Delivering on the promise of real-world data to enhance patient care in a financially sustainable way

10th September 2017
To help address the challenges of the increasing complexity and concerns about the financial sustainability of cancer treatment we first need to understand how medicines are actually being used in clinical practice.

At ESMO this year, the Collaboration for Oncology Data in Europe (CODE) was officially launched. CODE represents a concerted, large-scale effort to collate data from cancer centres across Europe, to better understand the real-world use of anti-cancer medicines. Through the creation of the Oncology Data Network, it aims to provide up-to-date information to all those who are involved in improving the delivery of cancer care.

The CODE launch event brought together representatives and stakeholders from across the oncology community to outline the imperative driving the creation of CODE and a dedicated Oncology Data Network (ODN). Fittingly, since the ODN requires broad collaboration to realise its collective benefit, the tone of the event was one of lively and open discussion.

There’s no greater common aim in cancer treatment than to improve the lives of patients. Those cancer centres that join the Oncology Data Network will be able to contribute to this important initiative. The data collected will allow us to understand trends in cancer treatment, with a myriad of onward benefits – some of which are outlined in this report.

I hope you’ll take the time to read through this brief but informative summary of the event.

If you would like to know more about becoming a part of this initiative, please visit www.code-cancer.com

Professor David Kerr
Professor of Cancer Medicine, University of Oxford
Chair of CODE’s Clinical and Analytical Steering Committee (CASC)
Introduction

IQVIA formally launched CODE (the Collaboration for Oncology Data in Europe) at a well-attended event at the 2017 ESMO Congress.

The event was chaired by Professor David Kerr, Professor of Cancer Medicine at the University of Oxford. Combining insightful presentations from Robert Madelin, an independent health and data policy adviser and former European Commission’s Director General both for Health and for Data Research and Dr Ashley Woolmore, CODE Lead and Vice President, Head of European Data and Evidence Networks at IQVIA with lively engagement, the meeting featured discussions on a number of key areas relevant to oncology, and healthcare as a whole, today.

We would like to thank our speakers for their insights and the members of our expert audience who contributed so actively to the discussion.

Event Overview

The following is a broad overview of the themes and messages highlighted during the event:

The European Context
(Robert Madelin)

- The European Union has a significant role to play in addressing key challenges facing oncology care: The EU has a constitutionally assured mandate to invest in non-communicable diseases, systems and research, as well as a single market for data in Europe which protects data privacy.
- Regulation must take a balanced approach: In the creation of health policy and regulation there is a tension which needs to be addressed between enabling data-driven innovation that is good for health, and creating data rules that protect public privacy. Ultimately, there is an imperative in finding ways to work together to harness the potential of data to benefit the lives of patients and help address some of the greatest challenges facing health care in Europe.
- Public engagement is vital: Just as regulation is key to facilitating both innovation and protection of privacy, so is public engagement to establishing a sense of trust and shared endeavour.

The challenge of rapid innovation and the data gap (Ashley Woolmore)

- The extraordinary pace of innovation in recent years means that oncology treatment is becoming a very complex field, not just due to the volume and nature of products, but also the increasingly personalised nature of their usage.
- This wave of innovation is bringing improved and increased survivorship for patients; however, it is also triggering concerns around the sustainability of healthcare systems across Europe.
- There is a widely recognised ‘data gap’ that is growing because of this complexity, with oncologists unable to access real world, and up-to-date data to inform decisions. This gap is thought to contribute to significant variations in use of anti-cancer medicines across Europe and accordingly has an impact on quality of care.

Speakers and Panellists:

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<tr>
<th>Speaker/Panelist</th>
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<td>Professor David Kerr, CBE</td>
<td>Professor of Cancer Medicine, University of Oxford, Chair of CODE’s Clinical and Analytical Steering Committee (CASC)</td>
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<td>Robert Madelin</td>
<td>Chairman of FIPPA, former European Commission’s Director General for Health &amp; Consumer Policy and Communication Networks, Content &amp; Technology</td>
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<td>Dr. Ashley Woolmore</td>
<td>CODE Lead, Vice President, Head of European Data and Evidence Networks, IQVIA</td>
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<td>Professor Winald Gerritsen</td>
<td>Professor of Tumour Immunotherapy, Radboud University Medical Centre Nijmegen, Member of CODE’s Clinical and Analytical Steering Committee</td>
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<td>Richard Bergström</td>
<td>Head of Pharma, SICPA and former Director General of The European Federation of Pharmaceutical Industries and Associations (EFPIA)</td>
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By actually understanding, benchmarking, learning from each other and sharing data, CODE will make a contribution to delivering a consistency of treatment across Europe. Without inventing a new cancer drug, if we could deliver that which we know consistently, we would save thousands of lives in Europe every year. This may be the secret of CODE that will allow us to make a real difference.

Prof. David Kerr

In 2016, we asked five different hospitals in the Netherlands, “are you prescribing chemotherapy to prostate cancer patients?” There were centres who were giving it to every patient, and centres who were not giving it to any patients. We need to know what daily practice really is, because patients deserve to know that we have full information about what we are doing.

Prof. Winald Gerritsen

Event Overview

**CODE: Meeting the Challenge (Ashley Woolmore)**

- To address the above mentioned data gap and its implications, IQVIA initiated the Collaboration for Oncology Data in Europe (CODE) with the support of leading biopharmaceutical companies Merck, Pfizer, Bristol-Myers Squibb, Eli Lilly and Company, AstraZeneca and Amgen.

- CODE’s aim is to achieve two parallel and equally important objectives:
  - To address today’s information gap by providing timely information on anti-cancer medicine use back to the healthcare system
  - To facilitate new models of payment, which will help address the challenges of financial sustainability, via an efficient infrastructure that flexibly provides reliable, up-to-date information on how anti-cancer medicines are actually used in clinical practice

- CODE is supporting the creation of the Oncology Data Network (ODN). The ambition for the ODN is to provide timely information back to the healthcare system on anti-cancer medicine usage data for all types of cancer, all patients, and all treatment centres in Europe that wish to join.

- Privacy and data protection is paramount to this initiative. Significant time and resources have been invested in understanding data privacy requirements and the implications of regulations such as the General Data Protection Regulation. Rigorous multi-stage processes have been put in place to ensure that patient, physician and treatment centre privacy are protected.

**Highlights from Q&A and Panel Discussion**

Some themes of discussion emerged particularly strongly in the conversation between panellists and audience members. Together they:

- Agreed that, ‘the data gap’ was an established issue, with consequences for consistency and quality of care across Europe.
- Welcomed the initiative as a timely and necessary piece of work; looked for by every part of the healthcare system.
- Emphasised the importance of patient engagement and consultation.
- Considered that a collaborative approach to sharing data, with a vision of collective benefit was a convincing, compelling and motivating factor for patients as well as healthcare professionals.

**The Call to Collaborate**

Perhaps the most strongly emerging theme was the call from both the panel and the audience for collaboration.

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Prof. Winald Gerritsen

We have set a very ambitious goal and it can only be achieved through large-scale collaboration. Over the next 10 years, our aim is that all of the 2000 treatment centres across Europe who are treating today’s cancer patients, will choose to join the network. As the network grows over time, the value of the insights we can generate and the value of the network itself, increase substantially for everybody who joins.

Dr Ashley Woolmore

By actually understanding, benchmarking, learning from each other and sharing data, CODE will make a contribution to delivering a consistency of treatment across Europe. Without inventing a new cancer drug, if we could deliver that which we know consistently, we would save thousands of lives in Europe every year. This may be the secret of CODE that will allow us to make a real difference.

Prof. David Kerr
CODE for Health! Real-World Data for Better Patient Care: the EU context

Robert Madelin - Chairman of FIPRA, former European Commission’s Director General for Health & Consumer Policy and Communication Networks, Content & Technology

The event started with a keynote speech from Robert Madelin which covered the nature of healthcare policy in Europe and the reasons why it is well positioned to drive advances in data sharing for health. He discussed the intersection of health, data and innovation in Europe, and the importance not just of an ethical approach, but of the perception of ethics. Below are highlights from his presentation.

The EU has a significant role to play

The EU’s role encompasses investing in non-communicable diseases, healthcare systems and research with a mandate to have a single market for data in Europe which is very positive context for the CODE initiative. Mr Madelin went on to say that EU policy-makers understand that data can support quality of healthcare. “Key leading commissioners are putting forward positive policy ideas on data and health, with a vision of using data and the digital single market to transform health and healthcare”

Regulation must take a balanced approach

In discussing the challenges of regulation, Mr Madelin observed that, “with data we can make health into personalised medicine”, but that innovation can only take place – and can only reach patients - in a supportive regulatory environment. “We need regulation that enables health innovation to take place, resulting in benefits for patients.”

Global data rules have both the potential to facilitate trust and data sharing as well as to inhibit these. “Faced with possible benefits, regulators should first do no harm, and so here the prescription is, let’s not over-regulate,” said Mr Madelin, “Let’s not chill health-saving research and clinical practice. We have to ask, will global data rules enable trust and sharing, or inhibit it?”

Public engagement is vital

Policy support for innovation is driven by values, evidence and politics, but the public can be engaged in this kind of initiative. Ethical values need to be explicit, in order to create a sense that all those involved own a continuous ethical process around data and innovation. Mr Madelin said, “When rolling out data rules, the ethical concepts that should be emphasised are fairness, values and personal ethics. Human beings know we break rules. It is not enough to be compliant. Underlining the fact that solutions for breaches exist will help grow trust and respect for the rules.”

In closing, Mr Madelin challenged everyone in the audience to consider the role of the individual in creating an environment of trust and collaboration.
An introduction to CODE and the ODN: Connecting the European cancer community with data in new and powerful ways

Dr Ashley Woolmore - Vice President, Head of European Data and Evidence Networks, IQVIA

Dr Woolmore took the floor to formally launch the CODE initiative. His presentation provided an insight into CODE’s background and ambitious objectives, along with an update on progress to date. Below are highlights from his presentation.

Rapid innovation and the data gap: the challenge we face

The field of oncology today is characterised by an extraordinary volume and unprecedented pace of innovation. The vast increase in the range of anti-cancer medicines in recent years brings with it an additional level of complexity – as illustrated by the following slide taken from Dr Woolmore’s presentation.

This wave of innovation is bringing improved and increased survivorship for patients; however, it is also triggering concerns around consistency of treatment and the sustainability of healthcare systems. Dr Woolmore said, “This is the backdrop for CODE. Can a platform be developed to help address these challenges by allowing us to understand - in as near to real time as possible - how patients are currently treated in Europe?”

CODE and The ODN: Meeting the Challenge

In 2014 IQVIA initiated discussions with a range of stakeholders, resulting in the establishment of CODE - with the support of five founding biopharmaceutical members, Merck, Pfizer, Bristol-Myers Squibb, Eli Lilly and Company, AstraZeneca and Amgen.

CODE’s aim is to achieve two parallel and equally important objectives:

• To address today’s information gap by providing timely information on anti-cancer medicine use back to the healthcare system

• To facilitate new models of access, to help address the challenges of financial sustainability, via an efficient infrastructure that flexibly provides reliable, up-to-date information on how anti-cancer medicines are actually used in clinical practice

The Oncology Data Network will provide timely information back to the healthcare system about all anti-cancer medicines for all patients who are actually being treated, from all treatment centres who choose to join. CODE’s goal is to work with all 2000 cancer centres across Europe in the next 10 years. The technology to support this has already been developed.

On the scope of data that the ODN will collect, Dr Woolmore said “To pull off such an ambitious exercise requires a realistic approach regarding the data that can be gathered. Care has been taken to identify a dataset that focuses on collecting the key data points needed to understand the patient’s clinical profile and their use of anti-cancer medicines longitudinally and across care settings.”

Figure 1: The unprecedented pace of innovation in new anti-cancer medicines. Key In-Market and Investigational Agents for NSCLC
Privacy and Governance are paramount

In this work, privacy – for patients, physicians and treatment centre - is paramount. IQVIA has designed a complete system of progressive de-identification of patient information, to provide exactly this assurance.

A Clinical and Analytical Steering Committee (CASC) has been established to provide a clinical perspective on CODE’s activities and the way data is being analysed. The CASC members are leading clinical oncologists from around Europe with deep expertise in cancer care delivery and clinical practice. European groups, including those representing patients, oncology nurses and pharmacists, have also been involved, reflecting the multidisciplinary nature of oncology care.

The ODN offers significant benefits

Each centre that joins the ODN will receive the analytical tools to explore their own data in real time.

As more centres join the network, there will be a move beyond individual centres being able to look at their own patients, to a collective benefit. “We will start to be able to offer insights that come from the network itself. As the network grows over time, the value of those insights and the value of the network increase for everybody who joins,” said Dr Woolmore.

He continued, “If we are successful, the data we offer back to the healthcare system will be a stimulus for clinical reflection and a catalyst for increasing research. It will open the door to a new range of powerful insights to inform patient care.” Some examples of these are:

- Understanding the adoption and actual implementation of treatment guidelines
- Charting the speed and variation in adoption of novel agents and evolved regimens
- Highlighting variations in patient’s access to anti-cancer medicines
- Providing clear insights into variations in the practice and use of anti-cancer medicines
- Collectively, a stimulus for continued clinical research

“CODE has been working for more than two years to ensure that, when a piece of information comes into the system it knows exactly what it is, where it is coming from, what it means, and what its context is whilst still ensuring data privacy. In addition, unlike many other data collation projects, the technology underpinning the ODN allows for direct extraction from clinical systems, significantly reducing the burden on healthcare providers.”

In Dr Woolmore’s view, success will now be determined by the level of engagement that is achieved, “Can we gain your trust that this is an initiative that’s worthy of your support? I’m very excited about the next 18 months, which will determine whether our ambition in offering this to the oncology community will come to fruition.”

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"The defined data set is concise and specifically focused in order to maximise the effective delivery of this initiative. All data flowing into the system will be structured, and that’s key to making a difference in latency. CODE has been working for more than two years to ensure that, when a piece of information comes into the system it knows exactly what it is, where it is coming from, what it means, and what its context is whilst still ensuring data privacy. In addition, unlike many other data collation projects, the technology underpinning the ODN allows for direct extraction from clinical systems, significantly reducing the burden on healthcare providers.”

Dr Woolmore said, “The beautiful thing about the network and its up-to-date data is that it provides incredible flexibility. The ODN will support the healthcare system to adapt, innovate and refine different models of agreement and assess their ability to address the issues of financial sustainability.”

Information can also play a key role in helping address issues and challenges around financial sustainability. The ODN can help support the implementation of new payment agreements linked to the specific use of treatments. These would be negotiated between pricing and reimbursement authorities and the biopharmaceutical members of CODE, acting independently of one another.

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Patient engagement is vital

Prof. Ian Banks (ECCO, Patient Advisory Committee):

"I agree with previous comments from the panel that involvement with patients is absolutely essential. Industry has already learned the value of involving the right patient voice in the right way at the right time - the sooner the better."

"When the public health message is well communicated, patients will come on board. People have more altruism than we give them credit for."

Lydia Makaroff (Director, European Cancer Patient Coalition)

"ECPC have been engaged with CODE for the past year. When we were first approached, we had many questions regarding patient privacy and data protection, all of which have been met with frankness and willingness to engage in open dialogue."

"I'm really happy to see EuropaColon and the ECCO Patient Advisory Group invited here today too, because I think we need a really diverse set of patient interests represented if we're going to ensure that this project actually does what it says and works in the best interest of the patient."

Robert Madelin

"I agree. I think that it's implicit in the way the process is designed that the patient will be involved, through real-time feedback that enables the doctor to say, "we can tell you stuff that we couldn't tell you a year ago about how this treatment is being used elsewhere." I very much agree that patients are motivated when it's not just about better treatment for me. It's also about better treatment for the group."

Professor Kerr

"In terms of that specific challenge, to include the patients' voice as early as possible, I think we can and are responding to that."

The ODN has the potential to help inform Research and Clinical Trials

Q: Geoffrey Henning (Policy Director, EuropaColon)

"Around ESMO today I have heard it said that there are so many studies going on, we're never going to be able to recruit enough patients, but I'm also conscious that there are a number of countries across Europe where patients don't get treatment or access to trials. Could CODE contribute to a potential model for a completely changed approach to clinical trials, where these trials will recruit using genetic and other profile details of the patients, across countries? If so, trials might be filled from a database of patients whose profiles fit those required for the trial, rather than be recruited using the current methods."

A: Dr Woolmore

"The ODN has been designed with a very specific purpose, not as a broad research tool but can it be a catalyst for research? Absolutely. To recruit to clinical trials we need to understand where a patient is in their disease and treatment pathway. Oftentimes, as you say, it's complex. If the piece of the puzzle that we can offer is an up-to-date picture of patients in terms of their disease and in terms of their current and previous treatment, can that be a catalyst for research? I think that is an excellent idea."

A: Prof Winald Gerritsen

"As an example from the field of prostate cancer, patients usually receive a first line of hormonal treatment, and then move on to chemotherapy. After that, it is difficult to decide on the next kind of treatment. The field is heading towards molecular and immuno-profiling as a basis for the best follow-up treatment. By means of the ODN, insight regarding which hospitals are providing these kind of services and are making decisions based on this information will be generated. This can be helpful in providing information to patients."

A: Richard Bergström

"Questions relating to clinical trials and the wider potential of CODE should be treated with caution as it can be tempting for policymakers to try and squeeze all relevant and outstanding issues into one promising and professionally managed project."

"In terms of that specific challenge, to include the patients' voice as early as possible, I think we can and are responding to that."
Conclusions from the panel discussion

Prof. Kerr asked the panel for their key insights from the discussion:

Prof. Winald Gerritsen commented "It is absolutely true that there is a gap in our understanding. We hear a lot about new drugs and clinical trials but we hardly know whether it’s really reflecting in daily practice. We need more data available to understand what we are delivering.”

Richard Bergström explained why he thinks CODE is different to other initiatives. “I’ve been a policymaker and lobbyist for the pharma industry, and this is one of the strongest things I’ve picked up on, that everybody is asking for the same stuff, real-world data, real-world evidence.”

“CODE is one of the most powerful and professional initiatives I have seen, which is going to enable everyone to work differently. It’s going to unlock the industry’s willingness to work differently, to price things differently.”

“I have met so many health ministers and finance ministers that say, “We know that we have to spend more money on cancer care, but we don’t currently have sufficient visibility on how it is being spent”. So this is all about creating that visibility so that everybody can be doing the right things for all the patients of this world.”

Prof Marc Peeters commented on the potential benefits of CODE and the possibility for treatment centres to benchmark themselves against one another, allowing a demonstration of the inconsistencies of treatment across Europe. He stated that in every country, attempts are made to put in place guidelines; but in many cases, these are not being followed.

“If we have critical analysis of these data sets, I think that the care of the patients will become of higher quality in Europe.”

Robert Madelin observed how this initiative could have an impact on the cost vs. value debate. “In the clinic, the value will increase, because we have stronger and more transparent evidence. This could transform the dynamic of health policymaking.”

In concluding the discussion and the event, Prof. Kerr asked the audience to estimate how many different chemotherapy regimens are delivered in an average large comprehensive cancer centre.

After several participants ventured suggestions in the region of a few hundred regimens; he revealed that the numbers varied dramatically across different centres from those with a few hundred to some with several thousand.

"Despite a precise description of the regimen in a practice-changing paper in the New England Journal of Medicine, people don’t always follow it. This lack of adherence to guidelines implies significant variations in care and poorer outcomes for the patient.”

Prof. Kerr went on to thank the speakers and members of the audience, and finished by saying, “By actually understanding, benchmarking, learning from each other, and sharing data, CODE will make a contribution to delivering a consistency of treatment across Europe. Without inventing a new cancer drug, if we could deliver that which we know consistently, we would save thousands of lives in Europe every year. This may be the secret of CODE that will allow us to make a real difference.”

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