ABPI Scotland consultation response

CSO Research Strategy 2014

30 September 2014

As general comment, we would like to point to the below areas that are of particular interest and relevance to ABPI Scotland and its member companies:

World-class clinical research:
- E-Health – develop UK capabilities for the use of large data sets – 'safe data' for faster/better R&D
- Improve current access to health data that is of high quality, with robust data linkages and at speed
- Continued investment to develop capabilities in data analytics
- Reliable electronic records to underpin R&D as an integral part of the entire healthcare spectrum

Trial performance – drive clinical research progress across NHSScotland:
- Further measures and additional (or more focused) targets to improve trial performance, delivery and quality across the Scottish health system
- Levers (reward, time allocated) for clinicians to be involved in research
- Nationwide communications strategy to engage patients and the public in clinical research (possibly linked to the SHARE register)

Working together more effectively:
- Talent development – sustaining the skills pipeline
- Action to improve skills capabilities, particularly in at-risk disciplines
- Increased opportunities for undergraduate placements in industry
- Improvement in teaching of practical skills in undergraduate courses
- Accelerate filling the pipeline for: informatics; genetics and genomics in healthcare; clinical pharmacology/ translational medicine; manufacture – chemical engineering, protein chemists

Optimise conditions for open innovation:
- Enhance people mobility (hence skills and knowledge) and enhance collaborative culture across sectors through:
  - More training and collaborative initiatives
  - Implementation of the Research Excellence Framework (REF) from 2014 positively influences university research funding
  - Removing barriers to cluster formation

Delivering new medicines to patients:
- A supportive licensing and regulatory regime that facilitates innovation
- MHRA to be a leading force in shaping the EU regulatory environment

- Raise innovative culture and joint working in regulators, SMC and NHSScotland, with essential key stakeholders; a more proactive approach to innovation at all levels
- Deliver an appropriate workable Early Access scheme; enable innovative pathways such as progressive licensing, and proactively engage with international activities as appropriate
- Improve understanding of how health informatics and new tools can facilitate innovation through awareness raising and systems implementation

Chapter 1 – Efficient R&D Support for Research

Question 1: Should CSO and the Health Boards set any eligibility criteria for nodal R&D Directors? Should appointment of a nodal R&D Director be for a specific time, and if so what term would be appropriate?

ABPI Scotland response:

Eligibility criteria would need to be set for nodal R&D Directors to ensure confidence and transparency in the individuals appointed. All areas of potential conflict of interest, in addition to any political allegiances would need to be declared.

A minimum term of 12 months would be a likely practical time-frame for such appointments.

Question 2: CSO proposes to approve the functions of staff in R&D Offices; should CSO seek to standardise local R&D functions across Scotland, or is it preferable to allow local flexibility?

ABPI Scotland response:

As often with such questions, there needs to be a degree of both. While local flexibility is important to allow responsiveness to local circumstances, there has to be a degree of standardisation to ensure quality and consistency of delivery.

We would suggest that there should be certain objectives and standards which are uniform across offices, with local flexibility allowed in delivery and other non-standard functions.

Question 3: Are there other NRS functions that might usefully be transferred from the Health Boards or CSO to the new NRS-GMS? Are there functions not currently being undertaken that the NRS-GMS might carry out?

ABPI Scotland response:

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The responsibility for optimising conditions for open innovation, for example by enhancing people mobility (hence skills and knowledge) and enhancing collaborative culture across sectors through:

- More training and collaborative initiatives
- Implementation of the Research Excellence Framework (REF) from 2014 positively influences university research funding
- Removing barriers to cluster formation

Question 4: To what extent should the joint planning of the deployment of infrastructure resources be formalised? Should there be a formal record of such discussions?

ABPI Scotland has no comment to make on this question.

Question 5: Taken together, will these steps to both free up and promote the availability of NRS resources address current concerns over lack of time and support? If not, are there other steps CSO should take?

ABPI Scotland response:

It is not possible to say whether the actions will have the desired effect. However it is possible to put in place measures to allow assessment to take place, for example KPIs and the correct governance.

Question 6: Are there any further changes that should be made to improve the efficient delivery of patients to studies through the NRS Networks and Speciality Groups?

ABPI Scotland has no comment to make on this question.

Question 7: To what extent do delays continue to occur as a consequence of differing NHS and university requirements? To what extent is closer integration of NRS and university functions possible and desirable?

ABPI Scotland has no comment to make on this question.

Chapter 2 – Partnership with Scottish Patients and Public

Question 8: Would a trial register be of benefit to patients seeking trials? Would it be an effective way to partner patients with researchers? Is there a danger that expectations of taking part could be unfairly raised?

ABPI Scotland response:

Patients' awareness of trial activity is low overall; and where they do understand the process it's often tough to know where to look for appropriate trials/research if not through their healthcare professional.

Trials should not be seen as a last resort to available healthcare options. We would welcome the introduction of a register, but would hope that necessary provisions are made to ensure patients and those that support them know where to find this register and easy guide on what to do next.

A greater public awareness of the benefits for patients, possibly via a nationwide communication strategy to engage patients would be beneficial.

Greater awareness of the SHARE register (which could be tied in to awareness raising) would also be of use.

Question 9: Would using electronic NHS patient records to alert GPs to research studies for which their patients may be eligible a service the NHS should offer? If so, would a process where NHS records are only accessed by identified NHS staff working in secure facilities, and only passing potential participant names to their GPs or hospital consultants for consideration, be a suitable way to proceed?

ABPI Scotland response:

We welcome the utilisation of electronic health records, not just for trial identification but to improve access to information, self-management, family inclusion and shared decision making.

Clearly patient confidentiality is of paramount importance in order to maintain the confidence and trust of the general public. It is therefore right and proper than only healthcare professionals should have access to patient records.

Again we would suggest that if possible, this should be tied into the SHARE register.

Chapter 3 – Targeted Deployment of Resources and infrastructure

Question 10: What proportion of CSO funding should be available for deployment in new research initiatives relevant to the NHS? In what areas should CSO seek to disinvest to free up resources?

ABPI Scotland response:

This is a difficult question to answer. Simply put, we want to see the key areas prioritised, along with what enables them and disinvestment in those areas not likely to change the environment. Of course we recognise that this has to be done with due regard to initiatives that are necessary due to providing a critical service.

We would suggest that both stratified medicines and eHealth are two of the top priorities with regards to maintaining and improving the Scottish R&D environment. New research initiatives relevant to the NHSScotland should be focused on enabling these areas where possible.

We would also point to our industry key messages, included at the top of this submission.

Question 11: Is the focus of the CSO response mode grant schemes adequately defined and understood by the research community? Should there be a narrower focus to complement and avoid overlap with other funding streams Scottish researchers have access to? What is a realistic upper level for CSO grants to allow worthwhile projects to progress?

ABPI Scotland has no comment to make on this question.

Question 12: What should determine the creation and continued funding of a CSO unit? Should any new unit have a plan for CSO funding to be time limited?

ABPI Scotland response:

We believe that the main factors for determining funding should be:

- The needs of Scottish patients
- Attracting investment to Scotland
- Leveraging the unique populations in Scotland and the strengths of Scottish research
- Better utilisation of bioresources and tissue banks
- the further development of the Farr Institute
- 'Safe haven' initiatives for the access of patient data

We support time limited funding where there are clear goals and milestones in place to judge success.

Chapter 4 – Working in Collaboration

Question 13: Are there other key areas of partnership CSO should be seeking to build?

ABPI Scotland response:

ABPI Scotland welcomes and concurs with the acknowledgement that successful collaborations have already taken place between CSO and the pharmaceutical industry. We are pleased to see the prominence placed in the desire to develop partnerships with patient groups and the 3rd sector. We support such integration and are happy to continue to work with all stakeholders as appropriate.

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We suggest that optimising the environment for open innovation should be looked at. For example by encouraging the universities to develop talent (see our opening statement, above). Another potential area is fostering developments with SMEs in open innovation and digital health start-up companies that may help to improve collaborative work between NHSScotland and the pharmaceutical industry. Optimising the conditions for open innovation

Question 14: Would the creation of a CSO International Advisory Board be a positive step in raising Scotland's research profile and supporting our ambition? What should be the make-up of such a Board be?

ABPI Scotland response:

ABPI Scotland believes that an international advisory board would be a positive step. Such a board would be able to reach out to other potential partners and raise Scotland's research profile.

Such a board would benefit from the inclusion of a number of international executives of European, Japanese and US based ABPI member companies.

Question 15: Are there other areas were CSO funded research could better support the Health Directorates Quality agenda?

ABPI Scotland has no comment to make on this question.

Chapter 5 – Investing in the Future

Question 16: Is the Primary Care Research Career Award scheme suitably focused to attract suitable high quality applicants? If not, what would a revised focus be?

ABPI Scotland has no comment to make on this question.

Question 17: Do the current CSO personal award schemes targeted to meet our future needs? If not, should CSO conduct a wider review of its capacity building schemes?

ABPI Scotland response:

There is s a need to sustain the skills pipeline and keep a skilled workforce, and so measures which support these needs should be encouraged.

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For example the proposed strengthening of Biomedical Informatics Research and the publication of a health and bio-informatics research strategy , that will do more to link health data.

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