Response to the Open Data Consultation

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Bringing medicines to *life*

ABPI response to the Open Data consultation

The ABPI represents innovative research-based biopharmaceutical companies, both large and small, leading an exciting new era of biosciences in the UK.

Our industry, a major contributor to the UK economy, brings life-saving and life-enhancing medicines to patients. Our members supply 80 per cent of all medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients to prevent and overcome diseases.

Working with our Research Affiliate Members, leaders in pharmaceutical R&D, is vital in promoting the UK as a destination of choice for international life sciences investment.

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Summary

The pharmaceutical sector contributes over £7 billion in trade surplus to the UK every year. However, an increasingly competitive clinical trials and commercial environment is making the UK a challenging place in which to invest. The Government is undertaking a number of initiatives to help support this sector, which are welcomed by the research-based pharmaceutical industry. The better availability of useful, quality data will be an important element of this support and will signal to the global industry that the UK is serious about improving the business environment for life sciences.

The UK has a unique offering in the NHS. The pharmaceutical industry invests £4.5 billion per year in research and development (R&D) in the UK. Encouraging more R&D may help to bring more direct investment, including associated research grants and help for the current investment to be targeted in a more effective way. Exploiting the data created by the NHS would allow better targeted research and decision-making for industry, which is ultimately likely to make the UK a more competitive place in which to invest.

Improved access to data can facilitate a raft of additional benefits, including:

- Providing data on the success of Government policy, to allow better understanding of where initiatives are working.
- Improved health outcomes as research is more targeted, helping to meet unmet need and to expedite improved medical care.
- A stronger return on public investment as patient care provides a fringe benefit of supplying data.
- Improved patient access to treatments as prescribing data is used to improve the efficacy and quality of healthcare delivery.
- Improved safety and effectiveness as more is learnt about the use of medicines and patient care in real world settings.
- Driving trust among the public in scientific research and the health service, as well as improving levels of trust among healthcare practitioners, academics and the life sciences industry.

While there are significant opportunities to be gained from Open Data, there are also a number of important caveats that must be considered as this agenda progresses. It will be important to consider the following caveats:

- It will be essential to distinguish between data that is commercial-in-confidence, and that which is not, in deciding which data should be made open and when.
- Commercial contracts that ensure the NHS and the public receive value for money from suppliers of goods and services should not be subject to Open Data if non-disclosure has already been agreed.
- It will be important to ensure that the ownership and origin of data are taken into account before opening datasets that would potentially compromise commercial interests (eg UK PharmaScan data, PPRS-related data, patient access schemes).

- There needs to be a commitment to and investment in providing good quality, accurate, clean data, as it is not necessarily the case that making data open incentivises improvements in the quality of that data.
- The agencies collecting the data need to understand the data's value and their use to support economic growth.

The ABPI welcomes proposals to examine how access to data could be opened up, and makes the following key recommendations:

1. The Government should commit to investing in providing good quality, accurate, clean data, as it is not necessarily the case that making data open incentivises improvements in the quality of that data. The agencies collecting the data need to understand the data's value and their use to support economic growth.

2. The Government should prioritise data provision that would result in direct or indirect growth in the commercial sector's investments over that which would not.

3. Analysis and interpretation of dataset skills are diminishing in the UK. The Government should invest in the training and retention of skilled people who will be able to analyse Open Data.

4. There is huge potential for the use of data collected outside the constraints of conventional randomised clinical trials to evaluate what is happening in normal clinical practice – i.e. Real World data. To realise the benefits of this area, the regulation and governance of Real World data could be improved, particularly with a view to understanding how these data will be used.

5. Access to Electronic Health Records across a wide range of functions, as well as access to timely, quality data, is essential for the development of effective and well-tolerated medicines that meet a patient's needs and provide value to the healthcare systems caring for those patients. This will complement proposals suggested by the ABPI in response to the Autumn Package for Life Sciences and the Chief Executive Review of Innovation in the NHS.

The six opportunities of Open Data – the ABPI response

Accountability

Improving transparency and allowing greater access to data will help drive accountability and improve trust in the services that are being provided. One aspect of this would be in the use of medicines within the NHS, an issue that is a focus of the NHS Chief Executive Innovation Review. More accurate and available data on the treatments made available to patients would ensure better accountability to patients and allow greater understanding of systems in the NHS.

Similarly, the collection and reporting of data on the clinical trials being conducted in the UK is vital for tracking progress to see if the comprehensive set of actions put in place by the Government to

improve the clinical research environment are having the desired effect – retention of business and attracting new investment.

There are key deficiencies in data collection and presentation systems in the UK, and difficulty in collecting a coherent set of data across the NHS which is clear, easy to understand, and which can be used consistently across many stakeholders to detail the number of research studies running in the UK in any given year. The provision of clear, easy-to-understand data will also facilitate the tracking of performance trends.

Opportunities to improve accountability include:

NIHR Clinical Research Networks: To attract investment from industry, the investment the Government has made in the National Institute for Health Research (NIHR) Clinical Research Networks and infrastructure in England needs to show demonstrable improvement in metrics in order to attract investment, along with consequences - such as loss of funding when targets, such as the 70 days target set in the Plan for Growth, are not met.

The UK has robust data on the number of Clinical Trial applications via Medicines and Healthcare Products Regulatory Agency (MHRA) data but not on the number of trials that are actually conducted following application approval. We also do not have a comprehensive picture of start-up times or performance (delivery to time and target) for all commercial trials conducted in the UK, including those using the NIHR Clinical Research Networks.

Enabling database holders to improve accountability: However, we believe a timely opportunity exists that may enable database holders (such as MHRA, National Research Ethics Service (NRES), NIHR, the new Health Research Authority (HRA), and others) to address this. The following are suggestions for how this might be achieved:

1. Use of IRAS (Integrated Research Application System) as a capture point and data repository for determining when a trial in the UK has been initiated.
    a. MHRA, NRES & European Union (EU) competent authority data only demonstrate the number of applications submitted or approved by the regulatory bodies, not the number of trials actually conducted.
    b. Modification of IRAS to include a tick box, which the sponsor representative returns to complete within a specified period of gaining approvals, to register that the trial / study has been initiated.

2. Consistent collection of data and reporting periods by all the organisations affiliated to the new Health Research Authority, i.e. NRES, MHRA etc., so that they can collect data and report in the same time period – e.g. January to December or April to March.

3. The Development of a map or catalogue of research active sites across the whole of the UK, and its use as a centrally-updated resource to demonstrate and track the number of research active sites in the UK annually.

4. Extension of Coordinated System for gaining NHS Permissions (CSP) or similar to encompass all research in England / UK, not just NIHR portfolio studies, in order to get a full picture of research undertaken by commercial sponsors in the UK.

The lack of cohesive systems for tracking data was highlighted by the Academy of Medical Sciences (AMS) in its review of Regulations and Governance of Medical Research. The AMS made a number of relevant recommendations, specifically 2, 3 and 17[1], that key metrics and indicators of research activity should be developed by the proposed new HRA, in consultation with stakeholders.

Choice

Open Data will give the pharmaceutical industry improved choice of NHS service providers for conducting clinical trials. Open Data and transparency of trial set-up times and costs will drive choice of NHS Trusts with which to partner in research projects, like Real World data and outcomes studies; or in which to sponsor clinical research. Likewise, public reporting will drive productivity – delivery of trials to time and target – with honourable competition between public services, such as NHS Trusts.

Productivity

The ABPI is supportive of the publication of comparative data and metrics relating to medicines uptake across different part of the NHS. The sharing of peer-to-peer comparative evidence at different organisational levels of the NHS (eg PCT, Cancer Network, and SHA level) has been shown to be effective in driving behavioural change towards more appropriate and quality prescribing of innovative medicines.

A service catalogue of the datasets that will be available, including dates when the datasets will be made live publicly, would be welcomed. The UK Data Archive needs to be fit for purpose with the capability of providing data responses quickly, in order to facilitate business.

Quality and Outcomes

As more data becomes available, the Government will need to commit to investing in public services where the data shows that these services are failing to deliver.

Making data open does not automatically ensure that the data made available is of a high quality. The provision of good quality, accurate, clean data will provide the most benefit. It will be important that the agencies responsible for collecting the data have a full understanding of the value of the data and their use to support economic growth.

Social Growth

Availability of Open Data can create a platform for more informed public debate on the value of medicines and the development of new practices in the NHS. As more data becomes available, and more sophisticated methods of linking data develop to look at health outcomes, there will be savings delivered on services and also better use of services, which leads to both social and economic growth. Providing the public with data they can use will transform the demand for, and availability of, services they can use.

[1] 'A new pathway for the regulation and governance of health research' available at http://www.acmedsci.ac.uk/p99puid209.html

The use of data by local NHS customers to help them understand their use of medicines or services, and to identify which medical interventions work and which patients benefit most from particular medicines or services, will drive better use of resources in the UK.

Economic Growth

A stronger pharmaceutical industry is good for the UK economy. Investment by the pharmaceutical industry will be encouraged by demonstrating the productivity and accountability of public services, such as increased trial numbers and increased recruitment of participants in research.

The pharmaceutical industry already invests £4.5 billion per year in research and development in the UK. Encouraging more R&D may help to bring more direct investment, including associated research grants.

Informatics skills: It is important to recognise that informatics skills – analysis and interpretation of datasets – are diminishing in the UK, and that there is an opportunity for growth in the employment sector driven by a need to invest in the training and retention of skilled people who will be able to analyse Open Data.

Real World data: There is huge potential for the use of data collected outside the constraints of conventional randomised clinical trials to evaluate what is happening in normal clinical practice – ie Real World data. The regulation and governance of Real World data and observational studies needs to be improved, with a clear understanding of how the data will be used, to ensure that the UK does not revisit the situation experienced in clinical trial governance, where there is a decline in investment due to the slow pace of acquiring governance approvals.

Electronic Health Records: The industry currently uses electronic health record (EHR) information across a wide range of functions. Access to timely, quality data can help to make significant advances in patient care as it allows more to be learnt about medicines and prescribing habits, and to enhance Real World data.

The use of EHR for observational study designs such as epidemiological studies offers opportunities to study medicines and disease in larger 'real world' populations, over longer periods in real life settings: these data in particular are of great interest to health technology assessment agencies, and local healthcare providers. Anonymised longitudinal patient data can be used to:

- Assess unmet medical need and medicine development opportunities
- Improve disease understanding – incidence, prevalence, disease progression, risk factors for disease development and progression, trends over time, relationships between diseases, healthcare resource use, patient care pathways, referral patterns, and managing multiple co-morbidities – through population-based observational studies within a real-world setting for improved healthcare delivery and deciding education / health policy priorities
- Enhance the efficiency of clinical trials – protocol development, site and investigator selection, and patient recruitment
- Conduct observational and epidemiology studies within normal clinical settings.

The ABPI has produced a White Paper, *The Vision for Real World Data – Harnessing the Opportunities in the UK*, which goes into more detail on the potential for economic growth relating

to the use of these data. The White Paper can be accessed via this link: http://www.abpi.org.uk/our-work/library/industry/Documents/Vision-for-Real-World-Data.pdf

Research Capability Programme: Industry has been working with Government over a number of years on the use of eHealth data and the development of more comprehensive eHealth records. To date, progress has been made through the Research Capability Programme's (RCP)[2] Health Research Support Service (HRSS) in building processes for anonymisation, confidentiality and privacy. Some enhanced data linkages have also been established. However, industry's involvement in the HRSS pilot programmes was suspended following the Spending Review in 2010. This has diminished the ability of industry partners to communicate their needs and to review or shape the services HRSS may offer. In the meantime, ABPI has produced a paper detailing industry requirements for eHealth research in the UK (see Appendix 1).

In addition, industry and other stakeholders are currently awaiting an announcement from the Department of Health on the future of the RCP. Most recently, the Government's Plan for Growth committed to building a consensus on using eHealth record data to create a unique position for the UK in health research. However, since the commitment was made, there has been no specific update on activities, development or implementation.

It is therefore important that the Government clarifies both the way forward on the Research Capability Programme and on the 'secure data service', including the vision for e-health records and the expected timeline. This would ensure that industry and other stakeholders understand what the UK will offer and by when, as well as when they will have the opportunity to provide details of their research requirements for a UK e-health system.

Consultation questions

Glossary of key terms

1. **Do the definitions of the key terms go far enough or too far?**

Dataset: Factual data, structured or unstructured. In relation to public services, these data will typically have been collected as a by-product of delivery. This includes, for example, key public datasets about public services; user satisfaction data; and the performance of providers. For non-government bodies providing public services, information about aspects unrelated to the delivery of their public service function are not in scope.

Information: Interpretation and analysis of data that, when presented in context, represents added value, message or meaning.

Open Data: Data which can be freely used, re-used and redistributed by anyone. In relation to public services, Open Data means data available under the terms of the Open Government Licence. The presumption is that data about public services will be Open Data. It may be that some data held in relation to public services is made 'available', but is charged for.

[2] http://www.nihr.ac.uk/systems/Pages/Research_Capability_Programme.aspx

Public Services: Public services are either provided by public bodies, or providers who have been funded, commissioned or established by statute to provide a service. In this document, we will refer to both these groups as 'public bodies' and 'public service providers', or 'providers' for brevity.

It will be very important to ensure that the ownership and origin of data are taken into account before opening datasets that would potentially compromise commercial interests (eg UK PharmaScan data, PPRS-related data, patient access schemes).

2. **Where a decision is being taken whether to make a dataset open, what tests should be applied?**

Similar tests applied to data provided under the Freedom of Information (FOI) Act responses would need to apply. It would also be good practice to let ABPI and / or individual companies know of any specific requests that would set a precedent, for example where interested parties could help in data analysis. where potential data analysis would be required where the interested parties could contribute in interpreting data.

3. **If the costs to publish or release data are not judged to represent value for money, to what extent should the requestor be required to pay for public services data, and under what circumstances?**

There is often a cost in putting a system in place that automates the opening of datasets. It would be unfair to expect this service to be paid for by one organisation, if it is then accessed for free by other companies in the future. Similarly, it would be unfair to charge businesses the same high amounts for data that become costless to produce. Initial set-up costs should be seen as investment for future growth and therefore paid for by the Government, as opposed to silo-budgeting for the provider of data.

4. **How do we get the right balance in relation to the range of organisations (providers of public services) our policy proposals apply to? What threshold would be appropriate to determine the range of public services in scope and what key criteria should inform this?**

Data provision which would result in direct or indirect growth in the commercial sector's investments should be prioritised over that which would not. For example pseudo-anonymised patient records would be very valuable for Real World data studies and general research purposes (for example, unmet needs).

5. **What would be appropriate mechanisms to encourage or ensure publication of data by public service providers?**

Publication schedules under the FOI can prove very useful. There should also be a way to submit proposals or business cases with a view to generating further datasets.

Main questions

1. **An enhanced right to data: how do we establish stronger rights for individuals, businesses and other actors to obtain, use and re-use data from public service providers?**

We can enhance the rights to obtain, use and re-use data from public-service providers by establishing a clear framework which sets out:

- The way information can be made available, including the process by which information should be obtained and the format it will be made available in, eg Microsoft Excel
- The type of information available and what is not available
- The cost involved.

The framework for the Freedom of Information Act requests could be used to model this framework for data. This way companies will be contacted to highlight requests and give them a chance to discuss the impact of releasing specific pieces of information.

1.1 How would we establish a stronger presumption in favour of publication than that which currently exists?

There should not be any presumption that datasets should be made available when there have not been any precedents, without discussing with the business sector or individual companies that would potentially be affected by the proposed publication.

1.2. Is providing an independent body, such as the Information Commissioner, with enhanced powers and scope the most effective option for safeguarding a right to access and a right to data?

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1.3. Are existing safeguards to protect personal data and privacy measures adequate to regulate the Open Data agenda?

Beyond the right to data, it may sometimes be advisable to investigate potential unintended consequences with the relevant business sector or companies.

1.4. What might the resource implications of an enhanced right to data be for those bodies within its scope? How do we ensure that any additional burden is proportionate to this aim?

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1.5. How will we ensure that Open Data standards are embedded in new ICT contracts?

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2. Setting transparency standards: what would standards that enforce this right to data among public authorities look like?

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2.1. What is the best way to achieve compliance on high and common standards to allow usability and interoperability?

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2.2. Is there a role for government to establish consistent standards for collecting user experience across public services?

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2.3. Should we consider a scheme for accreditation of information intermediaries, and if so how might that best work?

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3. **Corporate and personal responsibility: how would public service providers be held to account for delivering Open Data through a clear governance and leadership framework at political, organisational and individual level?**

As mentioned in the body of our response, the collection of data needs to be done in a consistent way. Suggestions for how this might be achieved are below:

a. Use of IRAS (Integrated Research Application System) as a capture point and data repository for determining when a trial in the UK has been initiated.

   i. MHRA, NRES & EU competent authority data only demonstrate the number of applications submitted or approved by the regulatory bodies, not the number of trials actually conducted

   ii. Modification of IRAS to include a tick box, which the sponsor representative returns to complete within a specified period of gaining approvals, to register that the trial / study has been initiated.

b. Consistent collection of data and reporting periods by all the organisations affiliated to the new Health Research Authority, ie NRES, MHRA etc., so that they collect data and report in the same time period - eg January to December or April to March.

c. Development of a map / catalogue of research active sites across the whole of the UK, and its use as a centrally-updated resource to demonstrate and track the number of research active sites in the UK annually.

d. Extension of CSP or similar to encompass all research in England / UK, not just NIHR portfolio studies, in order to get a full picture of research undertaken by commercial sponsors in the UK.

The lack of cohesive systems for tracking data was highlighted by the AMS in its review of Regulations and Governance of Medical Research. The AMS made a number of relevant recommendations, specifically 2, 3 and 17, that key metrics and indicators of research activity should be developed by the proposed new HRA, in consultation with stakeholders.

3.1. How would we ensure that public service providers in their day-to-day decision-making honour a commitment to Open Data, while respecting privacy and security considerations?

A framework should be made available to public service providers to hep them plan for opening data sets as well as to provide them with the incentives and sanctions for implementing this policy.

3.2. What could personal responsibility at Board-level do to ensure the right to data is being met include? Should the same person be responsible for ensuring that personal data is properly protected and that privacy issues are met?

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3.3. Would we need to have a sanctions framework to enforce a right to data?

If the data has been identified as being 'open', a sanction framework will be useful for assurances that access to this data is made and / or for justifications as to the reasons why the data cannot be made available, and when it will become available, should the issue be around timing.

3.4. What sectors would benefit from having a dedicated Sector Transparency Board?

As raised throughout this submission, there are a number of issues that need to be considered in the release of data, such as whether it is commercial-in-confidence, or any sensitivities around timing. A dedicated sector Transparency Board that understands the particular issues for the pharmaceutical industry could manage these sensitivities. Concerns around the release of health data may be alleviated through the work of a Sector Transparency Board.

4. Meaningful Open Data: how should we ensure collection and publication of the most useful data, through an approach enabling public service providers to understand the value of the data they hold and helps the public at large know what data is collected?

It would be useful to hold specific discussions on specific topics with stakeholders. For example, in clinical research, it would be useful to have a group representative of the different stakeholders involved in clinical trials to discuss and decide on the framework for collecting and sharing relevant data.

4.1. How should public services make use of data inventories? What is the optimal way to develop and operate this?

It would prove very useful to have a data inventory searchable using an advanced search facility. Under FOI, some public services providers publish a publication schedule to inform users as to when to expect updates (eg, the NHS information centre guide to information[3]). This would also be very useful in this context.

4.2. How should data be prioritised for inclusion in an inventory? How is value to be established?

Data provision that would result in direct or indirect growth in commercial sector's investments should be prioritised over that which would not. For example pseudo-anonymised patient records would be very valuable for Real World data studies and general research purposes (for example, unmet needs).

4.3. In what areas would you expect government to collect and publish data routinely?

There is huge potential for the use of data collected outside the constraints of conventional randomised clinical trials to evaluate what is happening in normal clinical practice – ie Real World data. The regulation and governance of Real World data and observational studies needs to be improved, with a clear understanding of how the data will be used, to ensure that the UK does not revisit the situation experienced with clinical trial governance, where there is a decline in investment due to the slow pace of acquiring governance approvals.

[3] http://www.ic.nhs.uk/data-protection/freedom-of-information-foi/guide-to-information

The industry currently uses electronic health record (EHR) information across a wide range of functions, as access to timely, quality data is essential for the development of effective and well-tolerated medicines that meet patients' needs and provide value to the healthcare systems caring for those patients.

The use of EHR for observational study designs such as epidemiological studies offer opportunities to study medicines and disease in larger 'real world' populations, over longer periods in real life settings: these data in particular are of great interest to health technology assessment agencies, and local healthcare providers. Anonymised longitudinal patient data can be used to:

- Assess unmet medical need and medicine development opportunities
- Improve disease understanding – incidence, prevalence, disease progression, risk factors for disease development and progression, trends over time, relationships between diseases, healthcare resource use, patient care pathways, referral patterns, and managing multiple co-morbidities – through population-based observational studies within a real-world setting for improved healthcare delivery and setting education / health policy priorities
- Enhance the efficiency of clinical trials – protocol development, site and investigator selection, and patient recruitment
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The ABPI has produced a White Paper, *The Vision for Real World Data – Harnessing the Opportunities in the UK*, which goes into more detail on the potential for economic growth relating to the use of these data. The White Paper can be accessed via this link: http://www.abpi.org.uk/our-work/library/industry/Documents/Vision-for-Real-World-Data.pdf

4.4. What data is collected 'unnecessarily'? How should these datasets be identified? Should collection be stopped?

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4.5. Should the data that government releases always be of high quality? How do we define quality? To what extent should public service providers 'polish' the data they publish if at all?

Many data do not get published for fear of not being 100 per cent accurate. Data should be published as early as possible with caveats as to why specific pieces of information might not robust at the time of initial publication and how this may result in changes at a later stage.

5. Government sets the example: in what ways could we make the internal workings of government and the public sector as open as possible?

5.1. How should government approach the release of existing data for policy and research purposes: should this be held in a central portal or held on departmental portals?

A central portal would be more helpful than a series of portals, particularly if data held in different locations were to be compared. This would help both with access to the data and consistency in the way data is held, presented and analysed. It is also very important to consider how users will

manipulate the data. Databases that can only be interrogated in certain ways online have proved to be of limited value.

5.2 What factors should inform prioritisation of datasets for publication, at national, local or sector level?

The prioritisation of datasets for publication should be decided by the proportionate growth of the sector that would benefit from the use of the datasets, as well as the links to innovation leading to potential improvements in health.

5.3. What is more important: for government to prioritise publishing a broader set of data, or existing data at a more detailed level?

More detailed data on specific information that can be easily downloaded and analysed is likely to prove valuable for the pharmaceutical industry.

A broader set of data would be useful to provide a starting point for discussion with stakeholders as to how the data can be improved in the future.

6. Innovation with Open Data: to what extent is there a role for government to stimulate enterprise and market making in the use of open data?

If the Government plans to invest in making use of Open Data it would be advisable also to communicate this to companies so that the opportunities are understood by industry. The UK Trade and Investment (UKTI) could take a central role in communicating this.

6.1. Is there a role for government to stimulate innovation in the use of Open Data? If so, what is the best way to achieve this?

'Real World data', defined as data collected outside the controlled constraints of conventional randomised clinical trials to evaluate what is happening in normal clinical practice, presents a unique proposition to encourage the investment, innovation and use of skills brought by the pharmaceutical industry in the UK. The investment in studies that demonstrate the value of medicines and aid the development of new practices in the NHS yields many benefits. It maximises the use of resources, benefits patients and their compliance with taking their medicines, and facilitates collaboration between the pharmaceutical industry, academic researchers and clinicians.

Appendix 1

Executive Summary - *'The Vision for Real World Data – Harnessing the Opportunities in the UK: Demonstrating Value with Real World Data* – September 2011

Executive Summary[4]

'Real World data' has been defined, for the purposes of this document, as: data that are collected outside the controlled constraints of conventional randomised clinical trials to evaluate what is happening in normal clinical practice.

• The conduct of Real World (RW) studies presents a unique proposition to encourage the investment, innovation and the use of skills brought by the pharmaceutical industry in the UK. The investment in studies that demonstrate the value of medicines and aid the development of new practices in the NHS yields many benefits. It maximises the use of resources, benefits patients and their compliance with taking their medicines, and facilitates collaboration between the pharmaceutical industry, academic researchers and clinicians.

• The high costs and complexity of conducting randomised clinical trials in the UK is counterbalanced by the relatively lower costs and simplicity with which RW data studies can be set up and conducted in the UK. This can maximise investment more quickly, add value to the evaluation of a new medicine, and encourage the faster access to innovative medicines by patients.

• Presentation of RW data is going to become increasingly important in decisions that affect patients' access to medicines. Given the capability and capacity developed in the last decade, the UK has a unique opportunity to become a centre of excellence for the collection and analysis of RW data to be used by healthcare decision-makers both in the UK and worldwide.

• In the past, decisions about whether to grant access to new medicines in national markets were mainly informed by data generated from clinical trials, particularly randomised controlled trials (RCTs). Increasingly, there is a recognition of the role played by data about patients' use of medicines in normal clinical practice or in settings better reflecting the reality of healthcare delivery.

• Recent reforms of the health system in England, including the publication of the White Paper and the Department of Health (DH) consultation document on Value Based Pricing, highlight the Government's intention to improve healthcare outcomes for patients. It is important for the pharmaceutical industry to demonstrate that its medicines can contribute to that improvement. The collection and use of RW data can enable all parties to achieve their objectives and, ultimately, to maximise patients' health gains.

[4] The full White Paper on Real World data can be found at: http://www.abpi.org.uk/our-work/library/industry/Documents/Vision-for-Real-World-Data.pdf

• The UK already has a comparative advantage in conducting RW data studies due to:

º The marked influence of the UK on global decision-making through recognition of its world class Health Technology Assessment (HTA) processes;

º The unique 'cradle to grave' healthcare system with many existing healthcare databases and disease registries;

º The strong links already in existence between the pharmaceutical industry and academia, enabling access to the required skills for the collection, analysis and use of RW data. These include epidemiology, research methodologies, health informatics, health economics, Patient Reported Outcome Measures (PROMs), etc.

• In order to establish the UK as a world leader in the conduct of RW data studies and overcome some of the challenges of the current research environment, the UK and the pharmaceutical industry needs a strategy for change.

Recommendations

In order to develop the UK to become a centre of excellence for RW research the following actions are recommended:

• Measure current pharmaceutical industry activity in RW data collection in the UK to define a baseline against which to benchmark any change in the RW data environment (ie activity, ease of implementation, acceptance, value) in the future.

• Lobby at a national level with all key stakeholders for the need for change in the approval processes, skills and capabilities, and acceptance of RW data to enable the UK to optimise return on investment in the area.

• Develop a toolkit for UK pharmaceutical companies to present the case to their global colleagues for collecting, analysing and using RW data in the UK.

• Engage at a national and European level to streamline the regulatory environment for the conduct of RW data studies. Encourage clarification or amendment of the current regulatory guidance to maximise the opportunities for RW data collection throughout the product lifecycle.

• Encourage NHS partnership with the pharmaceutical industry in the collection and interpretation of RW data and engage with the wider medical community to ensure RW data are published in the respected medical journals alongside more traditional clinical trials.

• Improve the incentives for NHS centres to engage in RW studies, including those that are industry-sponsored.

• Lobby for national investment in the development of research capabilities based on electronic health records in the UK and lever the opportunities for industry access to data collected in this way for the purposes of research.

• Adopt a consistent approach to internal pharmaceutical company procedures, including the involvement of all relevant individuals for the review and approval of RW study protocols that take into consideration the differences between RW studies and clinical trials and their

relevant regulatory requirements. This document sets out to highlight the importance of conducting RW data studies to the UK pharmaceutical industry, their uses, and the ultimate gain for patients. It details the key actions that the UK pharmaceutical industry and wider life sciences research sector need to take in order to harness the opportunity for the UK to be regarded as a centre of excellence for conducting RW data studies.

Appendix 2

ABPI Submission on Industry Requirements for eHealth Research in the UK – December 2010

The UK is on the threshold of a step change in the availability of patient-level data for scientific and medical research. Already a country of choice for researchers who rely on patient databases that have been developed over the past twenty years, the UK is poised to become more attractive with the progress being made by the Government's Research Capability Programme. Central to the success of the Programme will be the effectiveness of the proposed Health Research Support Service (HRSS) in facilitating a wide range of research activities undertaken by the life sciences industry

If the UK retains and develops expertise in eHealth research, more innovative medicines will be developed; the capital brought into the UK to invest in this type of research will be beneficial to the economy; and UK patients will benefit from better health care.

The purpose of this paper is to develop clarity on the service that the HRSS must provide to the UK life sciences industry for this country to retain its position as a world leader in eHealth research. This paper will focus firstly on general principles and then specifically on the 3 areas of:

a. Clinical trials – feasibility, recruitment and management
b. Pharmacovigilance
c. Outcomes Research

Although not covered in this paper, Personalised Medicine[5] has particular significance for the UK as it could offer an area where this country could be uniquely competitive, show international leadership and create a more conducive environment for novel drug and diagnostic R&D. Electronic health records are becoming more established in parts of the UK and this is a critical foundation stone for personalised medicine and will allow genomic and clinical data to be integrated into practice. This will be strengthened further with the implementation of the HRSS, creating a single network of clinical information facilitating both clinical care and biomedical research.

The service - our approach

As part of identifying key features that industry would ask the HRSS service to provide we have approached each of the three topics in the following way:

[5] Personalised Medicine: "the tailoring of medical treatment to the individual characteristics of each patient". The ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not". Critically, it also involves the development, validation and use of companion diagnostics to achieve the best outcomes in the management of a patient's disease or their predisposition. See the ABPI White Paper, *The Stratification of Disease for Personalised Medicines*, 16 April 16 2009

- Taken note of a recent survey of ABPI members on the HRSS pilot projects and recorded which of the research methodologies and questions were considered to be most helpful to the pharma industry in the UK and why
- Considered how that research would currently be conducted including details on timelines, different databases and "languages" used, time delays etc
- Reviewed approaches to eHealth research elsewhere in the world – e.g. the Observational Medical Outcomes Partnership (OMOP) and Innovative Medicines Initiative (IMI) including clarity on structures to be adopted and security of patient data methodology
- Described what sort of functionality HRSS needs to provide to industry researchers that would remove or improve current difficulties and provide a competitive service

General principles applicable to clinical trials, pharmacovigilance and outcomes research

Robustly linked HRSS component databases: As part of the development and ongoing operation of the HRSS, robust linkages between primary care databases, secondary care databases and registries; and specialized datasets will need to be established. In an ideal scenario, the linkage process would involve:

- Development of compatible data fields or a conversion program to allow data from the different sources to be merged, Health Level 7 (HL7) considerations may help here[6].
- Detailed work on coding terminology used for each source, either aligning on one terminology for all sources or developing mapping programs to allow the data to be merged if necessary. It is also important to consider the use of standardised data entry fields in future.
- Development of standard search criteria to define key disease areas validated by international bodies and accepted by Regulatory Agencies like the Medicines and Healthcare products Regulatory Agency (MHRA).
- HRSS development complementary with the e-health methodologies being developed, at the Innovative Medicines Initiative (IMI), in the US, across the International Conference on Harmonisation (ICH) region and worldwide
- The ability to query free text fields from individual patient records and electronically key word search (after anonymisation and/or removal of sensitive data).
- Appropriate data protection, consistent for all data sources. Large online databases containing personal information are routinely used in other sectors e.g. the fields of banking and insurance and similar progress must be made in the area of public health.

Improved General Practice (GP) coverage: The commonly used UK Primary Care Databases (PCD) – General Practice Research Database (GPRD) and The Health Improvement Network (THIN) – cover just 5-10% of the UK population, which limits their usefulness in epidemiology studies, e.g. the analysis of rarer signals; in economic studies, e.g. estimating the burden of illness; and in recruitment for trials. Collaboration between PCD providers (IMS, MHRA and Epic) and primary care software providers like Egton Medical Information Systems Ltd (EMIS) which cover over 59% of GP practices in England (52.5 % across the UK) could increase PCD coverage tenfold, greatly increasing

[6] http://www.hl7.org/about/index.cfm

the power of studies that can be conducted in the medium term. Implementation of the General Practice Extraction Service (GPES) could raise UK PCD coverage to almost 100% in future.

The expanded pool of data described would greatly increase the versatility of the HRSS and its range of applications: safety data analysis, clinical trial recruitment etc, and would enhance the robustness of results. This would enable more rapid and decisive analysis with great benefits to patient health. The development of the HRSS would create a world leading UK resource and associated skill set that could be marketed globally.

Access to HRSS: All HRSS functionality must be available to the researcher (academic, government or industry funded) at a single access point online for simple queries, with suitable advice and timelines for delivery for more complex queries. The data must also be kept as up to date as possible. A single access point is needed because of the tight timelines[7] needed to analyse safety signals and because frequent interrogation of the data will be required due to the wide range of applications. This method works well for similar service providers such as Lincoln Technologies for the large adverse event (AE) databases (AERS/ Vigibase) and the potential high demand for the HRSS, domestic and international, would ensure a significant revenue stream for the service provider.

HRSS has to have a transparent and robust framework for customer engagement and reliability. This should include a clear service agreement with timelines for responses to simple and complex queries, with a transparent fee structure for access and analytic services.

Consistent standards: Consistent standards across all UK databases consolidated to form the HRSS are needed to reduce complexity and to improve interoperability. HL7 standards are being implemented in:

- The message specifications of ICH E2B reports in the ICH region (EU, US, Japan and Canada), including upgrading of the EudraVigilance (EV) database.
- The development of messaging and vocabulary standards for AE reporting within the new US National Health Information Infrastructure (NHII)

The development of HRSS would greatly benefit from early collaboration with initiatives such as the IMI project in Europe and the OMOP initiative in the US; to ensure consistency / compatibility.

Scientific advice: As the group who will develop the best understanding of the strengths and weaknesses of the linked data sources, HRSS should offer advice on study design. It will be important for HRSS staff to be trained in and have experience in conducting research using patient level data. This will improve the quality of research undertaken, and increase the proportion of studies approved in formal review.

[7] The need for HRSS to be responsive within *very limited timescales (ideally hours, days)* cannot be overstated. Rapid access to data is required when addressing an emerging safety issue.

a. Clinical trials

The HRSS or any system for delivering eHealth support services to industry should have the capability to provide data of sufficient quality for clinical research.

Three key areas where industry would want to interface with such a Service in relation to clinical trials are:

- *Protocol Optimisation*

- *Patient Identification / Recruitment*

- *Trial Execution*

Protocol Optimisation

The HRSS should be suitable to provide protocol optimisation information efficiently. The system should allow for a set of eligibility criteria to be entered and estimate likely numbers of patients that match these inclusion / exclusion criteria. The HRSS should also allow inclusion / exclusion parameters to be varied e.g. by changing age range. Feasibility information could be used to optimise trial design, for example through the impact of modifying inclusion and exclusion criteria on patient populations for the study.

Patient Identification / Recruitment

The HRSS needs to support and enhance patient recruitment into studies. Since much of the patient characteristics relevant for patient identification – such as diagnosis, age, gender, lab values – are stored electronically, it should be possible to use the service to support patient recruitment.

The service should have the capability to:

- Identify potential sites[8] which have appropriate patients for the study.
- Identify principal investigators in each of the sites identified who could possibly approach and recruit potential participants.
- Identify potential patient participants and enable contact with them by investigators.

Trial Execution

[8] In addition to the 3 key features of patient identification and recruitment and site selection listed here, other considerations in choosing locations for trials are: concurrent trial workload, previous experience in similar clinical trials, recruitment and retention in previous clinical trials, site personnel study experience and training, availability of facilities such as laboratories, availability of trial specific equipment (e.g. imaging). However it is not anticipated that the HRSS would assist with the need for such information in addition to patient specific information for recruitment purposes.

Clinical research would be made more efficient by an effective interface between the Case Report Form (CRF)[9] and the HRSS. A two-way passage of information could facilitate a reduction in the administrative burden and duplicative form filling while running a study by:

- A pre-population of the CRF by the HRSS drawn from the data already held on a patients' electronic health record (EHR). For each subsequent visit made by the patient during the study, relevant information entered by the investigator in the EHR could be directly transferred into the CRF.
- Additional information needed by the study could be electronically filled in by the investigator and that information could be populated to both the EHR and the CRF via the HRSS.

This system would require the EHR and electronic CRF used to be compatible and the interchange of information between the two to be possible via the HRSS. Other benefits of this interaction could include electronic long-term follow-up and the ability to request the collection of additional clinical information during a routine patient visit.

Governance

Currently only physicians can assess the suitability of patients for trials and approach them since medical records are confidential and patients' consent is required either for trial participation or for use of identifiable data in EHR for research. Whether an "opt out" (allowing automatic use of EHR for research unless specifically instructed by the patient to "opt out") or "opt in" (specific consent from the patient for record use required) is used, will impact the speed and effectiveness that could be achieved for clinical trials through the HRSS. Clearly from the perspective of efficient research processes an "opt out" system is preferable, but this would need to be alongside a major education and awareness campaign for the population where knowledge of the methods and benefits of medical research is currently very low. The information governance framework for the HRSS must exceed UK minimum governance standards.

Overall benefits for clinical trials

An HRSS which is capable of facilitating the three key areas of research detailed would greatly enhance the competitiveness of the UK in the clinical research environment, reducing timelines and improving the quality and exchange of information. The HRSS should streamline current cumbersome processes of trial feasibility, allowing changes in the protocol to be assessed quickly; timely identification of sites and potential investigators; and recruitment of trial participants. The HRSS should ensure that patient EHRs are complete, reflecting key information gathered during and after participation in trials drawn in from the CRF, while ensuring that CRFs are accurate, reflecting information drawn from the EHR at the start of a trial.

Initiatives outside the UK to improve clinical trial capability from linked medical record databases

[9] The CRF is the electronic patient documentation used in clinical research and is used by sponsors to collect data from enrolled patients at each participating site.

1. The European public-private IMI project is considering prioritising funding for the development of the use of electronic patient records to underpin better trial recruitment and management along the lines discussed above. Specifically it has described and listed the following attributes of the system it would wish to fund development of:

   European Medical Information System

   - *Better patient selection for clinical trials based on complete and accurate data including. diagnostic and treatment information*
   - *Improved safety through post marketing surveillance*
   - *Reduce healthcare cost*
   - *Enhancing multiplicity and flexibility in clinical trials*
   - *Enrolling studies for rare disease*
   - *Potential link to genetic information; Improve ability for patients to join clinical trials*

2. In addition several groups in the US are working to improve clinical trial recruitment and management though better use of patient records. For example

   - *The PACER NY pharma / IT industry consortium - a consortium of leading pharmaceutical and information technology companies working to develop an innovative pharmaceutical-clinical research platform for translational medicine, adaptive trial management and follow-on pharmacovigilance, pharmacoeconomic and drug safety sciences. The pace of development is fast and the build and test phase is expected to be complete by 2015.*
   - *eCast corporation – 25 sites in 8 regions in the US – a data analytics focus but with a clinical trials division whose aims include the use of data to improve protocol design and clinical trial recruitment*

b. Pharmacovigilance

Current situation

In pharmacovigilance (PV), pharmacoepidemiological (or E-health) tools are most frequently used for evaluation of safety signals, as components of EU Risk Management Plans (EU-RMP) or in Phase IV or post authorisation safety studies (PASS).

At present, the most commonly used tools are primary care databases (PCD) like the General Practice Research Database (GPRD) or The Health Improvement Network (THIN). Prescription event monitoring (PEM) is another frequently used methodology, particularly as part of risk management activities early after product launch.

The tools described above are all UK based but are used across Europe and even globally, as part of risk management or to assess safety issues. There is however, a desperate need for expanded functionality, additional methodologies and larger data sets. The development of the HRSS would link many key UK databases to create a world leading resource for safety surveillance which will address these three key needs going forward.

Routine signal detection and evaluation

HRSS functionality will complement current signal detection methodologies such as data mining in AERS, Vigibase or EudraVigilance[10], literature review or Periodic Safety Update Report (PSUR) production. The key difference would be that the pharmacoepidemiological analysis of a potential signal would be more comprehensive and robust due to the expanded PCD coverage and new linked datasets. For example PCD only contain GP data but adverse events that occur in hospital can be equally important. Robust linkages of PCD with secondary care data (SCD), like Hospital Episode Statistics (HES), accessed via the HRSS, would allow the choice to work with PCD and SCD data combined or separately as appropriate. This creates a more representative sample than presently possible and increases the power and robustness of studies. Consideration must be given to the benefits and feasibility for research of standardised coding[11] and validate results from these studies to ensure they are highly regarded by decision makers, including regulators. Signal evaluation could also be performed by linking specific disease registries to the large power of the primary care databases and secondary care databases. Hospital prescribing is not collected centrally.[12] Consideration should be given to the benefits of central collection and perhaps a linkage with the Health Hospital Pharmacy Audit Index.

Risk Management

HRSS functionality should also be used in Phase IV studies and there are clear benefits for current study methods such as PEM and Exposure Event Tracking (ExEtrac), described below in more detail. The tracking possible via the HRSS could even be used to greatly simplify the conduct of extensions to Phase III studies.

- ***electronic Prescription Event Monitoring (ePEM):*** PEM studies are frequently performed soon after product launch, but the methodology is paper based and labour intensive. In PEM, GPs who prescribe a new medicine are asked to report on a 'Green Form', all events recorded in the patients' notes during a specific time-period since the patient started treatment with the medicine. PEM allows identification of AEs that may not have been suspected as due to the

[10] Compatibility with associated tools such as Prosanos CLAERITY needs also to be considered

[11] HES coding is currently for the purpose of charging and commissioning within NHS, not for research purposes.

[12] There is no central NHS collation of information on medicines used and issued in NHS hospitals similar to that in primary care. The Prescribing Support Unit has, however, access to the Health Hospital Pharmacy Audit Index (HPAI) database. Data is collected and collated, on a commercial basis, by IMS Health (Intercontinental Medical Statistics) and made available to The NHS Information Centre under a commercial contract.
The HPAI is based on issues of medicines recorded on hospital pharmacy systems. Issues refer to all medicines supplied from hospital pharmacies: to wards, departments, clinics, theatres, satellite sites and to patients in out-patient clinics and on discharge. Therefore, the HPAI monitors usage levels by hospitals rather than purchases by trusts which may be acting for a consortium of trusts. This avoids bias introduced by hospitals redistributing medicines after purchase.
Costs are calculated by IMS Health using the Drug Tariff and other standard price lists. The coverage of hospitals is not complete, although 97 per cent of acute NHS beds across England are included.
The PSU publishes a national report, based on this data each year.

drug under surveillance by removing the need for the prescriber to give an opinion on whether an AE was caused by the medicine.

The development of tools, with appropriate governance, to access the free text fields of electronic medical records as part of the HRSS, coupled with increased PCD coverage, will allow PEM to be performed electronically as a database study, where information is gathered from the free text as well as structured fields of EHR. ePEM, would be faster and cheaper and could potentially link with additional sources of data via the HRSS. PEM often covers 40-60% of the UK population however so expansion of the current PCDs is the first step required to develop this methodology.

- ***Exposure-event tracking:*** Exposure-event tracking by GPRD (ExEtrac) uses software to track an exposure to a medicine/ vaccine and a particular AE from primary care notes but is currently limited by the size of UK PCD. As above, expansion of PCD coverage (via partnerships/ GPES) and the linking of PCD and SCD etc. is essential if we are to make this tool a world leading resource. The ability to track AE in close to real time, from a range of sources (PCD, SCD and registries) via a single HRSS query tool, will be a powerful and cost effective addition to the safety surveillance toolkit for when close surveillance of a medicinal product is needed.
- ***Phase III clinical trial extensions:*** HRSS functionality could even be used to conduct cheaper extensions to Phase III clinical trials to examine safety outcomes. Patients enrolled in a clinical trial could be tracked via the HRSS in the open label extension phase, which would link to the patients' EHR and automatically update at pre-specified time periods.

Developments such as these can not take place however, without significant investment in UK IT infrastructure.

Overall benefits for pharmacovigilance:

The greatest benefit of the HRSS would be a step change in the management of drug safety in the UK and the generation of a world leading system and skill set. Rarer signals could be evaluated and more common signals could be analysed with greater robustness. This improved functionality will allow MAH and Regulatory Agencies to more quickly decide if a safety issue is real and to more rapidly inform patients as a result.

Risk management has become standard practice in pharmacovigilance and the use of Phase IV/ PASS studies is increasing. The HRSS will enable the development of novel risk management methodologies like ePEM, large linked database exposure event tracking and cheaper follow up of Phase III study extensions.

The HRSS is an IT resource that is much cheaper than conventional interventional methodologies to operate and will enable significant additional savings through improved patient protection.

Initiatives outside the UK to improve pharmacovigilance from linked databases:

1. The OMOP initiative in the US was established to inform the appropriate use of observational healthcare databases for active surveillance by:

- *Conducting methodological research* to empirically evaluate the performance of alternative methods on their ability to identify true drug safety issues
- *Developing tools and capabilities* for transforming, characterising, and analysing disparate data sources
- *Establishing a shared resource* so that the broader research community can collaboratively advance the science.
- The OMOP partnership has developed, through the use of a common data platform, a range of methods to improve surveillance of safety signals appearing across disparate patient record databases. A recent publication[13] describes the transparent, open innovation approach designed to systematically and empirically study critical governance, data resource, and methodological issues and their interrelationships to establish a viable national program of active drug safety surveillance using observational data. The article describes the governance structure, data-access model, methods-testing approach, and technology development of this effort, as well as the work that has been initiated.

In parallel to the OMOP initiative, the Food and Drug Administration has established *Sentinel* - a network of distributed observational databases (administrative claims and electronic health records) to monitor the effects of medicines post-approval for safety purposes. The aim is to have linked databases and be able to retrieve information from 100,000,000 patient records by July 2012.

2. As noted above one of the aims of an IMI "European Medical Information System" would be to improve safety through post marketing surveillance.

c. Outcomes research & Epidemiology

The UK has long been considered a leader in outcomes research and epidemiology due to the NHS providing 'cradle to grave' healthcare, and the availability of large primary care datasets. A wide range of studies can be performed with the data, such as outcomes research studies assessing the relative effectiveness of treatments; economic studies evaluating the burden of disease or costs of treatment; and pharmacoepidemiology studies exploring the use and impact of drug treatments. More recently the growth in linkages between GPRD, Health Episode Statistics and registries that has taken place in parallel with the planning phase of HRSS has given some indication of what advantages a national linked dataset would offer. The success of HRSS in building on this foundation will depend on a number of factors;

The breadth, depth and quality of linked datasets

[13] 'Advancing the Science for Active Surveillance: Rationale and Design for the Observational Medical Outcomes Partnership', in *Annals of Internal Medicine*, *November 2, 2010 153:600-606.*

- The linked data from primary care must include the majority of English practices to enable outcomes studies in recently licensed medicines and in rare conditions.
- HRSS should maintain a flexible approach to the timely inclusion of additional datasets where they are of sufficient quality. The addition of prescribing information from secondary care sources, including outpatients, should be considered a priority from a research perspective.
- It should provide feedback to data providers on the quality of data submitted, and include quality indicators on all data for researchers to assess whether it is suitable for their own project.
- Ability to follow patients longitudinally over an extended period is crucial. Tools should be provided (e.g. accurate registration dates) that allow researchers to follow a patient between different localities without duplication of events. This could be performed via a unique patient identifier, subject to appropriate governance.

Timely access to linked data

- Ability to conduct feasibility studies quickly and easily, preferably via an online tool which can inform on numbers of patients and datasets available.
- Transparent and rapid approval process for research protocols. Sequential review across multiple database owners may cause significant delays, particularly where smaller database owners have infrequent review meetings.
- Where feasible, broad approval for types of research using linked databases and the methodologies adopted in making the linkages should be in place. Individual research requests would then only require a review of the scientific merits of the proposed study rather than repeating the review of the databases used and the linkage mechanisms which is a lengthier process and leads to delays which would appear to be unnecessary.

Access to additional data

- Free text may contain data necessary to assess outcomes not formally coded (e.g. minor symptoms, quality of life). It should be available either directly (anonymised) or via automatic queries.
- The HRSS should provide a clear process for the validation of events detected in the EHR with the recording physician. Facility to include Patient Reported Outcomes (e.g. Quality of Life questionnaires) should be considered

Initiatives outside the UK to improve outcomes research from linked databases

The objectives of the initiatives outside the UK relating to improving trials recruitment and pharmacovigilance will also underpin improved capability in outcomes research.

Conclusion

We support the development of the HRSS and recognise its importance to industry in conducting clinical trials, pharmacovigilance and outcomes research. It will also have the knock-on effect of generating inward investment that will be boost the UK economy. The ABPI will continue to provide input and support as HRSS develops, with a view to making this tool the best possible resource for this country.

END

ABPI eHealth Research Group

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