McKinsey & Company

Pharmaceuticals & Medical Products Practice

Fulfilling the promise of advanced analytics in oncology

Advanced analytics will transform cancer care, but companies have been slow to adopt it. Progress requires a strategy that not only builds data and talent but also embraces experimentation.

by Taulant Bacaj, Cynthia Cozzetto, Olivier Leclerc, and Lydia The

April 2021

In recent years, dozens of large corporations and tech start-ups announced that they would deliver self-driving cars by 2020, thanks to the power of advanced analytics. It seemed like a daunting but plausible goal, as newer models already included semiautonomous features such as adaptive cruise control and driver-assist parking. But over time, we discovered, based on the massive amounts of data, machine-learning models, and expert engineers required, just how complex it is to build a fully autonomous vehicle. Nevertheless, while no company is producing self-driving cars on their assembly lines yet (due to the continual pushback of estimated delivery dates), it is only a matter of time.

In oncology, the story is much the same. We have read the exciting headlines predicting that big data and advanced analytics will transform cancer care and research and that all patients, thanks to machine learning, will soon receive personalized treatment plans. But progress has been arguably slower than initially envisioned.

However, without a doubt, important advances are being made. Researchers have built a model that can accurately predict molecular subtypes in head and neck cancers using radiomics, a machine-learning technique that can help identify, classify, and monitor solid tumors from CT, MRI, or PET scans, rather than relying entirely on radiographers and often-painful biopsies. Elsewhere, machine-learning models have outperformed board-certified dermatologists in identifying melanoma through image recognition.[1]

Yet most pharmaceutical companies still do not systematically apply advanced analytics to their work in oncology, even though it can deliver value[2] at every stage of the product life cycle, from research and early development to market access and commercialization (see sidebar, "The value of advanced analytics in oncology.") They do not, for instance, routinely analyze real-world evidence to identify additional indications for existing therapies—analysis that could prove particularly helpful in treating rare cancers where it is difficult and time intensive to find patients for a trial. And they are unable to use data to understand the full network of a patient's care team—specialists, primary-care providers, and sites of care. At a time when the COVID-19 pandemic has so hindered cancer care, think of the advances that might be made if companies could use such data to help oncologists keep abreast of the often-bewildering array of new combination therapies and targeted treatments, ensuring that patients receive the best standard of care based on their history, genetics, and biomarkers

Lack of talent is one reason why pharmaceutical companies are not making more progress applying advanced analytics to oncology—data scientists with expertise in oncology are few and far between. Lack of data is also an issue. But perhaps the biggest impediment is a culture that is suspicious of the kind of experimentation inherent in developing advanced-analytics capabilities. As a result, many companies are simply postponing a steep learning curve, as advanced analytics will, without doubt, come to play a huge role in cancer research and care, as well as pharmaceutical companies' success in oncology.

[1] Titus J. Brinker et al., "Deep learning outperformed 136 of 157 dermatologists in a head-to-head dermoscopic melanoma image classification task,"*European Journal of Cancer*, May 2019, Volume 113, pp. 47–54, ejcancer.com.
[2] "Seven lessons on how technology transformations can deliver value: McKinsey Global Survey results," March 11, 2021, McKinsey.com.

The value of advanced analytics in oncology

Advanced analytics has value across all segments of the product life cycle in oncology: research, development, manufacturing and the supply chain, and commercial.

Research

There are four areas where advanced analytics can raise the probability of identifying high-potential molecular candidates:

— *Disease drivers and targets.* Unsupervised learning (machine learning on data without a clear output or target variable) and network mapping can deepen understanding of disease drivers. It can help analyze complex phenotype data, for example, to drive innovation in personalized therapies.

— *Unmet medical need.* The analysis of claims and electronic-health-records (EHR) data can help identify unmet patient need, including for subtypes of patients, and therefore help prioritize research efforts.

— *Novel mechanisms of action.* With advanced analytics, organizations can move beyond historical methodologies of on/off single targets to predict network-perturbation effects and identify combination therapies or novel mechanisms of action (MOAs) for tumor subtypes that are driven by genetic lesions. Oncology uses combination therapies more than any other therapeutic area (TA), so predicting how different MOAs could be used together could be extremely powerful.

— *Safety and clinical transition.* Internal and public data, as well as in silico modeling, can be used to better predict safety profiles earlier in the discovery process. The analysis of large volumes of program-research data can help assess patient eligibility and response to therapy, for example, and molecular and network modeling can assess what the results of animal trials for immunotherapy might mean for clinical trials.

Development

During development, advanced analytics can boost the probability of success, enhance trial speed, and optimize costs.

— *Study concept.* Analytics can help companies make data-driven recommendations for the design of study protocols by understanding patients' clinical journeys and how they differ by geography, setting, and healthcare provider. They can, for example, size potential patient pools eligible for trial based on different treatment-related inclusion and exclusion criteria, then compare the outcome of different design choices—the trial time, its cost, and likely patient outcomes, for example.

— *Study setup.* Selecting suitable study sites is a critical factor in the successful development of any drug. Advanced analytics can help ensure that the best are selected. Analytics can help identify patient pools for each site and treating healthcare providers, for example, based on claims and EHR data, and rank sites in terms of attractiveness. Country-level data on time to enrollment, enrollment rates, and total patients enrolled can also guide site selection, while scenario analysis will reveal how specific site combinations could affect overall costs.

— *Execution.* Analytics can help predict the trial end date based on current performance or "what if" scenarios, such as missing the enrollment target. They can also optimize management of the trial budget by indicating how much will be needed at different stages.

— *Vigilance and safety.* Advanced analytics can help teams to continually refine risk-based monitoring metrics to detect deviations. They can also automate workflows, decreasing the time and effort required for manual tasks such as individual case processing and aggregate reporting.

Manufacturing

Advanced analytics can increase productivity and deliver value within manufacturing in five areas:

— *Procurement.* By centralizing and analyzing procurement data from across the company, teams can spot anomalies and rationalize costs.

— *Yield.* The cost of goods sold for oncology products—biologics and, in particular, antibody-drug conjugates (ADCs) and viral vectors—are significantly higher than those in other TAs. Monitoring and analyzing manufacturing parameters and sensor data raises productivity.

— *Personalization.* The cost of production of personalized therapies is high and the supply chain often complex. Chimeric antigen receptor (CAR) T-cell therapies are a case in point: a patient's cells are extracted in the clinic, dispatched to specialized labs where the treatment is manufactured, then sent back to the clinic to be administered, all under time

The value of advanced analytics in oncology (continued)

pressure and with strict quality control. By tracking and analyzing supply-chain data, companies can predict manufacturing needs and improve the scheduling of patient appointments. This reduces the cost of production and the potential risks, such as delays to patients' treatment.

— *Quality monitoring.* Analytics can help identify and trace the root cause of deviations, improving quality control and overall productivity.

Commercial activities

Advanced analytics offer a range of opportunities to optimize the commercial framework.

— *Healthcare-provider engagement and field-force deployment.* As treatments become more targeted, the number of physicians and healthcare providers involved in patient care rise. There are also more treatments to choose from, including immunotherapies, combination therapies, and mutation-targeted therapies. Against this backdrop, commercial organizations can deploy advanced analytics to map patients' clinical journeys and the choices made by their healthcare providers, offering advice where appropriate. And when real-world data, such as lab tests and results, are integrated, the analysis can identify high-impact moments of engagement, such as when a test shows disease progression.

— *Patient services.* Analysis of rich, integrated data that map each patient journey can reveal pain points such as treatment delays and therapy drop-off points, as well as outcomes, and can also show how they might relate to whether or not a patient receives support and what optimal support might look like. It can also reveal risk factors in relation to adherence and compliance.

Paving the way for advanced analytics in oncology

A management-aligned technology road map that makes clear the expected impact, timeline, and investment required to deliver on priority initiatives is the starting point for any successful advanced-analytics strategy, regardless of sector. Advanced analytics can cover a range of approaches, from statistical models to artificial intelligence (AI) and the deployment of machine-learning tools such as the neural networks used for image recognition. Analytics models can be built without a clear, strategic road map, but they won't necessarily give the business a leading edge or, of critical importance in the case of pharma companies, help patients. A strategic technology road map is the first of our six-component framework for successfully integrating digital and analytics technologies to create value,[3] the others being talent management and planning, an agile delivery model, data-strategy and data-management capabilities, technology capabilities, and the implementation of measures to drive adoption of a new operating model (Exhibit 1).

While all are key, we focus here on the elements that can prove particularly important in overcoming challenges in oncology, namely, building the right talent within the right organizational structure, kick-starting the program by leveraging existing data assets first, and embedding a culture that will speed adoption.

[3] "How top companies excel with digital and analytics: Six key areas to help senior executives manage a tech-enabled transformation," McKinsey Digital interactive, October 2019, McKinsey.com.

Exhibit 1

A six-component framework can successfully transform commercial analytics.

	1	2	3	4	5	6
What is needed	**Strategic road map:** a clear vision and priorities	**Talent:** a strong team with diverse skill sets (technical and business)	**Agile delivery:** ways of working efficiently across functions to deliver value	**Technology:** architecture to enable integration and deployment	**Data:** robust, integrated data assets with defined architecture and governance	**Adoption and scaling:** pilot, show value, and drive change and adoption
Lessons from experience	In the absence of an overall strategy, it is difficult to get senior leadership to align and commit to priority efforts	Analytics talent is hard to recruit, and some roles (eg, translators) require both business and technical knowledge to unlock value, making talent even more challenging to find	Most agree on principle to agile delivery, but few put it into practice; time commitment and team empowerment are the main friction points	Failure to link the technology road map to the overall strategy creates ongoing challenges	There are no perfect data sources or universal business rules; clear governance and leadership are needed to reduce the inevitable complex and seemingly unsolvable problems	Most pilots fail due to insufficient change management, which should be incorporated as early as possible

Build the right talent in the right organizational setup

Large, established pharmaceutical companies are not short of data scientists, but most of them work on commercial analytics, executing repetitious analyses such as performance reporting. If companies are to capture the full power of analytics, they will need to consider devoting specialist resources to different therapeutic areas (TAs). This is particularly important in oncology, which poses unique analytical challenges, such as integrating pharmaceutical and medical data, translating clinical markers, and building complex lines of therapy.

Finding such expertise is a tall order. It is rare to find talent with a strong technical background as well as a medical understanding of a disease area, the ability to link clinical guidelines to all manner of data in the patient journey, and the business sense to recognize and prioritize the most valuable insights.

Some companies might therefore turn to data-science companies and contractors to resource analytics projects and deliver insights fast. But if the aim is to establish a competitive advantage through advanced analytics in oncology, companies will probably need to build analytics excellence in-house. This, in turn, will require a strong talent-recruiting strategy that differentiates the cutting-edge role of analytics in the pharmaceutical industry—particularly oncology—and ensures well-defined career paths and growth opportunities.[4]

[4] Peter Bisson, Bryce Hall, Brian McCarthy, and Khaled Rifai, "Breaking away: The secrets to scaling analytics," May 22, 2018, McKinsey.com.

Another question to settle is whether these new data scientists should sit in a centralized analytics center of excellence, which provides platform services across the organization, or within the oncology division itself. Centralization versus decentralization is a much-debated design choice in all sorts of companies. Some opt for a centralized model to help ensure resources are used efficiently and data scientists learn from one another. Some prefer decentralization to keep data scientists more attuned to the needs of the business. And some strike a balance with a hybrid model. The size of the oncology portfolio could guide the choice. With a single oncology drug, the best option might be for analysts to sit within the business unit. With a larger portfolio, there could be benefits to them sitting within an oncology cell in a centralized analytics function to share and scale their knowledge.

Kick-start the program with existing data assets

Data needs for oncology use cases are more specialized than those for other TAs. For example, mapping a patient journey containing combination chemotherapies requires integrating medical, prescription, and laboratory-results data sets, while identifying later lines of therapy may require three or more years of patient-history data.

The quality, availability, and cost of oncology-specific data sets have undoubtedly improved over the past five years.[5] Yet, there is still a long way to go. Data remain relatively sparse, and sample sizes tend to be low, particularly for biomarker data due to the collection cost, potential errors in measurements, and the risks to patients when collecting specimens such as neural tissue.[6] Additionally, with the exception of electronic-medical-records (EMR) data, clinical data seldom include the outcomes of tests or procedures. Claims data, for example, exclude laboratory values and genomic test results.

Notwithstanding the pressing need, time should not be wasted waiting for perfect data. To kick-start the analytics program, pharmaceutical companies should identify and put to quick use as many existing data assets as possible—including those typically used for operations and standard reporting, which often get overlooked when it comes to supporting advanced analytics. Data on rebate cards, oncology practices and cohorts, and oncologists who have participated in clinical trials could all prove valuable.

At the same time, companies should look to acquire novel external data sets, including biomarker data and even data from digital-health monitors. Ultimately, they can combine existing and new data sets to reveal even more powerful insights, notwithstanding that new data assets can take time and most companies already have data that they consider "good enough."

As more data is incorporated and use cases proliferate, data governance becomes critical if the data are to be usable, accessible, and secure. This should include governance of top-level issues, such as who owns the overall data strategy, as well as of tactical issues, such as how to define data fields. Take the data field for physician affiliation, for example. Oncologists are often linked to several hospitals, clinics, and offices, which means the best definition of "affiliation" would depend on which question you are trying to answer: Where are oncologists seeing patients, where do sales reps interact with them, or through which entity do they order or bill for medications?

Change the culture

Even companies that build strong data-science teams and strong data assets can struggle to get new tools adopted. The problem is pervasive across sectors, but it can be more prevalent in life sciences, including pharmaceuticals, where the prevailing orthodoxy is that data and models must be perfect before being harnessed for decision making. That orthodoxy is correct when applying analytics to some areas within R&D, but there are plenty of other areas where a less-than-perfect analytical tool can be beneficial. Moreover, given how quickly standards of care can change and the complexity of different lines of therapy, companies will struggle to get off the starting line if they wait for perfection.

[5] Stephanie Carlton and Shubham Singhal, "The era of exponential improvement in healthcare?," May 14, 2019, McKinsey.com.
[6] Richard Mayeaux, "Biomarkers: Potential uses and limitations," *Neurotherapeutics*, April 2004, Volume 1, Number 2, pp. 182–8, link.springer.com.

Lack of transparency and training can also hamper adoption. Field teams handed a tool backed by complex models are often skeptical that it can outperform their years of institutional knowledge, particularly if the drivers of a recommendation are unclear, which is often the case with AI models. The skepticism is compounded if the tool also fails to make clear what action to take as a result of the analytics—a situation that is not uncommon.

Overcoming such issues requires a cultural change that embraces advanced analytics. Several actions can help drive one:

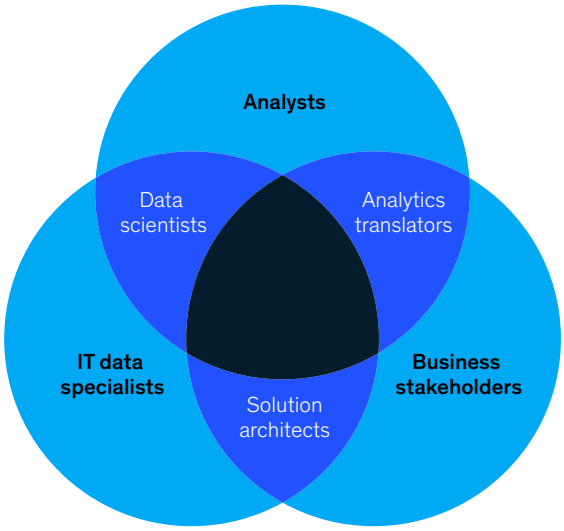
— *Change the way teams work.* Tools will only be adopted if the teams that build them are integrated, putting to use the expertise of data scientists, analytics translators, and business leaders.[7] Translators are the bridge between the technical knowledge of the data scientists and the operating expertise of business leadership. Their role is to ensure data scientists are going after the highest priority business problem and that the business will adopt new analytical tools by explaining their output and value. Teams also need to adopt agile ways of working, rapidly building solutions and testing and learning as they go, rather than striving for the perfect answer at the outset (Exhibit 2).

— *Identify quick wins.* To build enthusiasm, start with high-priority pilots that are not overly complex to conduct but that might deliver important insights. In development, that could be identifying patients eligible for a given protocol in each hospital in a region or country. For medical affairs, it might be understanding oncologists' treatment regimens in terms of dosage and duration with a view to improving them where appropriate.

Exhibit 2

Advanced analytics requires the support of several key roles, with translators being of critical importance.

Roles to support analytics strategy



— *Standardize.* Standardizing the way new projects are launched and their progress measured accelerates adoption across the organization, positioning them as continuous, ongoing efforts to build competitive advantage as opposed to one-off pilots.

[7] Nicolaus Henke, Jordan Levine, and Paul McInerney, "Analytics translator: The new must-have role," February 1, 2018, McKinsey.com.

Different companies will find themselves at different starting points, facing different challenges when considering an advanced-analytics strategy for oncology. Larger, established pharmaceutical companies will likely benefit from a wealth of internal data sets and more data scientists. On the other hand, they might struggle to shift a more deeply engrained, cautious culture. Smaller biotech companies are likely to be more agile and more attractive to data scientists and other technical experts. However, they will have fewer existing data assets; a smaller portfolio of products, each perhaps critical to the company's success, could also make them more averse to a new, advanced-analytics-led approach because of the perceived risk.

Scarcity of data is also a challenge for companies researching and developing treatments for rare cancers or therapies with small eligible populations. Particularly sophisticated statistical techniques will be required to derive valid insights from the data.

Whatever their circumstances, however, all pharmaceutical companies will need a strategy for applying advanced analytics to their work in oncology. Failure to establish one amounts to a decision not to participate in a technical development that is reshaping cancer care. Companies have a choice of whether to keep pace with the development or lead it, but falling behind is not an option.

Taulant Bacaj is an associate partner in McKinsey's Southern California office, where **Olivier Leclerc** is a senior partner; **Cynthia Cozzetto** is a consultant in the New York office; and **Lydia The** is a partner in the Silicon Valley office.

The authors wish to thank Björn Albrecht, Alex Davidson, Anas El Turabi, and Paul Gurney for their contributions to this article.

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