sources, as planned in integrated structures such as CaBIG or the BC Cancer Agency increase the evidence base for efficacy and provide more information to clinicians about treatment options? How and where will knowledge markets have an impact on transparency and availability of clinically useful health information?
- Do knowledge markets have any impact on the ability of health systems to take up new health technologies? Do they improve the innovation cycle by making it a more integrated bench to bedside system? Which sorts of Knowledge Markets have health care providers as an element integrated in their structure? Is there any evidence that inclusion of users encourages early adoption of treatments?