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Commentary

The Oncology Data Network (ODN): A Collaborative European Data-Sharing Platform to Inform Cancer Care

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Disclosures of potential conflicts of interest may be found at the end of this article.

The Challenges of Precision Cancer Medicine

In a relatively short space of time, daily practice in oncology has changed almost beyond recognition. Only 20 years ago, it would have been difficult to imagine the scale and pace of the progress that has been achieved. Increasingly specific diagnostics and unprecedented acceleration in the development of innovative new therapies have opened up a myriad of new treatment options [1]. At the same time, there is growing evidence that cancer is a generic term for thousands of distinct and rare diseases [2], with exemplars like breast cancer, for which 11 genetically distinct disease types have been identified [3]. Collectively, these insights and innovations are driving the need for a highly personalized approach to treatment, which is transforming routine practice and brightening the outlook for people with cancer globally [4]. Across all cancers, long-term patient survival now exceeds 50% in many developed countries [5].

But progress like this brings its own challenges. The dramatic expansion of therapeutic options and the rise of precision oncology have made clinical decision making far more complex than ever before. Although oncologists are guided by a number of best practice recommendations underpinned by formal research, they face the everyday challenge of interpreting and implementing these guidelines within the diverse and heterogenous real world, where individual patient characteristics often do not match those in defined clinical trial populations. Inevitably, day-to-day clinical decisions are influenced by personal experience and that of close contacts or an immediate peer group—sometimes on the basis of very small numbers of patients within a particular disease subtype. This, in turn, has given rise to notable variations in practice, with implications for quality of care [6, 7]. Such variations are also driven by differing national cancer care programs, which have evolved through localized perspectives.

Meanwhile, the number of patients with a diagnosis of cancer is rising inexorably. A 10% increase in cancer incidence is expected over the next 15 years in Europe [8], and greater cancer survival beyond primary treatment means patients are often living long enough to require further interventions down the line. Furthermore, innovation is expensive; increasing pressure on health care budgets is challenging financial sustainability, which in turn may limit patient access to the treatments most likely to benefit them [9, 10].

Urgent questions need to be answered. How can oncologists ensure they are using the novel and costly treatments now at their disposal in the most optimal way? How can they address variations in practice? How can they identify the best treatment approaches for particular biomarker-defined subgroups? How can they efficiently identify new priorities for clinical research in an increasingly crowded research arena? How can they balance the desire to sustain innovation with the need to deliver better value cancer care?

Vital clues to how to answer these questions can be found within real-world data (i.e., the huge volume of data on the day-to-day use of cancer medicines residing in sources outside of formal clinical trials). The untapped potential of real-world data has long been recognized [11, 12], but practical hurdles to efficient data capture and concerns about issues like validity, comparability, bias, and data protection have stood in the way [13, 14]. Although daunting, these challenges are not insurmountable. The solution must lie in collaborative data sharing, supported by technological innovation.

A range of real-world data initiatives are already under way. These include cancer registries that typically focus on specific malignancies. Although registry capabilities are evolving, many are still focused on elucidating epidemiology [15], and, although they play a valuable role, they are not set up to generate insights across the board at speed. Other initiatives

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take a broader focus but depend on manpower for data extraction, data analysis, or both [16]. The geographical scope varies and some notable ventures are U.S. centric [17–19]. Many have time-limited funding. Many require sites to modify or adapt their current information technology systems and infrastructures. Significantly, there is almost always a time lag between data capture and the availability of validated, aggregated analyses [16].

However, technology has now advanced to the point at which data from diverse and fragmented clinical systems can be collated without the need for manual intervention and can be validated, rendered nonidentified, aggregated, translated into a "common language," and analyzed in close to real time. This opens the door to a major new opportunity: an opportunity for true collective learning. By coming together from across Europe to share data on daily clinical decision making within a robust and centralized framework, a mechanism is created that enables the clinical community to keep on top of the vast amount of change and to access, at speed, potentially practice-changing insights from an immeasurably greater network than their own personal peer groups. The Oncology Data Network (ODN) has been established to deliver the practical reality of this vision. It is a fully cooperative, collaborative data-sharing European network providing near real-time information on cancer medicine usage at scale.

The ODN Captures Big Data to Meet the Challenges of Precision Cancer Medicine

Creation of the ODN was supported by the Collaboration for Oncology Data in Europe, a multistakeholder, multidisciplinary initiative that was established in 2017 by human data science company IQVIA (Durham, NC; formerly QuintilesIMS), with the backing of leading biopharmaceutical companies. The key features of the ODN are summarized in Table 1. Data on cancer medicine use are collated through technology-enabled automation direct from participating hospitals' existing systems. A "common data model" translates data from diverse sources into a common language enabling direct comparability via an automated regimen mapping algorithm.

A data-sharing platform of the size, scale, and ambition of the ODN could deliver a wide range of clinically relevant benefits: (a) insights from ODN analyses may enable clinicians to reflect on their current practice at a "big picture" level; compare their own clinical decision making with that of their peers in privacy-protecting ways locally, regionally, nationally, and internationally; carry out assessments comparing real-world treatment regimens with those recommended by best practice guidelines; and benchmark clinical endpoints against other institutions to drive up quality. (b) The network may offer an agile way for participating sites to connect and set up new collaborations, both at scale and within special interest subgroups (e.g., groups focused on specific tumors or genotypes). (c) ODN analyses could help inform policy making within oncology by providing regulators with clinical context for new drug candidates and insights on real-world use of postapproval products. In addition to using data from randomized controlled trials, decision-makers are increasingly valuing robust, dependable real-world data analyses when considering the role and value of particular treatments and when formulating clinical guidelines [20, 21]. (d) The ODN has the potential to stimulate and catalyze research in numerous ways. For example, it could be used to shed light on parameters such as the case mix, speed of adoption and performance of novel medicines, and the anecdotal use of therapies in rare tumor types and defined subgroups. It could

Table 1. Features of the ODN

Scale	Any oncology treatment center in Europe may join the Oncology Data Network (ODN) free of charge and may contribute data for any patient and any cancer type
	Built for the long term, the ODN dataset is amenable to expansion and responsive to emergent needs
Speed	Validated, aggregated analyses are made available to contributors in near real time, ensuring they reflect current practice
	Contributors are able to access a suite of versatile, intuitive tools allowing in-depth exploration of their own practice, benchmarking against others, tracking over time, and an ability to store and repeat analytics
Comparability	Irrespective of its source or configuration, the ODN accepts data capture in ways that make sense to each center, then translates the data in auditable ways into a common language (common data model) to allow comparability across the community of practice
	The ODN maintains comprehensive central catalogs (e.g. of cancer types and treatment regimens) to ensure that reference data are kept up to date based on emerging practice and evidence
Security	The ODN is fundamentally committed to protecting the privacy of individual patients and healthcare professionals. Fully aligned with both General Data Protection Regulation and national regulations, the architecture of the platform was built following the principles of "data protection by design"
	All contributed data are rendered nonidentified through a validated multistage process
	The ODN platform has undergone extensive security checks to safeguard data from unauthorized access and has been tested and certified by an independent industry-accredited security company
Efficiency	Technology-enabled collation of information direct from clinical systems—and automated daily transmission to an independent approved data center—ensures seamless integration and minimum disruption to existing hospital processes
	Joining the ODN may ultimately reduce the burden of manual data entry onto different platforms within individual sites and may help sites improve data quality
Integrity	Robust, transparent governance by expert committees at both European and country levels guides the conduct of the initiative both scientifically and ethically and ensures outputs are of optimal value centrally and locally
	Defined processes are in place for making outputs available to the entire oncology community and to ensure insights are never deployed for marketing, promotional, or insurance purposes, but always in the interests of patient care.

Table 2. Data set parameters included in the ODN

Patient Attributes	Disease	Regimen	Timeframe	Geography
Weight and body surface area	Primary cancer diagnosis	Reference standards	Cycle duration	Comparing across ODN
Age range	Histology and morphology	Cancer medicines	Prior month	Center-level[a]
Gender	Biomarker	Line of therapy, cycle, and dosing	Prior quarter	Region(s), national
Performance status	Stage	Local regimen variations	Prior year	Country peer group
	Date of death		Monthly	
			Multiyear	
			Regimen duration	
			Cycle duration	

[a]Nonidentified patient-level information is only available to the individual centers.
Abbreviation: ODN, Oncology Data Network.

enable observational-type studies to be carried out quickly and cost-effectively. It could also facilitate recruitment for clinical trials by identifying sites that have potentially eligible patients. (e) Finally, ODN insights on the real-world use and benefits of cancer medicines may enable flexible, value-based payment agreements to be put in place, which will help to safeguard long-term financial sustainability without disincentivizing innovation.

ODN Progress to Date

The ODN's long-term vision is highly ambitious. To realize this ambition, a pragmatic, focused approach to building the network has been taken:

Geographic reach: the ODN has been initially established across more than seven countries (including Austria, Belgium, England, France, Germany, The Netherlands, and Spain). The intention was to start in a focused way to maximize the chances of success, but the ultimate objective is to expand across Europe.

Data set: a concise initial data set, focusing on the key parameters that describe cancer medicine use, has been defined (Table 2). However, this is likely to expand and evolve once the backbone of the platform has been established. In addition, the value of the data fields summarized in Table 2 is being extended through a collaboration with the European CanCer Organisation, which has identified "pragmatic" outcome metrics in cancer care that can be measured at scale in routine clinical care. These include parameters such as duration of therapy and early discontinuation.

As of July 2019, 119 cancer centers have joined the ODN, representing approximately 83,000 patients receiving active cancer medical treatment. The infrastructure is in place, prospective data are being collated, and analyses have been successfully generated in close to real time. Participating sites are already benefiting from the ability to interrogate their own data, and comparative analyses across centers and countries are expected to be available toward the end of 2019.

Conclusion: A Call to Collaborate

Only by pooling their routine clinical experiences can oncologists generate the statistical power to validate specific therapeutic approaches within each of the distinct and rare conditions they treat [22]. In a recent white paper, the European Organisation for Research and Treatment of Cancer and the BioMed Alliance called for "an integrated pan-European infrastructure to support the use of patient data for health research" [23]. There is also strong global interest in the concept of a "learning health care system" in which knowledge accumulates as a direct byproduct of ongoing patient care [19].

The ODN offers Europe's cancer centers the opportunity to collaboratively fill the information gap that is preventing full optimization of routine cancer care—and to collectively benefit from the outputs. By revealing how cancer medicines are actually used in daily practice across Europe, ODN insights will help demonstrate the benefit that innovative treatments bring to patients in the real world while broadening the opportunity for individual patients to receive the therapies most likely to benefit them. Once mature, the size, reach, and statistical power of the ODN should provide the most inclusive and extensive picture of real-world cancer care across Europe to date—and every center that joins helps the network to grow, increasing its impact for all members and ultimately for the wider oncology community.

Acknowledgments

All authors receive a fee from IQVIA for participation in the Clinical and Analytical Steering Committee of the Collaboration for Oncology Data in Europe.

Disclosures

David Kerr: IQVIA (C/A); **Dirk Arnold:** Bayer, Biocompatibles, Bristol-Myers Squibb, Merck Serono, Eli Lilly & Co, Roche, Sanofi, Servier, Sirtex (H, SAB), Amgen (H), IQVIA (SAB); **Jean-Yves Blay:** IQVIA (RF, C/A, H); **Christian Buske:** Janssen, Roche, Celltrion, Hexal (C/A), Janssen, Roche, Pfizer, Celltrion, Hexal, Abbvie (H), Janssen, Roche, Bayer (RF), Roche (Other); **Marc Peeters:** Amgen, Bayer, IQVIA, Ipsen, Remedus, Sanofi, Servier, Sirtex, Terumo (C/A). The other authors indicated no financial relationships.

(C/A) Consulting/advisory relationship; (RF) Research funding; (E) Employment; (ET) Expert testimony; (H) Honoraria received; (OI) Ownership interests; (IP) Intellectual property rights/inventor/patent holder; (SAB) Scientific advisory board

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