# ANONYMOUS CONTACTABLE v ASTRAZENECA

## Failure to publish joint working executive summary

**An anonymous, contactable complainant considered that a cancer data project, operating in a named Scottish region, appeared to be a joint working project although it had not been declared as such by the four companies involved including AstraZeneca. The complainant stated that the ABPI had, *inter alia*, published news of the collaboration. The complainant had not checked AstraZeneca's website but noted that he/she had not seen details published on the other three companies' websites. The complainant noted that an executive summary should be published before such projects start. If such details were on the websites of the other three companies, they were not visible and hence transparent – the project was not listed alongside those companies' other joint working projects.**

**The complainant acknowledged that it might be a very positive joint working project but queried whether, as long as their project was endorsed by the ABPI, member companies did not have to comply with the Code. The complainant queried whether the ABPI was leading companies to flagrantly bypass the Code.**

**The detailed response from AstraZeneca is given below.**

**The Panel noted that joint working between the NHS and others and the pharmaceutical industry was defined by the Department of Health as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pooled skills, experience and/or resources for the joint development and implementation of patient centred projects and shared a commitment to successful delivery. The relevant supplementary information to the Code described the features of joint working including that it must be for the benefit of patients, but it was expected that the arrangements would also benefit the NHS and the pharmaceutical company or companies involved. The Code required a formal written agreement to be in place and an executive summary of the joint working agreement to be made publicly available before arrangements were implemented.**

**The first issue that the Panel had to decide was whether the arrangements referred to by the complainant constituted joint working.**

**To determine whether an arrangement was joint working one had to consider whether the project was for the benefit of patients. The Panel noted the benefits for all stakeholders listed in the protocol and considered that these were primarily, although not exclusively, for the benefit of patients. In the Panel's view, that there were ancillary benefits to pharmaceutical companies did not preclude the overall arrangements being considered a joint working project even if such benefits primarily influenced a company's decision to participate.**

**The Panel noted that AstraZeneca did not explain why the contract at issue was between the ABPI and the NHS region and not directly with the companies in question. The ABPI and the companies had discussed the classification of the project. Ultimately, and irrespective of such discussions, companies had to take responsibility for the project classification under the Code. In the Panel's view, it was clear from an overall evaluation of the contract between the NHS region and the ABPI, and between the ABPI and each individual company, that the ABPI was contracting on behalf of the four companies and the use of a third party did not, in the Panel's view, mean that the companies could circumvent the requirements of the Code. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.**

**In relation to the project at issue, its protocol set out benefits for stakeholders. Benefits for patients were listed first and described as 'Improved patient concordance, adherence and benefit from therapy through additional support of data to ensure optimal use of their medicines'; and 'Better information as a basis for patient specific treatment decisions'. The first two of three benefits for the regional NHS board were relevant to patients and included an audit framework as a basis for improved quality of care for breast cancer patients across a Scottish region and 'Improved capture of patient outcomes'. The four benefits to ABPI/industry included 'Improved reputation by working jointly with NHS to benefit patients' and 'The optimal use of medicines in the appropriate patients which should mean better proactive treatment and management of patients'.**

**The Panel noted that the four companies had each paid £32,480.50 and that the ABPI SCG had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.**

**The Panel noted AstraZeneca's submission that the project fell within the requirements of Clause 21, that it was a contract to provide funding for the purpose of supporting research. The Panel noted that the project included features of joint working, namely: industry and NHS resources had been pooled to implement a project for the benefit of patients; outcomes that would also benefit the NHS and the four companies involved; both the health board and the four companies had made significant financial contributions towards the project and defined project outcomes were to be measured and documented. However, not all of the benefits for stakeholders as set out in the protocol were for the benefit of patients. The Panel noted its comments above in this regard and considered that the benefits**

**as listed in the protocol in relation to Phase 1 of the project could be predominantly characterized as for the benefit of patients. The Panel considered that the arrangements at Phase 1 of the project in relation to the NHS region were a joint working project and thus an executive summary of the written agreement ought to have been published before the arrangements were implemented. The Panel ruled breaches of the Code including that high standards had not been maintained. These rulings were appealed by AstraZeneca. In the Panel's view, the circumstances did not warrant a ruling of a breach of Clause 2 which was reserved to indicate particular disapproval of a company's activities and reserved for such use. No breach of Clause 2 was ruled. This ruling was not appealed.**

**Upon appeal by AstraZeneca the Appeal Board considered that the documents could have been better worded to more accurately reflect the arrangements and this included the information issued by the ABPI.**

**The Appeal Board noted AstraZeneca's submission that the project fell within the requirements of Clause 21, that it was a contract to provide funding for the purpose of supporting research and queried whether that was indeed so. The Appeal Board noted that its role was solely to determine whether the activity at issue was joint working thereby triggering the requirement to publish an executive summary.**

**The Appeal Board noted that in its appeal AstraZeneca provided further and better particulars than had been provided to the Panel notably with regard to the vision for utilising the dataset resulting from Phase 1 and the potential benefit for patients, which AstraZeneca acknowledged could have been communicated better in the contract. AstraZeneca also commented on the misleading nature of the ABPI press release.**

**The Appeal Board noted that the whole project included features of joint working, namely, the pooling of industry and NHS resources to implement a project with outcomes listed in the protocol for the benefit of patients and the benefit of the NHS and the four companies involved including AstraZeneca; both the Scottish region health board and the four companies including AstraZeneca had made a significant financial contribution towards the project; and defined project outcomes were to be measured and documented. However, the Appeal Board noted that the protocol of agreement was limited to completing Phase 1. The outcomes of Phase 1 were a data dictionary, a data quality report and example epidemiological, clinical pathway and outcomes reports that would be aggregated and anonymised and only available to the companies when they had been published by the NHS region. Although referred to in the protocol, Phases 2 and 3 were not part of the current protocol of agreement and there was no agreement or obligation that the company would be involved in them.**

**The Appeal Board noted its comments above and considered that the benefits listed in the protocol in relation to patients and would only come about if Phases 2 and 3 were undertaken and completed; there was no patient centred benefit at the end of Phase 1. The purpose of Phase 1 and its outputs were data centred rather than patient centred. The Appeal Board considered that the arrangements at Phase 1 of the project in relation to NHS region were not a joint working project and thus no executive summary of the written agreement needed to have been published before the arrangements were implemented. The Appeal Board ruled no breaches of the Code in this regard. The appeal on both points was successful.**

**Following its completion of the consideration of the appeals in Case AUTH/3045/6/18 (Pfizer) and Case AUTH/3046/6/18, the Appeal Board noted that the respondent companies in Case AUTH/3043/6/18 (Novartis) and Case AUTH/3044/6/18 (Roche), had accepted the Panel's rulings of breaches of the Code and had not appealed. Pfizer had appealed Case AUTH/3045/6/18.**

**The Appeal Board agreed that Novartis and Roche should be contacted and informed of the outcome of the appeals in Case AUTH/3045/6/18 and Case AUTH/3046/6/18. The PMCPA Constitution and Procedure did not cover this unusual situation where more than one company was involved in the same set of circumstances and the Appeal Board had taken a different view to the Panel. Novartis and Roche should each be offered the opportunity to appeal out of time and the appeal process would operate in the usual way. The complainant should also be informed. The reports for Case AUTH/3043/6/18 and Case AUTH/3044/6/18 should be updated to reflect the situation and to cross refer to the cases which were successfully appealed. Roche declined the opportunity to appeal. Novartis appealed and the Appeal Board subsequently ruled no breaches of the Code.**

An anonymous, contactable complainant considered that a cancer data project operating in a named Scottish region appeared to be a joint working project although it had not been declared as such.

The complaint was taken up with all four companies including AstraZeneca.

**COMPLAINT**

The complainant stated that in May 2018, the ABPI had, *inter alia*, published news of the project in question.

The complainant queried whether the project was a joint working project with the NHS. The complainant had not checked AstraZeneca's website but noted that he/she had not seen details published on the other companies involved websites. The complainant noted that an executive summary should be published before such projects started. If details were on the websites of the other three companies, they were not very visible and hence transparent – the project certainly was not listed alongside those companies' other joint working projects.

The complainant noted that the ABPI news alert stated that funding of the project from the region was being matched and queried whether matched funding was one of the principles of joint working.

The complainant acknowledged that it sounded like good news and it might be a very positive joint working project but queried whether, as long as their project was endorsed by the ABPI, member companies did not have to comply with the Code. The complainant queried whether the ABPI was leading companies to flagrantly bypass the Code.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 20.

**RESPONSE**

AstraZeneca explained that a named health board, requested support from the ABPI Scotland Collaborations Group (SCG) to undertake a project with the overarching aim of harnessing the existing breast cancer data opportunities in Scotland. The project was set out to address high level questions such as could comprehensively linked cancer datasets be used to:

- understand the epidemiology of a tumour specific group to support HTA?

- facilitate the assessment of outcomes including effectiveness, tolerability and value of recently adopted new technologies for cancer?

- support improvement in patients' experience through medicines optimisation?

In order to achieve the desired outcomes outlined above, assessment of the breast cancer patient pathway from the point of diagnosis onwards, in a Scottish region, was necessary. This would entail:

- describing the data completeness, data quality and scope of a comprehensive linked regional cancer dataset and

- building an analytics framework for the quantification of population size, population characteristics, clinical and patient outcomes, tolerability, healthcare costs and value of recently adopted new technologies for cancer.

This project was intended to build a suitable linked data resource within NHS Scotland for breast cancer, with the objective of enabling future research. The project focused on the creation of a unified data resource, that the collaborators could independently interrogate under an appropriate regulatory and legal framework. Data exchange was outside the scope of the project.

**Confirmation that this project was not joint working**

Following a discussion at an ABPI SCG meeting, the ABPI confirmed to the SCG (19 June 2017) that the project between ABPI SCG and the NHS region was not joint working as outlined in Clause 20. AstraZeneca noted that the requirement for a published executive summary, as referred to by the complainant, was a pre-requisite of a joint working project as stated in Clause 20. Neither the ABPI nor AstraZeneca considered that the project was a joint working project thus no formal certification of an executive summary was undertaken. The ABPI stated that it could not enter into joint working projects and was satisfied that the project in question was collaborative working between ABPI SCG and the NHS region.

On that basis, the ABPI drew up a contract on behalf of stakeholders, including AstraZeneca, which was subsequently signed by the ABPI on 13 March 2018 and the NHS region health board on 20 March. The project started in March.

AstraZeneca considered that the project fell within Clause 21 (Relationships and Contracts with Certain Organisations) where funding was permitted for the purposes of supporting research; the project was intended to build a suitable database foundation within NHS Scotland for breast cancer with the aim of enabling future research to support HTA assessments.

AstraZeneca noted that it separately signed a contract with the ABPI in November 2017, in relation to the project.

The main internal project steps and any external project steps with AstraZeneca involvement were:

| **Project Timelines** | **Date** |
|---|---|
| First Discussions | October 2016 |
| Initial Scoping meeting | January 2017 |
| ABPI confirmation of project governance | May 2017 |
| AstraZeneca Contract review | June 2017 |
| AstraZeneca signed agreement with ABPI | November 2017 |
| AstraZeneca Transparency Disclosure | November 2017 |
| Contract Signed by ABPI President and the NHS region | March 2018 |

Apart from the initial attendance of the scoping meeting in January 2017 to gain clear oversight of the agreed aims of the project, there had been no other AstraZeneca involvement other than finalising the contract with the SCG and committing to the provision of funds.

AstraZeneca stated, in summary, that together with ABPI SCG, it considered that the funding provided to the NHS region towards the project at issue did not constitute joint working as outlined in Clause 20; the company thus did not consider that the activity was in breach of Clauses 20, 9.1 or 2.

AstraZeneca submitted that as the project was not assessed as joint working, formal certification of an executive summary, which was a pre-requisite of joint working, was not undertaken.

AstraZeneca queried the rationale for breaches of the above clauses of the Code, which it had been asked to consider in relation to this project when the complainant's request appeared to be for information only rather than a formal submission of a complaint.

In response to a request for further information, AstraZeneca stated that the protocol was an integral part of Schedule 2 of the contract signed between ABPI and the NHS region in March 2018. The final aims and objectives of the project were stated in the protocol. Proposed aims and objectives were discussed at a meeting in January 2017. The discussion at this meeting led to the final aims and objectives in the protocol. By way of ABPI membership, AstraZeneca had a position on the steering committee as defined in the protocol. The role of which was to monitor implementation of the milestones and support the development of sub-study work packages. Outside of the 'core work package' there was also a 'cross-cutting work package' described in the protocol. The purpose of which was to use high-level test queries on the newly formed linked data resource, to support development of a process for researchers to submit queries to be securely run on the data resource via the NHS. It was agreed that participating companies would suggest the test queries to be used. These test queries were documented in the protocol. Subsequently, participating companies would go on to work with relevant representatives of the NHS region to support the design of this process from an 'end user' perspective. This was expected to lead to a process enabling both manufacturers and researchers to submit requests in the future, to gain secure access to anonymised, aggregated analysis outputs that they could use to gain insights into real world cancer treatment and outcomes. Governance aspects of the project were reviewed by a senior compliance staff member and the proposed legal framework was discussed with legal to ensure that it was appropriate, and a decision was subsequently made to progress the necessary supporting documentation for the project through the usual company contractual processes. It was AstraZeneca's view that this project did not meet certification requirements in the Code. As outlined in its previous correspondence, AstraZeneca submitted that the project fell within the requirements of Clause 21, specifically that it was a contract to provide funding for the purpose of supporting research. There was no specific requirement in the Code for such contracts to be certified. AstraZeneca submitted that the definition of joint working under the ABPI Code was a formal agreement between one or more pharmaceutical companies and the NHS and others. The ABPI was the signatory of this contract, not AstraZeneca. AstraZeneca stated it was advised by the ABPI, following advice that it had taken, that this agreement was not joint working. AstraZeneca reiterated that the project fell within the requirements of Clause 21, specifically that it is a contract to provide funding for the purpose of supporting research.

AstraZeneca noted that the press release concerning the project was not submitted to AstraZeneca for review as per obligations set out in the contract between the ABPI and the NHS region. In AstraZeneca's view, the nature of the engagement should have been more explicit in the press release to avoid reader confusion.

**PANEL RULING**

The Panel noted that joint working between the NHS and others and the pharmaceutical industry was defined by the Department of Health as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pooled skills, experience and/or resources for the joint development and implementation of patient centred projects and shared a commitment to successful delivery. This definition was reproduced in the supplementary information to Clause 20 Joint Working. The relevant supplementary information to Clause 20 then described the features of joint working including that it must be for the benefit of patients, but it is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Clause 20 required a formal written agreement to be in place and an executive summary of the joint working agreement to be made publicly available before arrangements were implemented.

Thus, in the Panel's view, it was clear that joint working would produce benefits to the NHS and pharmaceutical companies in addition to outcomes for the benefit of patients. That a joint working arrangement produced other benefits including in relation to a company's commercial interests would not necessarily preclude the overall arrangement being classified as a *bona fide* joint working project.

The complainant alleged that certain companies had failed to publish an executive summary of joint working arrangements. The first issue that the Panel had to decide was whether the arrangements constituted joint working.

The Panel noted that the complaint concerned four pharmaceutical companies including AstraZeneca. All four companies were members of the ABPI Scotland Collaborations Group (SCG). The Panel noted that although the complaint concerned the same project the companies gave differing accounts about some aspects of the project including its internal classification. Not all companies had provided all relevant documentation.

The Panel noted that the project protocol was set out in a document titled Data Intelligence for the Value Appraisal of Personalised Healthcare Technologies for Cancer within the [named] cancer Network, Version 9, Date of Preparation June 2017, which was appended to the agreement between the ABPI and the Scottish health board dated 13 March 2018. The background section of the project protocol explained that the parties had identified a need to provide a robust and prospectively designed technology adoption and evaluation framework to exploit rich routinely collected datasets for value assessment and evidence development in real world settings. The protocol explained that such data was needed by NHS decision makers and, *inter alia*,

local service managers. It was noted that existing patient access schemes were inefficient and such data would also make possible more preferable population level schemes. It was also noted that there was potential for such data to be exploited by others including academic communities which relied on routine capture of electronic health data. The protocol explained that there was an urgent need to understand the detail of what was currently possible and what further developments needed to be undertaken. There were three geographical phases to the overall project: Phase 1 in relation to breast cancer patients and the NHS region; Phase 2 in relation to four health boards comprising the named cancer network; and Phase 3 was national in scope and broader than breast cancer and would be in collaboration with another organisation.

The project work plan including costings set out in the protocol was in relation to Phase 1 of the project only and had 3 milestones. Breast cancer data had been identified for Phase 1 of the project and hence the proposed collaboration with the NHS region health board which had a pre-existing data set. In the Panel's view the complaint was about this regional Phase 1 collaboration rather than subsequent phases of the project which were referred to but not detailed in the protocol. The funding provided was in relation to Phase 1 of the project.

In relation to the project at issue, the protocol set out benefits for stakeholders. Benefits for patients were listed first and described as 'Improved patient concordance, adherence and benefit from therapy through additional support of data to ensure optimal use of their medicines'; and 'Better information as a basis for patient specific treatment decisions'. The first two of three benefits for the NHS named health board were relevant to patients and included an audit framework as a basis for improved quality of care for regional breast cancer patients and 'Improved capture of patient outcomes'. The four benefits to ABPI/industry were listed as 'Improved reputation by working jointly with NHS to benefit patients', 'Improved professional and transparent relationship and trust between ABPI, Industry and NHS Health Boards', 'Access to anonymized aggregated data through public domain reporting to highlight the outcomes of the project to allow greater disease understanding' and 'The optimal use of medicines in the appropriate patients which should mean better proactive treatment and management of patients'.

Four sub-project work packages were listed and included direct-from-data clinical pathway modelling for outcomes estimation in support of, *inter alia*, cost-effectiveness modelling for Scottish Medicines Consortium Submissions and local business cases and expanding beyond NHS activity into social care. It appeared, although it was not entirely clear, that the sub work packages related to Phases (work packages) 2 and 3 rather than the phase in question.

In relation to Phase 1 of the project, the Panel noted the companies' and the NHS region's contributions as set out in the protocol. The Panel noted the companies' ongoing role on the steering committee. To determine whether an arrangement was joint working one had to consider whether the project was for the benefit of patients. The Panel noted the benefits for all stakeholders listed in the protocol and considered that these were primarily although not exclusively for the benefit of patients. In the Panel's view, that there were ancillary benefits to pharmaceutical companies did not preclude the overall arrangements being considered a joint working project even if such benefits primarily influenced a company's decision to participate.

The Panel noted that AstraZeneca had not explained why the contract was between the ABPI and NHS region rather than directly with the companies in question. The Panel noted that there had been discussion between the ABPI and the companies about the classification of the project. Ultimately and irrespective of such discussions companies had to take responsibility for the project classification under the Code. In the Panel's view, it was clear from an overall evaluation of the contract between the NHS region and the ABPI, and between the ABPI and each individual company, that the ABPI was contracting on behalf of the four companies and the use of a third party did not, in the Panel's view, mean that the companies could circumvent the requirements of the Code. The agreement between the ABPI and the NHS region dated 13 March stated at the section headed Compliance in relation to declaration of the companies' involvement in the project that ABPI SCG comprised four named companies including AstraZeneca. The four companies were also listed alongside their financial contributions in an appendix to that agreement. The project protocol appended to the agreement did not name the companies.

The Panel noted that the four companies had each paid £32,480.50 and that the ABPI SCG had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.

The Panel noted AstraZeneca's submission that the project fell within the requirements of Clause 21, that it was a contract to provide funding for the purpose of supporting research. The Panel noted that the project included features of joint working, namely: the pooling of industry and NHS resources to implement a project for the benefit of patients; outcomes that would also benefit the NHS and the four SCG group members; both the regional health board and the four SCG companies, including AstraZeneca, had made a significant financial contribution towards the project and defined project outcomes were to be measured and documented. However, not all of the benefits for stakeholders as set out in the protocol were for the benefit of patients. The Panel noted its comments above in this regard and considered that the benefits as listed in the protocol in relation to Phase 1 of the project could be predominantly characterized as for the benefit of patients. The Panel considered that the arrangements at Phase 1 of the project in relation to the NHS region were a joint working project and thus an executive summary of the written

agreement ought to have been published before the arrangements were implemented. The Panel ruled a breach of Clause 20 in this regard. High standards had not been maintained, a breach of Clause 9.1 was ruled. In the Panel's view, the circumstances did not warrant a ruling of a breach of Clause 2 which was reserved to indicate particular disapproval of a company's activities and reserved for such use. No breach of Clause 2 was ruled.

**APPEAL BY ASTRAZENECA**

AstraZeneca submitted that the Panel's ruling that the interaction between it (and other associated pharmaceutical companies), utilising the ABPI as a group representative agency, and the Scottish region health board was Joint Working was erroneous.

AstraZeneca submitted that to some extent, it was true that the scope of the project could appear to meet the definition for joint working as set out in the 2016 Code: 'Joint working is where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery'.

However, AstraZeneca submitted that when considering the whole joint working framework definition, whilst the outputs of the project undertaken did have potential future longer term patient benefits, the delivery of the project outcomes (as outlined in the contract between the ABPI and the Scottish region health board, namely a data dictionary, a data quality report and example epidemiological, clinical pathway and outcomes reports), would not produce any immediate or direct patient benefits as the project aim was to create and validate a data framework, that could then be used for research or health technology evaluation in the future.

AstraZeneca outlined key aspects of this project below that set it apart from the requirements of the definition of joint working.

**1 Project objective and aims**

AstraZeneca submitted that the Scottish region health board were seeking funding to create a comprehensive linked cancer dataset, mapping out the patient pathway for breast cancer patients in their locality. In creating the resource, the authority envisaged the dataset being useful for third parties to answer key research questions, generate data for health technology submissions or to collaborate with NHS Scotland bodies to improve the patient experience and pathway. The NHS authority believed the dataset would allow them and other healthcare providers to gauge the impact of any interventions (including utilisation of particular medicines) on patient outcome measures. These ambitious benefits, that could in future be supported by the dataset, were not objectives of this project. To realise them would require new agreements, objectives and funding. To achieve their first aim of creating the linked dataset and mapping the patient pathway, the Scottish region health board chose to work with AstraZeneca and three other pharmaceutical companies. To provide equity in the collaboration with the companies, it chose the ABPI to act as the representative body for the companies. The contract that was signed was an agreement of funding between ABPI and the Scottish region health board to create the dataset, with the four pharmaceutical companies and ABPI providing a share of the funds. By funding the project, the companies were also allowed to attend project steering group meetings, with the primary intention of overseeing progress and to supply 'test' questions to ensure the validity of the dataset being created. The output of the test questions were not being utilised for any other purpose than assessing the ability of the dataset generated to answer questions typical of those that might be asked in future. The project group decided to focus on breast cancer and its related patient pathway in the first instance, with three planned phases of the project to map out pathways locally, regionally and nationally, with the contract in question focussed on delivering the first of these phases (the core work package).

**2 Direct benefits of the project to collaborating parties**

AstraZeneca submitted that the benefit of this project (if completed) would be the existence of a validated dataset that mapped the patient pathway for breast cancer patients in the Scottish region health board. The owner of this dataset was the NHS region. The industry partners would not have access to the dataset and would only see aggregated summary reports based on the high level test questions once they were published in the public domain. The existence of the dataset allowed both the industry and healthcare provider to consider initiatives or research ideas in the future, that might benefit patients and future collaborators however any further activities would be delivered under separate agreements. This project did not have any facet that was dependent on a particular medicine being prescribed or being placed in treatment algorithms.

**3 Reference to patient benefits in the contract**

AstraZeneca submitted that the patient benefits that potentially would be available at the end of the project were outlined in the contract. However, to realise the benefits (as stated above), further activity would be needed beyond the scope of this project.

AstraZeneca submitted that in hindsight the vision for utilising the dataset being created and potential benefits for patients should have been communicated better in the contract, as the current wording could propagate confusion to the nature of the collaboration when read by third party observers.

In summary, AstraZeneca submitted that whilst this project demonstrated certain aspects of joint working; the NHS and industry pooling financial resources, the true nature of the collaboration, objective and proposed output of the project did not meet the criteria of joint working as set out in Clause 20.

As AstraZeneca mainly envisaged utilising the data

for research purposes in the future, once the project had been completed, it was its opinion that the collaboration fell under the scope of Clause 21; (i) it was providing funds to support research, iregione a validated dataset on the Scottish region health board breast cancer patient pathway and aggregated outcomes; (ii) by providing funding for the project there was not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

AstraZeneca also submitted that this project could not be considered to be a grant, due to the industry members being on the steering committee and hence being an integral part in delivering the activity. Neither was the collaboration a MEGS, as the output of this project did not enhance patient care, or benefit the NHS and maintain patient care, rather it provided a validated dataset and a theoretical future opportunity to improve or maintain patient care.

AstraZeneca, based on the above, refuted that there had been a breach of Clause 20 and Clause 9.1.

**COMMENTS FROM THE COMPLAINANT**

Firstly, the complainant confirmed that his/her notification to the PMCPA was indeed intended as a complaint and not to seek further information as speculated by AstraZeneca in its response.

The complainant apologised if he/she had misinterpreted or concluded anything. Deciphering the details and complexities of this project was difficult for an individual not connected with the project and with a layman scientific understanding.

The complainant was disappointed that AstraZeneca had chosen to appeal the Panel's rulings. The complainant addressed AstraZeneca's submission regarding three key aspects which set the project apart from the requirements of the definition of joint working.

**1 Project objectives and aims**

The complainant was unclear why AstraZeneca thought that a new agreement was needed – the protocol attached to the contract quite clearly laid out the schedule of the activity and also what was being supported by the money. Any new agreement would not necessarily be needed. In addition, this seemed irrelevant as it was the responsibility of the company to better understand the project from the outset and ensure any agreement put in place was appropriate. AstraZeneca also seemed to argue because the project was about creating a comprehensive cancer dataset it could not be considered a joint project. However, AstraZeneca had another joint working project registered on its website. The complainant alleged these projects both had similar objectives in setting up a database or creating a complete/robust e-registry.

The complainant noted AstraZeneca had explained that the Scottish region health board sought to provide equity in the collaboration with the four companies by choosing the ABPI to act as a representative body for the companies. The complainant understood the advice given by the ABPI was that it could not enter into a Joint Working agreement. Further detail was given in the Novartis response (Case AUTH/3043/6/18) and from the minutes of the ABPI Scotland Collaborations Group. The complainant alleged that it was unclear why the NHS group wished to partner with ABPI Scotland (as stated in Novartis response letter – no evidence was given to support ABPI SCG meeting (9 May 2017) minutes). It might simply have been that they anticipated complexities in trying to manage creating and signing four separate contracts with the companies. However, it was up to the industry partners to explain the valid and compliant ways in which the project could be supported rather than concede and rush to support through funding.

The complainant alleged that the ABPI did not appear to be a 'supporter' and stated in the contract that it was acting on behalf of the ABPI SCG which it stated was also known as 'the Group' – it later defined this group as being made up of the four named company supporters each paying a fee of £32,480.50. However, in the meeting minutes highlighted earlier, the ABPI SCG appeared to include many more companies (based on the company attendees and those who sent their apologies) and in addition in the Supporter Terms and Conditions Section 5 Fees – the wider ABPI SCG appeared to have provided an additional separate funding of £10,000. The meeting minutes stated 'Suggested that SCG use some of its residual funds to plug any funding gaps, if it meant project could proceed where otherwise it might not'. Based on the terminology used in the minutes, the complainant made an assumption that the companies which were members of this working group pooled funding into a central pot rather than this money coming from the ABPI itself. The use of the ABPI SCG to define two separate and distinct groups within the contract was confusing.

**2 Direct benefits of the project to collaborating parties**

The complainant stated that AstraZeneca appeared misguided in its interpretation of any requirement for Joint Working to have direct benefits of the project to collaborating parties – it stated that there would be a validated dataset for the Scottish region health board, that the industry partners would not have access to the data or preferential access before publication in the public domain. AstraZeneca appeared to argue that this could not be a joint working project because 'this project does not have any facet that is dependent on a particular medicine being prescribed or being placed in treatment algorithms'. The complainant did not accept this was a valid reason to appeal the Panel ruling nor that without these benefits to the industry partners it could not be joint working. Once again, the complainant referred to the 'Joint Working Project' posted on AstraZeneca's website. Furthermore, there could be broader more general benefits for industry partners which were reputational and could build on trust for the company in working with the NHS through Joint Working arrangements.

**3 Reference to patient benefits in the contract**

The complainant noted AstraZeneca's statement that there was no immediate or direct patient benefits and that this meant that it could not be considered as Joint Working Arrangements. The complainant did not believe this was a valid reason as there was no requirement for immediate or direct patient benefits in Joint Working arrangement requirements.

The complainant allowed that the Scottish region health board had laid out its protocol in a way which seemed to suggest that it might have considered the activity to be Joint Working – it had outlined the benefits to the Board, industry and to patients. Additionally, the Scottish region health board had also laid out the protocol to show the pooling of resources by highlighting what its monetary and benefit in kind contribution would be.

The complainant alleged that each of the companies appeared to have approached the defining of this activity within the ABPI Code in a different way. AstraZeneca suggested the arrangements should be considered under Clause 21 'Contracts between companies and institutions, organisations or associations of health professionals under which such institutions, organisations or associations provide any type of services on behalf of companies (or any other type of funding by the company not otherwise covered by the Code) are only allowed if such services (or other funding): - comply with Clause 19.1 or are provided for the purpose of supporting research'.

However, the complainant's understanding of this clause was that it was the institution, organisation or association which provided a service for the company – nowhere in the proposal or the contract did it suggest that the Scottish region health board was providing a service for AstraZeneca. The ABPI SCG meeting minutes provided in the Novartis submission (Case AUTH/3043/6/18) explained the background of the project was the frustration and the difficulty of accessing and utilising data and the lack of resources. It was unclear the significance of this statement in the minutes, but it did appear to hinge on a lack of resources to interrogate or manage the data that it had.

The complainant alleged that as in his/her original complaint he/she did not deny that it might be a worthwhile project, but it was the responsibility of the companies to comply with the ABPI Code and to ensure the correct and compliant procedures were followed and where necessary to advise NHS partners as to how something could be done compliantly.

**APPEAL BOARD RULING**

The Appeal Board noted that the complaint highlighted the ABPI news publication and tweet about the Scottish collaboration with four of its member companies (including AstraZeneca) in a named Scottish region cancer data project. The Appeal Board noted that the news article stated that 'A ground-breaking collaboration will use real-world data to investigate how well different cancer treatments really work, changing Scotland's approach to breast cancer research like never before.' The Appeal Board noted from the AstraZeneca representatives at the appeal that the communications should have been agreed by AstraZeneca and this had not been so. AstraZeneca submitted that it would not have approved the ABPI press release as issued.

The Appeal Board noted that Joint Working between the NHS and others and the pharmaceutical industry was defined by the Department of Health as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pooled skills, experience and/or resources for the joint development and implementation of patient centred projects and shared a commitment to successful delivery. This definition was reproduced in the supplementary information to Clause 20 Joint Working. The relevant supplementary information to Clause 20 described the features of Joint Working including that it must be for the benefit of patients, but it was expected that the arrangements would also benefit the NHS and the pharmaceutical company or companies involved. Clause 20 required a formal written agreement to be in place and an executive summary of the joint working agreement to be made publicly available before arrangements were implemented.

The Appeal Board noted the 'ABPI Joint Working A Quick Start Reference Guide for NHS and pharmaceutical industry partners' included a criteria checklist which stated, *inter alia*, that if the answer was no in response to any one of a list 10 questions then the project would not be a true Joint Working arrangement. The 10 questions included that 'The main benefit of the project is focused on the patient', 'There is a significant contribution of pooled resources (taking into account people, finance, equipment and time) from each of the parties involved', 'There is a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved' and 'Patient outcomes of the project will be measured and documented'. The Appeal Board noted that the guidance was not part of the Code or the supplementary information. It, nonetheless, provided helpful points for the companies to consider when assessing such arrangements. The relevant supplementary information noted that the ABPI Guidance referred to the requirements of the Code but went well beyond them.

The Appeal Board considered that the documents could have been better worded to more accurately reflect the arrangements and this included the information issued by the ABPI.

The Appeal Board noted that the four companies had each paid £32,480.50 and that the ABPI SCG had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. In the Appeal Board's view, the role of the ABPI did not preclude the arrangements being joint working. The Appeal Board noted that AstraZeneca's involvement in the steering committee was to monitor progress

and recommend five example test questions for use in validating the utility of the dataset.

The Appeal Board noted AstraZeneca's submission that the project fell within the requirements of Clause 21, that it was a contract to provide funding for the purpose of supporting research and queried whether that was indeed so. The Appeal Board noted that its role was solely to determine whether the activity at issue was joint working thereby triggering the requirement to publish an executive summary.

The Appeal Board noted that in its appeal AstraZeneca provided further and better particulars than had been provided to the Panel notably with regard to the vision for utilising the dataset resulting from Phase 1 and the potential benefit for patients, which AstraZeneca acknowledged could have been communicated better in the contract. AstraZeneca also commented on the misleading nature of the ABPI press release.

The Appeal Board noted that the whole project included features of joint working, namely, the pooling of industry and NHS resources to implement a project with outcomes listed in the protocol for the benefit of patients and the benefit of the NHS and the four companies involved including AstraZeneca; both the Scottish region health board and the four companies including AstraZeneca had made a significant financial contribution towards the project; and defined project outcomes were to be measured and documented. However, the Appeal Board noted that the protocol of agreement was limited to completing Phase 1. The outcomes of Phase 1 were a data dictionary, a data quality report and example epidemiological, clinical pathway and outcomes reports that would be aggregated and anonymised and only available to the companies when they had been published by the NHS region. Although referred to in the protocol, Phases 2 and 3 were not part of the current protocol of agreement and there was no agreement or obligation that the company would be involved in them.

The Appeal Board noted its comments above and considered that the benefits listed in the protocol in relation to patients and would only come about if Phases 2 and 3 were undertaken and completed; there was no patient centred benefit at the end of Phase 1. The purpose of Phase 1 and its outputs were data centred rather than patient centred. The Appeal Board considered that the arrangements at Phase 1 of the project in relation to the NHS region were not a joint working project and thus no executive summary of the written agreement needed to have been published before the arrangements were implemented. The Appeal Board ruled no breach of Clause 20 in this regard and consequently no breach of Clause 9.1 was ruled. The appeal on both points was successful.

During its consideration of this case the Appeal Board noted that the ABPI advice on joint working was last revised in 2008. In the Appeal Board's view, it would be helpful if such advice was revised. The type of project in the above case concerning data was increasing.

Following its completion of the consideration of the appeals in Case AUTH/3045/6/18 (Pfizer) and Case AUTH/3046/6/18, the Appeal Board noted that the respondent companies in Case AUTH/3043/6/18 (Novartis) and Case AUTH/3044/6/18 (Roche), had accepted the Panel's rulings of breaches of the Code and had not appealed. Pfizer had appealed Case AUTH/3045/6/18.

The Appeal Board agreed that Novartis and Roche should be contacted and informed of the outcome of the appeals in Case AUTH/3045/6/18 and Case AUTH/3046/6/18. The PMCPA Constitution and Procedure did not cover this unusual situation where more than one company was involved in the same set of circumstances and the Appeal Board had taken a different view to the Panel. Novartis and Roche should each be offered the opportunity to appeal out of time and the appeal process would operate in the usual way. The complainant should also be informed. The reports for Case AUTH/3043/6/18 and Case AUTH/3044/6/18 should be updated to reflect the situation and to cross refer to the cases which were successfully appealed. Roche declined the opportunity to appeal. Novartis appealed and the Appeal Board subsequently ruled no breach of Clauses 9.1 and 20.

**Complaint received** **5 June 2018**

**Case completed** **17 January 2019**