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Commentary

The Oncology Data Network (ODN): Methodology, Challenges, and Achievements

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Introduction

The Oncology Data Network (ODN) is a cooperative collaborative European data-sharing platform providing near real-time information on cancer medicine usage at scale. Its rationale and vision were described in a recent Commentary [1]. Figure 1 summarizes recent advances in oncology and the consequent emergence of significant new challenges that the ODN seeks to address.

Faced with these challenges, recognition is growing that the oncology community needs to share information on its daily decision making. By pooling routine clinical experiences, validation of specific therapeutic approaches within each cancer subtype will become achievable [2]. Professional associations, regulatory agencies, research institutions, and health economists are increasingly focusing on real-world data (RWD) as a powerful tool for tackling clinical and policy-related challenges [3–5]. In rare diseases, which we now know the field of oncology exemplifies, RWD is particularly important because the feasibility of conventional trials diminishes when eligible patient populations shrink [6]. A recent publication stated that RWD enables "crucial insights into quality of care and effectiveness" [7]. In addition, insights gained from the ODN could help quantify the value each treatment brings, paving the way for new value-based pricing models [8]. Importantly, the ODN could also expedite clinical research by providing an efficient means of searching for specific characteristics of nonidentified patients. In turn, this would trigger a mechanism to alert relevant sites that they have potentially eligible trial candidates.

To overcome the limitations in scope, scale, manpower requirements, practicality, and speed inherent to other RWD initiatives [1], the human data science company IQVIA established the Collaboration for Oncology Data in Europe (CODE), which in turn supported creation of the ODN. Measures have been implemented to ensure that ODN-derived insights are deployed in the interests of patient care and public benefit and never for direct promotional or insurance purposes. Open to all European cancer centers, all patients with cancer, and all cancer types, the ODN aims to create an extensive infrastructure of real-world cancer care information. This article describes the ODN's methodological approaches, challenges encountered, and achievements so far.

Scale of the ODN

Because a fundamental aim of the ODN was to establish a real-world collaborative infrastructure empowered to inform precision medicine, inclusivity and reach were critically important. As of October 2019, the ODN is established across over seven European countries (including Austria, Belgium, England, France, Germany, The Netherlands, and Spain). A total of 124 cancer centers, caring for an estimated 92,000 patients annually, have joined the ODN, which continues to grow. A network of independent, highly secure data centers is in place and contracts are being executed with ODN member sites. A European Data Warehouse in France acts as the central repository for collated nonidentified information. However, achieving a critical mass of contributors has proved challenging. First, securing commitment from centers to join a new venture tends to gain momentum only when it is already popular. Second, there has often been no single decision maker within hospitals, many of which have required extensive internal consultation before joining. Early joiners have therefore played an important role in catalyzing the ODN's growth, as have those involved in its governance.

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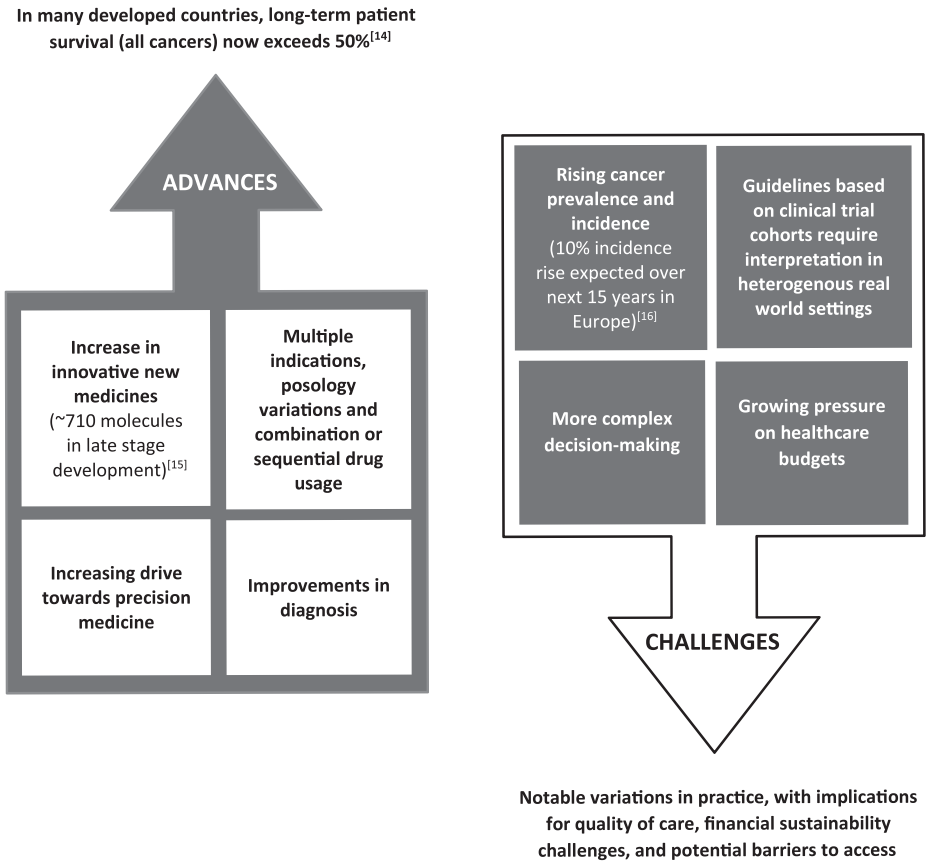

Figure 1. Recent advances and current challenges in oncology. Sources: Lawler et al. [14], Aitken et al. [15], Eggermont et al. [16].

Data Set

To fulfill the ambitious objective of delivering continuous analyses of European oncology practice within only 24 hours from "clinic to insight," and in accordance with the European Union (EU) General Data Protection Regulation (GDPR), which states that data collection should be limited to the minimum information required [9], the initial data set has been kept concise and focuses on cancer medicine use (excluding supportive care drugs). However, certain insights relating to outcomes were also envisaged. In 2018, CODE partnered with the European CanCer Organisation on a project designed to identify a set of "pragmatic" real-world metrics in cancer care that are readily measurable at scale with existing clinical systems [10]. Some of these pragmatic outcomes, such as duration of therapy, treatment interval, and early discontinuation, are already accessible via the ODN.

Data Extraction

In extracting data, the ODN has achieved three key aims: (a) to unify and integrate the fragmented data set across hospitals, (b) to use technology-enabled automation to minimize the impact on hospital resources, and (c) to work seamlessly with existing hospital systems, preserving sites' ability to use their existing information technology setups. Whenever clinical data at sites is updated, corrected, or enhanced, ODN data is amended accordingly.

Data Protection

To protect the privacy of individuals and to safeguard data security, the platform's architecture followed the principles of "data protection by design." A robust, reliable, and proprietary technology platform called CoTrack was built and privacy ensured through the following information governance measures:

- Data are rendered nonidentified through several stages of automated processing involving different secure computer algorithms.
- Each stage of processing is segregated using separate security zones.
- Nonidentified data is processed and stored in independent, highly secure data centers which are either certified by the local Data Protection Agency (DPA) and other government agencies according to individual country requirements or comply with industry security standards.
- All data centers are experienced with handling sensitive health care data.
- Individuals retain the right to control inclusion of their personal data, including the right to opt out.
- Analytics reports are created using only fully processed, nonidentified, aggregated data (from at least five patients).

As one of the first new initiatives to fall under GDPR, the ODN has been at the forefront of the steep learning curve on how best to align with the new regulations. Intensive collaboration with authorities and stakeholders has

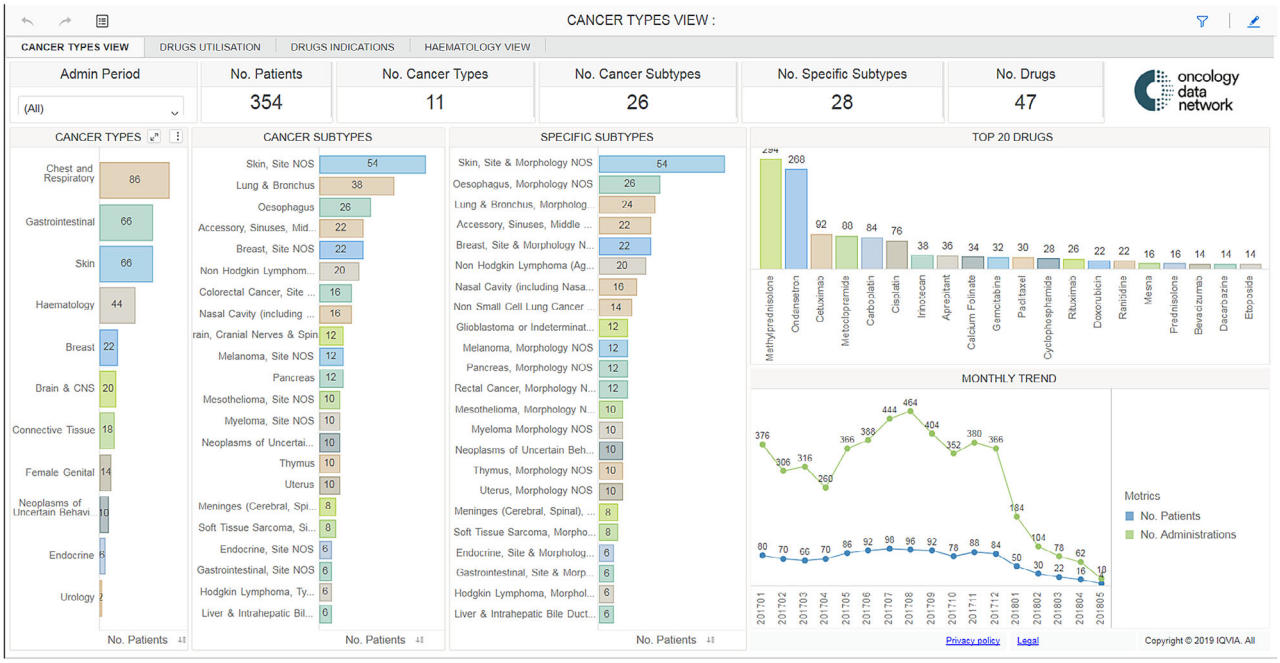

Figure 2. Screen capture of analytic output (from dummy data).

made the journey a lengthy one. A key milestone was the granting of authorization by the French Commission National de l'Informatique et des Libertés (CNIL), the only European authority that formally approves data platforms, which viewed the ODN as "in the public interest" and confirmed that its data protection measures are robust. In addition, "penetration testing" has confirmed the low risk of cyber attacks on ODN data centers by both outsiders and insiders, as well as the robustness of the techniques used to render the data nonidentified.

Data Comparability

To enable data aggregation and comparability, a Core Regimen Reference Library (CRRL) has been compiled. This has created a means of codifying treatment regimens used in clinical practice and mapping them against guidelines. The CRRL works with a "common data model" that translates data from diverse sources across Europe in auditable ways into a common language.

Analytical Capabilities

ODN member centers have access to a bespoke set of analytical tools and services via a user-friendly interface. This allows assessment of their own practices, benchmarking against others, tracking over time, and an ability to store and repeat analytics. Validated, aggregated ODN analyses, enabling comparisons locally, nationally, across Europe, and within specified subnetworks, are made available to contributors in near real time. This "low latency," which is believed to be unique to the ODN [11], ensures that insights can be obtained with the minimum of delay and factored into clinical teams' own review processes. Figure 2 provides an illustration (based on simulated data) of the analytical interface. Analytical capabilities are expected to become even more sophisticated as the network scales.

Information Access and Publications

The ODN has established an information access and publication policy (IAPP) for both commercial and noncommercial stakeholders, which governs all analytical requests. This includes formal procedures for review of all requests by the Clinical and Analytical Steering Committee (CASC); the review process has been established to be transparent, as the conclusions of their review of analytical requests will be published on the ODN web site. The IAPP also ensures recognition for centers whose data significantly contributes to published analyses.

The IAPP sets the different modalities for accessing information from the ODN:

- Centers that are members of the ODN have access to analyses of their own data at patient level and to aggregated analyses of their own data and nonidentified information across the Network in near-real time at no charge.
- There is also an analytical service available to the public and ODN members, in which stakeholders can submit a protocolized study request for customized information. There is a nominal administrative fee for these requests. Requests made through the analytical service are each reviewed by the CASC before they are accepted.
- The ODN is also committed to sharing insights with the general public and will publish information on the ODN Web site. The nature of the information made available is reviewed and approved by the CASC prior to publication.
- Commercial organizations can also request access to predetermined, aggregated analytical output for a fee.

In all cases, only analyses that have been agreed to serve a public benefit can be executed. This is in line with the overall information governance, privacy, and data protection approach that has been adopted by the ODN and approved by information authorities (notably, by the French national data protection authority, CNIL).

Table 1. Potential benefits of the ODN for each stakeholder group

Patients and advocates	Create opportunities for patients with cancer to be involved in research Support informed, effective, and efficient care Provide insights that support the work of patient advocacy groups
Oncologists	Enlighten local practice and adoption of innovative treatments Inform local, national, and international best practice Provide insights for personalized care, rare cancers and subpopulations
Oncology nurses	Reveal variations in care Provide insights that support treatment path conversations with colleagues Help patients see how their treatment compares with others with similar cancers
Clinical researchers	Link a particular patient population to upcoming clinical trials Identify new areas for research studies and publications Facilitate collaboration between network members
Pharmacists	Automate data collection and reporting processes Support efforts to optimize drug use and minimize wastage Help predict formulary needs
Hospital managers and executives	Reveal how cancer is being treated at own center Benchmark own center against other centers and best practice Facilitate better resource and budget planning
Payers and policymakers	Provide insights on pragmatic outcomes and real-world value of treatments Support efficient use of resources Support flexible payment agreements and continued investment in innovation

Information on the IAPP and how to request analyses is available on the ODN Web site (www.odn-cancer.com), along with information on how to contact the ODN to request further information.

Governance

Robust governance was key to ensuring that the work of the ODN is ethically and clinically aligned with the interests of patients and the broader oncology community, the methodology is scientifically robust, and outputs are of optimal value centrally and locally.

The CASC was established as the central governance body of the initiative. Originally, the CASC was a group of leading international oncologists, but the group has been expanded to include patient advocacy representation from the European Cancer Patients Coalition as well as a representative from the European Society of Oncology Pharmacy. Independent of IQVIA in its decision making, the CASC has authority on key issues, which applies to the initiative across Europe.

It is one of the mechanisms, in addition to IQVIA's internal governance, to ensure IQVIA operates within its established information governance (which in turn have been established with key information authorities, primarily CNIL) and permissions.

The CASC governs the ODN through the following:

- Analytical governance: ongoing oversight of data analyses, interpretation of information, and providing clinical context to analyses.
- Assessment of public benefit: reviewing parameters to ensure ODN analyses meet public interest requirements defined by public authorities.
- Public information release: ongoing oversight of publications and the information for the ODN Web site.
- Evolution of the ODN: such as overseeing deployment of research capabilities (e.g., support for candidate identification for studies).
- Connecting the ODN to EU-level bodies, initiatives and opportunities (e.g., European CanCer Organisation, European Cancer Patient Coalition, European Society of Oncology Pharmacy, Organisation of European Cancer Institutes).

In addition to the CASC, Country Advisory Groups, made up of a broad representation of oncology stakeholders, have been established to provide country-specific guidance on the establishment and operations of the ODN.

Conclusion

A recently published editorial states that "It remains critical for health care systems to expand their ability to provide prospective and real-time data that can fuel innovation and improve the quality of the cancer care that physicians deliver" [12]. This realization, coupled with the impetus for collaboration, gave rise to the ODN, which has had to overcome a range of formidable practical and logistical challenges. Examples of potential benefits for different sectors of the oncology community are shown in Table 1. Looking forward, the ODN aims to continue its growth and explore increased research applications. There is also an ambition to extend the data set, focusing on additional pragmatic outcomes. Aligned with the strong focus by the American Society of Clinical Oncology and the Institute of Medicine on "learning health systems" [13], the ODN, empowered especially by its low latency, should enable knowledge to accumulate as a direct benefit of ongoing patient care, creating a "living research machine" to guide future clinical practice, accelerate research, help realize the potential of precision medicine and drive innovation.

Disclosures

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(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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