Access to real-world cancer data: challenges and opportunities to improve patient care and financial sustainability across Europe

Berlin, 22 February 2018
IQVIA formally launched CODE (the Collaboration for Oncology Data in Europe) and the Oncology Data Network (ODN) on 22 February 2018 at the German Cancer Congress 2018, which took place in CityCube Berlin.

The goal of the event was to explore the challenges and opportunities to improve patient care and financial sustainability across Europe. It brought together views from across the healthcare systems – including policy makers, payers, clinicians, patient organisations, industry experts, scientific associations and technical experts.

The event explored some of the challenges faced by the oncology community in Germany today. The participants heard presentations from Professor Frank Griesinger, Director of the Department of Haematology and Oncology at the Pius-Hospital and Dr Ashley Woolmore, CODE Lead and Vice President, Head of European Data and Evidence Networks at IQVIA.

The event also brought about active engagement between the event participants and panellists.

### Speakers and Panellists:

- **Professor Christian Buske**
  - Medical Director, University Hospital Ulm

- **Dr. Ashley Woolmore**
  - CODE Lead, Head of IQVIA European Data and Evidence Networks

- **Professor Dirk Arnold**
  - Head of Department of Oncology, Section Haematology & Palliative Care, Asklepios Klinik Altona

- **Professor Frank Griesinger**
  - Director, Department of Haematology and Oncology, Pius-Hospital Oldenburg

- **Tino Sorge**
  - Member, Bundestag, Member, Health Committee; Rapporteur for eHealth and Health Economy, Conservative Parliamentary Group

- **Professor Dr. h.c. Herbert Rebscher**
  - Managing Director, Institute for Health Economics and Healthcare Research (IGV research); former CEO, DAK (2004-2016)
Executive Summary

The rapid pace of innovation in medical oncology offers significant potential to improve treatment for cancer patients, yet little is known about how different anti-cancer medicines are used in today’s clinical practice. In this environment of increasing treatment complexity, there is an ever-growing need for clinicians to review information on a large scale, as well as analyse anti-cancer medicine usage in their own practice. This will help them identify treatment patterns in near real-time and gain valuable insight to help inform patient care.

The event explored the challenges faced in cancer care and the opportunities that having greater access to real-world data would bring.

The event included perspectives from a wide range of stakeholders – German policymakers and representatives from different organisations in the oncology community, clinicians from cancer treatment centres, and a representative from CODE.

There was a discussion around the extent to which information derived from clinical trials can be complemented by real-world data. Real-world data represents patients who do not necessarily fulfill clinical trial’s inclusion and exclusion criteria and therefore may not be represented in prospective clinical trial programmes.

The speakers and panellists emphasised the benefits of having access to real-world data. In their view, real-world data on the usage of anti-cancer medicines will help inform appropriate treatment options for patients. The speakers also stated that having access to European data would enable clinicians to understand how treatments are being carried out in other cancer patients with similar profiles.

There was a call to determine how real-life data can be analysed and evaluated to provide better insights into overall treatment costs and to help inform financing of cancer therapies.

The participants highlighted the need for a data collection system that does not create extra work for clinical teams – one that allows automated extraction from existing data system.

There was also a consensus that data protection and privacy are of utmost importance, and that there should be patient engagement to explain the safe usage of their data to establish trust.

An initiative such as CODE fulfills all these needs and provides complementary information to the data recorded in clinical cancer registries in Germany. A policy maker welcomed the CODE initiative as it would allow clinicians to easily access information on the use of anti-cancer medicines that they need to help inform research and clinical practice.

The speakers and panellists were supportive of the aims of CODE and the ODN, and welcomed the value that this Europe-wide collaborative network would bring to the broader oncology community in Germany. The participants endorsed the CODE initiative and offered to collaborate to achieve the target of recruiting 2,000 centres much earlier than 2026.

Key Highlights

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

**Real world data complements clinical trial data and is needed to help inform patient care (Professor Frank Griesinger)**

- In Germany today, oncologists are faced with challenges from not having access to adequate real world oncological data to inform patient care. Data derived from clinical trials do not reflect patients in clinical settings as many studies focus on narrowly defined patient types with particular profiles.
- Insights from real-world data on medication usage will complement data from clinical trials to help inform patient care in oncology.

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

- The unprecedented pace of innovation in new anti-cancer medicines brings with it an additional level of complexity in planning treatment strategies for patients.
- At the same time, there is a widely recognised ‘information gap’ where relatively little is known of the actual clinical use of anti-cancer drugs.
- Such complexity is also triggering concerns about the financial sustainability of the healthcare system across Europe.
CODE and the ODN as part of the solution (Dr. Ashley Woolmore)

- To address the above-mentioned concerns, IQVIA initiated CODE to collate information on the use of anti-cancer medicines for all cancers, all patients and all cancer treatment centres across Europe who want to join.
- CODE is building a co-operative data sharing network, the ODN, and aims to achieve two parallel and equally important objectives:
  - Address today’s information gap by providing timely information on anti-cancer medicine use back to the healthcare system
  - Facilitate new models of access, to address 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
- Each contributing centre gets access to the ODN’s HCP Analytics Offering, which provides a suite of standardised reports and benchmarking capabilities.
- Privacy, data protection and governance are paramount to this initiative. Significant time and resources have been invested in understanding data privacy requirements to ensure that the ODN adheres to current EU and national regulations and is designed in anticipation of the EU General Data Protection Regulation (GDPR).

Highlights from Q&A and panel discussion
Panelists and audience members were aligned on:
- The issues of lack of timely information on the use of anti-cancer medication in clinical practice and the need for real-world cancer data to help inform patient care.
- The importance of having data which is complementary to the data currently captured by the German clinical cancer registries.
- The importance of real-world data to inform agreements which reflect the value that innovative treatments bring.
- The need for a data collection system that does not create extra work for clinical teams, one that allows automated extraction from existing data systems.
- The importance of data protection and privacy.

Opportunities to generate knowledge to help inform patient care in oncology thanks to real-world data
Prof. Dr. Frank Griesinger, Department of Haematology and Oncology, Pius-Hospital Oldenburg

In his keynote speech, Professor Griesinger provided a clinical perspective on the importance of having access to oncological data to inform treatment decisions and the challenges that are faced by oncologists in Germany today.

He remarked that oncologists primarily aim to improve their patients’ survival length (reflected by the endpoints overall survival, OS, and progression free survival, PFS) and quality of life (reflected by the endpoint Quality of Life, QoL). The latter is particularly important in palliative cancer care, where the focus is on relieving symptoms and improving the quality of life for patients. Professor Griesinger questioned whether or not the PFS and OS endpoints from randomised clinical trials (RCTs) reflect real-life clinical setting.

Clinical trial data do not reflect patients in real-life situations

Based on an example of data derived from a clinical trial of patients with renal cell carcinoma, Professor Griesinger observed that “data from RCTs do not necessarily reflect the broad spectrum of patients in real-life situations.” Patients in real-life situations may not fulfil an RCT’s inclusion and exclusion criteria, and may therefore be precluded from participating in the study. This explains why the effects of new agents seen in RCTs might be different in the real-world situation.

Moreover, the clinical trial rates in certified cancer centres have decreased in recent years. This coincides with most RCTs having increasingly narrow inclusion criteria, and because of this, fewer patients qualify for these studies. It is more and more common for clinical studies to have increasingly more selective patient groups.

Real-world data complements clinical trial data and is needed to inform patient care

Professor Griesinger stressed that ‘real-world data is very important and helpful because it is more representative’ of a broad spectrum of patients. Real-world data complements data from clinical trials and may help to inform clinical decisions and patient care.

"In the age of precision medicine and combination therapies, oncologists no longer want to know whether treatment A is better than treatment B in a patient group. In light of the growing complexity, the question is instead ‘if treatment A truly modulates target X, how can we identify the patients who will benefit from this and which treatment combinations are effective?’"
Dr. Ashley Woolmore outlined the mission of CODE and the value it brings by understanding at a very large scale how anti-cancer medicines are used in clinical practice, and collating up-to-date trusted data.

Rapid innovation and the data gap: the challenge we face

Citing an example of the pipeline of new drugs against lung cancer, Dr. Woolmore remarked that there is an extraordinary volume and unprecedented pace of innovation in new anti-cancer medicines. This increase in the range of treatment options brings with it an additional level of complexity: multiple indications, sequential therapies, posology variations, combinations of innovative drugs. At the same time there is relatively little knowledge of actual clinical use of anti-cancer drugs. The financial implications of such complexity on the healthcare system are also particularly topical in Germany.

CODE and the ODN as part of the solution

This is the impetus behind the creation of CODE, which is a broad collaboration designed to be able to collate information on the use of anti-cancer medicines for all cancers, all patients and all cancer treatment centres across Europe who wish to join.

Building a co-operative data sharing network, the ODN, will enable the achievement of two parallel and equally important objectives:

- Address today’s information gap by providing timely information on anti-cancer medicine use back to the healthcare system
- Enable flexible payment agreements, to address financial sustainability which may improve access to innovation

Privacy and Governance are paramount

CODE has addressed data privacy by establishing that all data contributed will pass through a highly secure, multi-stage process to render the data non-identified and are aggregated before analyses are released. The ODN adheres to current EU and national regulations and is designed in anticipation of the EU GDPR.

Each contributing center gets access to the ODN’s HCP Analytics Portal offering customized reporting and benchmarking capabilities. The hospitals that join the network will gain insights into treatment patterns in their own centres and compare their data with information across their country or region using only non-identifiable data, while retaining control of their own data. An expert scientific committee, the Clinical and Analytical Steering Committee (CASC) has been established to provide clinical governance.

Call to join CODE and the ODN

Dr. Woolmore addressed the challenges in achieving this ambitious objective and highlighted the need to be selective in the types of data gathered in the early years. He stressed that the aim is to complement existing initiatives and have a minimal impact on everyday clinical life thanks to automated extraction from existing systems.

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Call to join CODE and the ODN

Dr Woolmore concluded his presentation with a call to join CODE and the ODN, to contribute and collectively benefit from the network. “With your help, we endeavour to achieve 2,000 participating centres across Europe by 2026. We have already made significant progress since the project initiated in 2016,” he added. “CODE aims to create an efficient, pragmatic way to gain powerful insights that can improve access to care and to be a catalyst for further clinical research,” he concluded.
Real-world cancer data is needed to help inform clinicians on suitable treatment options for patients

The speakers and panellists reflected on the challenges that oncologists face in clinical decision making. Real-world data can complement the information derived from clinical trials, which would represent the broader spectrum of patients in real-life situations. This is because patients in the ‘real world’ clinical settings can often be more diverse in terms of age, ethnicity, gender and have more comorbidities which may have an impact on the efficacy of a treatment.

They stressed the value of real-world cancer data in helping clinicians plan treatments that would suit the individual needs of patients and allow for treatment comparability.

At the same time, the clinician, Professor Dick Arnold highlighted the need to enhance data quality by ensuring a systematic inclusion of data, e.g., biomarker status.

"We need to ensure a systematic approach to inclusion of data. For example, clinicians need to include information such as molecular biomarkers so that we have good quality data from the data collection initiative."

Professor Frank Griesinger, Director, Department of Haematology and Oncology, Pius-Hospital Oldenburg

"Real-world data is very important and helpful because it is complementary with data from clinical trials. One of the main benefits of having real-world data is that it allows clinicians to identify adequate sub-population of patients for targeted therapies."

Professor Frank Griesinger, Director, Department of Haematology and Oncology, Pius-Hospital Oldenburg

"Understanding the genetics profile of cancer is crucial. When collecting patient’s data, molecular data such as biomarker status should be incorporated as this level of data depth is necessary to tailor treatments for patients."

The lack of timely information on the use of anti-cancer medicines in clinical practice to inform patient care raised a need for an initiative that could address this issue.

Professor Dr. h.c. Herbert Rebscher, Managing Director, Institute for Health Economics and Healthcare Research

"We need to focus on the added value that a project such as CODE aims to create. We are unable to derive meaningful information from clinical trials – how these therapies are actually used and what patient-oriented benefits they bring. There are outstanding questions that call for more care research."

Professor Dirk Arnold, Chief Physician, Haematology and Internal Oncology at the Asklepios Klinik Altona

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Herbert Rebscher stated that there are currently fewer patient cases that clinicians could look into to derive meaningful insights into treatment plans, as the diagnosis for each patient varies greatly due to the molecular differentiation of their tumours. It is therefore important to have access to a European data initiative to allow analyses into variation of treatment patterns in greater detail and derive meaningful insights into treatment plans and manage the transnational data protection standards.

"To access European data, you need an institution like IQVIA, which has experience with data protection regulations and issues, and stakeholders. We need an initiative such as CODE, which can provide a comparative European dimension in addition to the national and state cancer registries, to provide a basis for health care research."

"There are many good initiatives in Germany, but nothing is centralised and the data protection laws governing this data makes it difficult to access them for research. I therefore welcome CODE as an initiative that allows easy retrieval of data for clinicians. I endorse this initiative and believe that the target of including 2,000 centres will be achieved much earlier than 2026. If there is anything that policy-makers can do to help, we'd be happy to do it."

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Parliamentarian Tino Sorge provided an insight into how the sheer number of data initiatives in Germany and the data protection laws makes it a challenge to access data for research. It was stressed that CODE is a welcomed initiative as it allows clinicians to easily access and retrieve the data that they need to inform research and clinical practice.
Policy makers and payers need real-world insights to help inform financing of cancer treatments

Tino Sorge stated that policy makers rarely consider the overall costs of cancer care and instead tend to discuss therapy costs and financial stability from a short-sighted angle. He called for a revisit on how real-life data should be analysed so to provide them with better insights into the overall costs of cancer treatments.

**Tino Sorge, Member of the Bundestag; Health Committee, Rapporteur for Health Economy and Health Research of the Conservative Parliamentary Group**

“To what extent is real-time evaluation of data realistic when the type of documentation is so inconsistent? How does that work? What about the extra work for hospital staff when information has to be transmitted into various databases manually?”

Herbert Rebscher commented on the payer’s perspective on financing of cancer treatments, in which he suggested that real-world data could help support the identification of treatment patterns. This can be used to better predict and plan the need for resource and budgets to deliver optimum benefits for patients.

**Professor Dr. h.c. Herbert Rebscher, Managing Director, Institute for Health Economics and Healthcare Research**

“From a payer’s perspective, not everything can be reimbursed. Real-world data can reveal the superiority of certain diagnostics and/or therapies. Thus, financing could be based on these results. Specialist centres could receive upfront financing as a result of generating real-world data. In general, real-world data will help us identify suitable therapies.”

An efficient data collection system that allows automated extraction from hospital system and does not create extra work for clinical teams is pivotal

Q: Simon Kreuzfeldt, ICT Heidelberg

“To what extent is real-time evaluation of data realistic when the type of documentation is so inconsistent? How does that work? What about the extra work for hospital staff when information has to be transmitted into various databases manually?”

A: Dr. Ashley Woolmore, CODE Lead, Vice President, Head of IQVIA European Data and Evidence Networks

“The data collection process needs to be time and cost efficient. That is why we defined a very precise data set with structured information. CODE works with data system providers and uses the system the clinic already works with. Automation is enabled by working in partnership and customising the database for each participating centre. There is no impact on clinical teams who continue to input data into their clinical systems.”
Conclusion

The event saw a lively discussion between the panellists and the event participants debating the challenges and opportunities that the access to real-world data will bring. A summary of the key themes that emerged from the day are:

Real-world data is seen as a complementary source of information to the data derived from clinical trials, to support more informed treatment decisions and better patient care.

The oncology community saw the value in an initiative that could address the lack of timely information on the use of anti-cancer medicines to allow treatment comparability and planning.

Oncology professionals highlighted the need to have access to data that is complementary to the data recorded in clinical cancer registries in Germany. Although cancer registries offer data that is representative of the population, the registries do not have the same depth of data to help inform clinical decisions.

The speakers and panellists welcomed the information derived from the ODN as a complementary source of information, which will provide more in-depth real-world information that will help clinicians understand how treatments are being used in other cancer patients with similar profiles.

It was agreed that there is a need for a data collection initiative that allows easy retrieval of data, fulfils data protection regulations, data privacy issues and allows easy access for clinicians.

Real-world data could help support the identification of treatment patterns. This can be used to better predict and plan the need for resource and budgets to deliver optimum benefits for patients.

Healthcare providers need an automated data collection system that does not create additional work to the clinical team, from data entry through to data extraction.

Data protection and privacy are paramount and it’s important to engage with patients to explain that their data is used safely and protected. The speakers and the panellists were supportive of the aims of CODE and the ODN and believed that the Europe-wide collaboration would provide a significant contribution to cancer care in Germany.
Find out more at www.code-cancer.com

To register your interest in joining the Oncology Data Network, email CODE Country Lead Germany Thorsten Dusberger at thorsten.dusberger@iqvia.com