20 SENSE

THE 20SENSE REPORT

Spotlight on the Canadian Specialty Pharmaceutical Market

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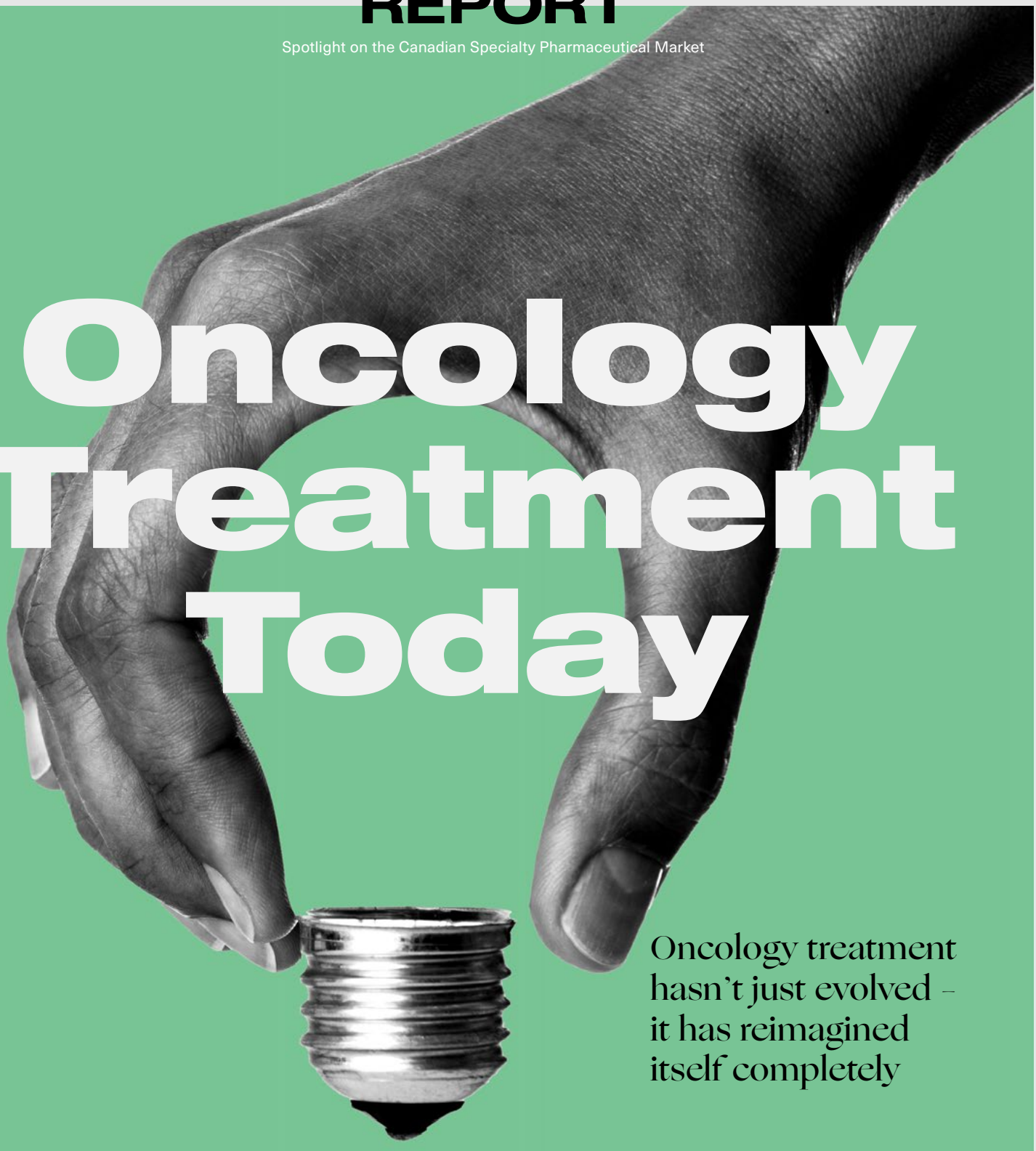


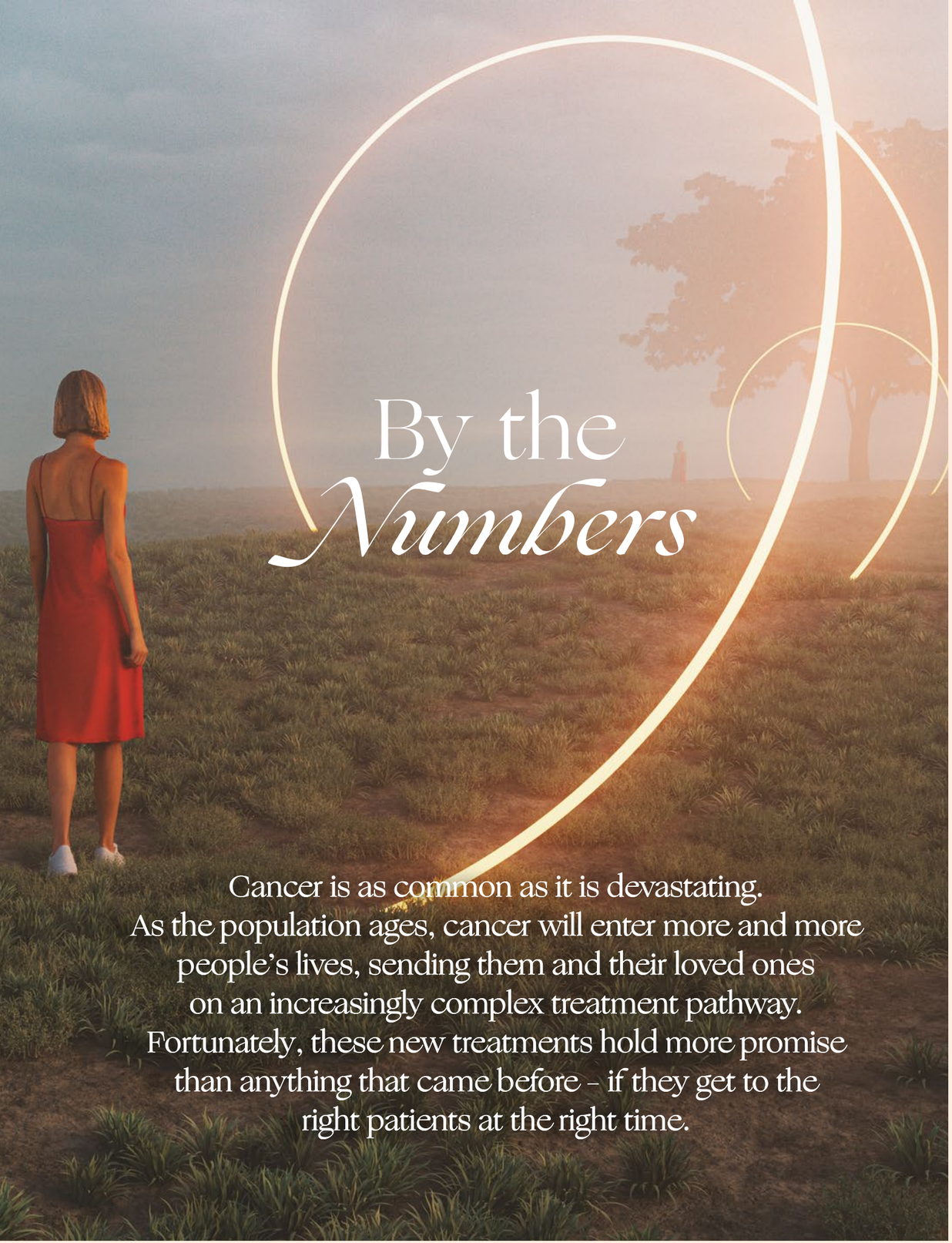
Oncology Treatment Today

Oncology treatment hasn't just evolved – it has reimagined itself completely

The numbers speak volumes. Innovation in oncology is taking place at a significant pace.

New oncology treatments are taking medical science to new heights and offering real hope to patients.

Dr. Parneet Cheema on how real-world evidence accelerates access to life-saving medications.



By the *Numbers*

Cancer is as common as it is devastating. As the population ages, cancer will enter more and more people's lives, sending them and their loved ones on an increasingly complex treatment pathway. Fortunately, these new treatments hold more promise than anything that came before – if they get to the right patients at the right time.

CANCER IN CANADA

50%

Nearly 1 in 2 Canadians will get a cancer diagnosis at some point in life, and about half of those diagnosed will die of the disease. These figures make cancer the leading cause of death in Canada.[1]

225,880

Number of new cancer cases that were anticipated in 2020 – about 617 per day.[2]

48%

Proportion of all new cancers attributed to the "big four": breast cancer (25% of new cancer cases in women), prostate cancer (20% of all new cancer cases in men), lung cancer (14%), and colorectal cancer (12%).[2]

20%

Decrease in the number of cancer surgeries performed in Canada from March to June 2020 compared to the same period in the previous year – a collateral effect of the COVID-19 pandemic.[3]

NONSTOP INNOVATION

35%

Oncology's share of the global 2020 medication pipeline (at all phases of clinical trials).[4]

15

Cancer drugs approved by Health Canada in 2020 (out of a total of 84 approved medications).[5, 29]

3

Precision oncology drugs approved by Health Canada in 2020: alpelisib, entrectinib, and tucatinib. [5, 29]

62

New cancer drugs launched in the US between 2015 and 2020, jointly covering 130 indications across 24 different tumour types.[6]

21

Number of precision oncology drugs approved by the FDA in the first half of 2021, a record.[7]

RISING COSTS

$164B

Global spending on oncology drugs in 2020, a figure expected to grow to $269 billion by 2025.[6]

$46.9B

Value of the global oncology precision medicine market alone in 2019, expected to triple (to $148.7 billion) by 2030.[8]

$3.9B

Sales of oncology drugs in Canada in 2019 – almost triple the $1.4 billion figure of 2010.[4]

14.6%

Oncology slice of the total Canadian drug-sales pie in 2019.[9]

37%

Share of oncology drug spend in Canada devoted to high-cost medicines (28-day treatment cost > $10,000) in 2019, up from just 7% in 2010.[10]

IMPROVED OUTCOMES

48%

Reduction in mortality from breast cancer since the peak rate in 1986.[11]

11 weeks

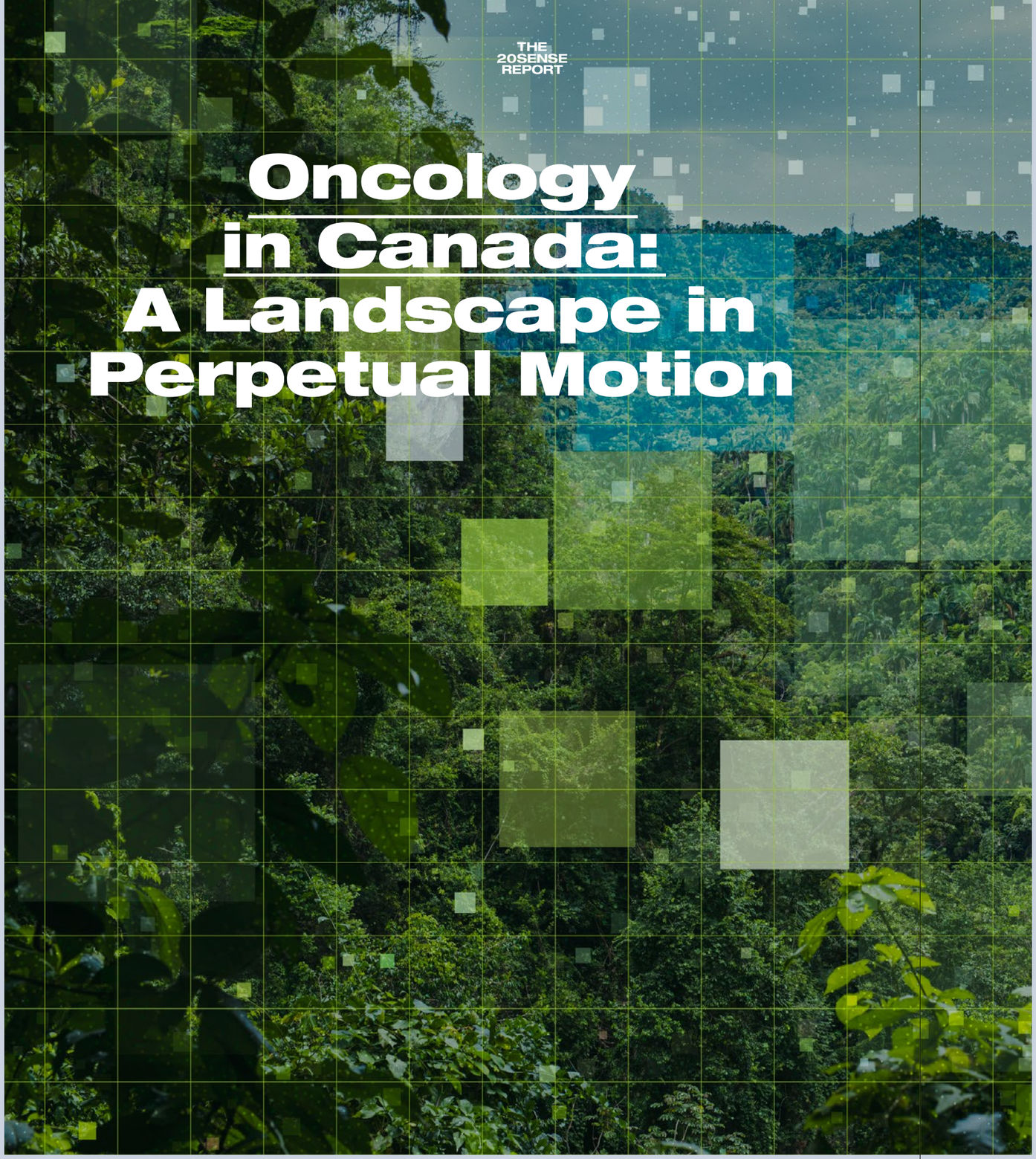
Extra progression-free survival (with no increased costs) attributed to precision medicine in an analysis of patients with advanced cancer.[12]

30 days

Reduction in time from referral to treatment for lung cancer patients at a leading institute in Quebec (26 days, down from the provincial average of 56 days), thanks to an optimized approach to diagnosis and molecular testing.[13]

63%

Proportion of Canadians expected to survive for at least 5 years after a cancer diagnosis, up from 55% in the early 1990s.[2]



THE 20SENSE REPORT

Oncology in Canada: A Landscape in Perpetual Motion

Cancer. We still haven't cured it, and the disease continues to devastate individuals and families. But cancer is not what it used to be. Today's new treatments take medical science to new heights and offer real hope to patients previously considered terminal.

In Canada, four types of cancer continue to dominate: lung, breast (in women), prostate (in men), and colorectal, collectively accounting for about half of all cancer cases.[2] Although we still don't have the final tally for 2020, researchers estimated that 225,800 Canadians would be diagnosed with cancer during that year and that 83,400 would die of the disease.[2] This translates to a daily total of 617 cancer diagnoses and 228 cancer deaths. While the number of new cancer cases continues to grow[14] – an effect of the country's increasing and aging population – we can take heart in knowing that survival rates have gone up significantly. At least 63% of Canadians diagnosed with cancer are expected to survive for 5 years or more after a cancer diagnosis, up from 55% in the early 1990s and just 25% in 1940.[2]

Same diagnosis, different treatment

Traditionally, we have thought of cancer as a war, with a beginning and an end. We fight it. If we're lucky, we beat it, and if we're unlucky, it beats us. New treatments are pushing this model to the sidelines, making cancer more of a chronic, manageable condition than a fatal one.

Some patients previously considered untreatable go on to live cancer-free for years, perhaps having to fend off a flare-up now and again. In this sense, the new treatments serve more as peacekeepers than as combat soldiers: they prevent the invader from launching a full-blown attack rather than pushing back enemy troops already on the field. Of course, these medicines can't work their magic unless they reach the right patients at the right time. And this is where it gets complicated – and costly. Identifying the right patients for a particular treatment often requires sophisticated screening and laboratory tests, including genetic and tumour tests. The treatments themselves don't come cheap – a reflection of the enormous R&D investment required to bring them to market. And if cancer is indeed becoming a chronic disease, managed with medications, testing and drug costs will keep rising.

ON TARGET

While an obvious concern to policymakers, the spectre of rising costs is hardly slowing cancer treatment research down. No longer content with the scattershot results of traditional chemotherapy – effective in some, less so in others – researchers and clinicians are increasingly focusing on targeted therapies, which target specific genes and proteins involved in the growth of cancer cells and generally cause fewer side effects.[15]

At the same time, the cancer pie is breaking up into smaller and smaller pieces. There is no such thing as "treatment for lung cancer" anymore. Current treatments target specific subtypes of the disease based on the characteristics of the cancer cells and the gene mutations driving a particular tumour type. This increasing segmentation has effectively turned some cancers into rare diseases (affecting fewer than 5 in 10,000 Canadians[16]) or rare conditions. For example, adenosquamous carcinoma, a rare subtype of lung cancer, falls into this category.

ADVANCED CANCER DIAGNOSTICS AND TREATMENT: THE LINGO

The new cancer treatment ecosystem has its own language. Here are some of its key terms.[17,18,19]

Precision medicine: A treatment approach focused on delivering the right drug to the right patient at the right time, based on biological information (e.g. genes or proteins) to stratify patients.

Personalized medicine: Sometimes used interchangeably with precision medicine, with an added emphasis on customization for each patient..

Biomarkers: A molecule or alteration (e.g. protein, mutated gene) that reveals pathogenic processes or predicts response to a treatment. Common cancer biomarkers include HER2 (breast cancer), AFP (liver cancer), and EGFR (non-small cell lung cancer).

Companion diagnostics: Tests for biomarkers to identify patients who are candidates for precision medicines.

Genetic testing: Medical test that identifies mutations in specific genes. For example, the test for the BRCA1 and BRCA2 genes can help predict the risk of breast or ovarian cancer.

Genomic profiling: Next-generation sequencing techniques enabling rapid characterization of a tumour's genome to help predict its behaviour. Within breast cancer, the Oncotype DX test can help predict the aggressiveness of a tumour and its response to chemotherapy.

Tumour-agnostic therapy: A drug or other therapy that treats cancer based on the disease's genetic and molecular features, without regard to the tumour's location in the body.

Guided by genes

We have grown accustomed to grouping cancers according to tumour site – breast, lung, colon, and so on – but this tradition is giving way to a classification based on a tumour's genomic characteristics. The advent of next-generation sequencing (NGS) technologies, which can identify a variety of mutations across many cancer types, has driven this shift.[20]

To date, researchers have identified four major genomic alterations involved in cancer development.[15] They have also discovered that tumours with a similar genomic makeup, regardless of their location in the body, may have more in common than genomically different tumours in the same body site.

This scientific insight has spurred the development of so-called tumour-agnostic therapies – therapies that target tumours with similar genomic profiles, irrespective of location. These pioneering therapies are now entering the market – drugs like Vitrakvi and Rozlytrek, both approved in 2019 by Health Canada for patients with solid tumours with an NTRK gene fusion mutation.[21,22] Such mutations, which can cause two genes to fuse together and produce altered proteins that promote uncontrolled growth of cancer cells, have been identified in breast, colorectal, gynecological, non-small cell lung, and pancreatic cancer, among others.[23]

The vast majority of patients with solid tumours do not carry this mutation. But for the small proportion who do, drugs like Vitrakvi can make the difference between, well, life and death.

Take Ted Taylor, a patient in B.C. who developed glioblastoma multiforme (GBM) in 2018 and had emergency brain surgery six days after his diagnosis. The prognosis with standard of care – 14 months left to live – did not sit well with the single father of three, who immediately began researching his options.

After hearing about Vitrakvi on television, he asked his oncologist about the medication – which was so new the oncologist hadn't heard about it yet. A second oncologist arranged for Taylor to get preliminary testing done locally. Against all odds, he had the mutation. The oncologist applied to Health Canada to give Taylor special access to the drug, which was shipped from the UK to Vancouver with a stop in Germany. "My dad and I were waiting with the pharmacist at her location," Taylor recalls. "It came in a special package."[15]

Taylor began taking Vitrakvi twice a day in the spring of 2019, initially under Health Canada's special access program. After two years of treatment, "there's only a small cavity where the tumour used to be," he said in a recent Canadian Cancer Survivor Network (CCSN) presentation. "This drug has saved my life, I can unequivocally tell you."[15]

Not all candidates for precision medicines respond as well as Taylor, of course. Fortunately, today's sophisticated genetic tests allow clinicians to identify additional mutations that predict resistance to a therapy, thus sparing the patient from challenging and costly treatment with other potentially less effective therapies.[15]

> "There's only a cavity where the tumour used to be. I can tell you without any doubt that *precision medicine has saved my life*."
>
> **Ted Taylor, GBM patient**

Uneven terrain

Triumphant outcomes such as Taylor's depend on a well-functioning diagnostic and treatment infrastructure, which not all patients can count on. In Canada, responsibility for most biomarker testing falls to hospitals and third-party laboratories.[24] Those without the capacity to conduct genetic testing may need to forward samples to other locations, often sending them in batches to reduce costs. All the steps involved in obtaining results – preparing biopsies, pathologist review, delivery to testing site (which could be out of the country), booking the patient to discuss results – take time and resources, and can delay a patient's access to therapy.

The current system also suffers from a lack of coordination between the decision-makers responsible for companion diagnostics and for drug therapies.[17] "Essentially, it's the postal code that dictates what therapy a patient receives," says Dr. Calvin Law, chief of the Odette Cancer Centre at Toronto's Sunnybrook Hospital. "There should be a national plan."[17]

For the time being, no such plan exists. A test may be available. Or not. Or the public purse doesn't cover it. Even after a drug gets Health Canada approval, public funds don't necessarily cover the corresponding biomarker test. In such cases, the patient may have to take on the cost of the test – or figure out a way to get coverage from private payers or pharmaceutical companies.[17]

Amid these uncertainties, each province is deploying its own initiatives to improve access to testing. Albertans can count on Alberta Precision Laboratories, a subsidiary of Alberta Health Services, to deliver high-quality diagnostic lab services,[25] and the organization's recent collaboration with Oncology Outcomes (O2) will facilitate the collection of population-level biomarker data.[26] The lucky patients recruited to B.C.'s Personalized OncoGenomics (POG) program have access to genomic sequencing that can help inform treatment decisions.[27] Quebec's INESSS has a written process enabling drug companies to include companion diagnostics in their submissions. According to INESSS director Sylvie Bouchard, this bundled review process ensures "that the recommendation to the minister will not delay access to patients who require the test."[17]

Cancer Care Ontario (CCO), meanwhile, is filling in some testing gaps with the launch of a comprehensive program for cancer testing at diagnosis.[28] Factors guiding the process include tumour type, availability of a biomarker test, and availability of testing facilities. As it happens, the program can test for lung cancers targeted by the world's first KRAS inhibitor, Lumakras, approved by Health Canada in September 2021. While an encouraging development for Ontarians, it raises questions about equitable access throughout the country. In addition, the CCO's program only covers NTRK testing for limited cancer types, attesting to the patchwork coverage available at the moment.

TESTING IN FLUX: INCOMPLETE COVERAGE OF VITAL BIOMARKER TESTS IN CANADA

While making headway, biomarker testing for cancers targeted by the newest treatments remains inconsistent across the country.[29] As highlighted in the examples below, these uncertainties place an extra navigation burden on patients and clinicians seeking access to the tests. [Note: The access scenarios represent a snapshot in time and may change following publication.]

Sotorasib: The first KRAS inhibitor in Canada, sotorasib targets some subtypes of NSCLC. The CCO's new diagnostic program covers the KRAS biomarker, but testing availability throughout the rest of Canada remains unclear.

Entrectinib: This tumour-agnostic drug targets 10 tumour types. The current CCO program only tests the relevant NTRK biomarker for thyroid and lung cancer.

Alpelisib: CCO testing for the biomarker (PIK3) that determines suitability for this breast-cancer medication is only covered for lung, colorectal and endometrial cancer.

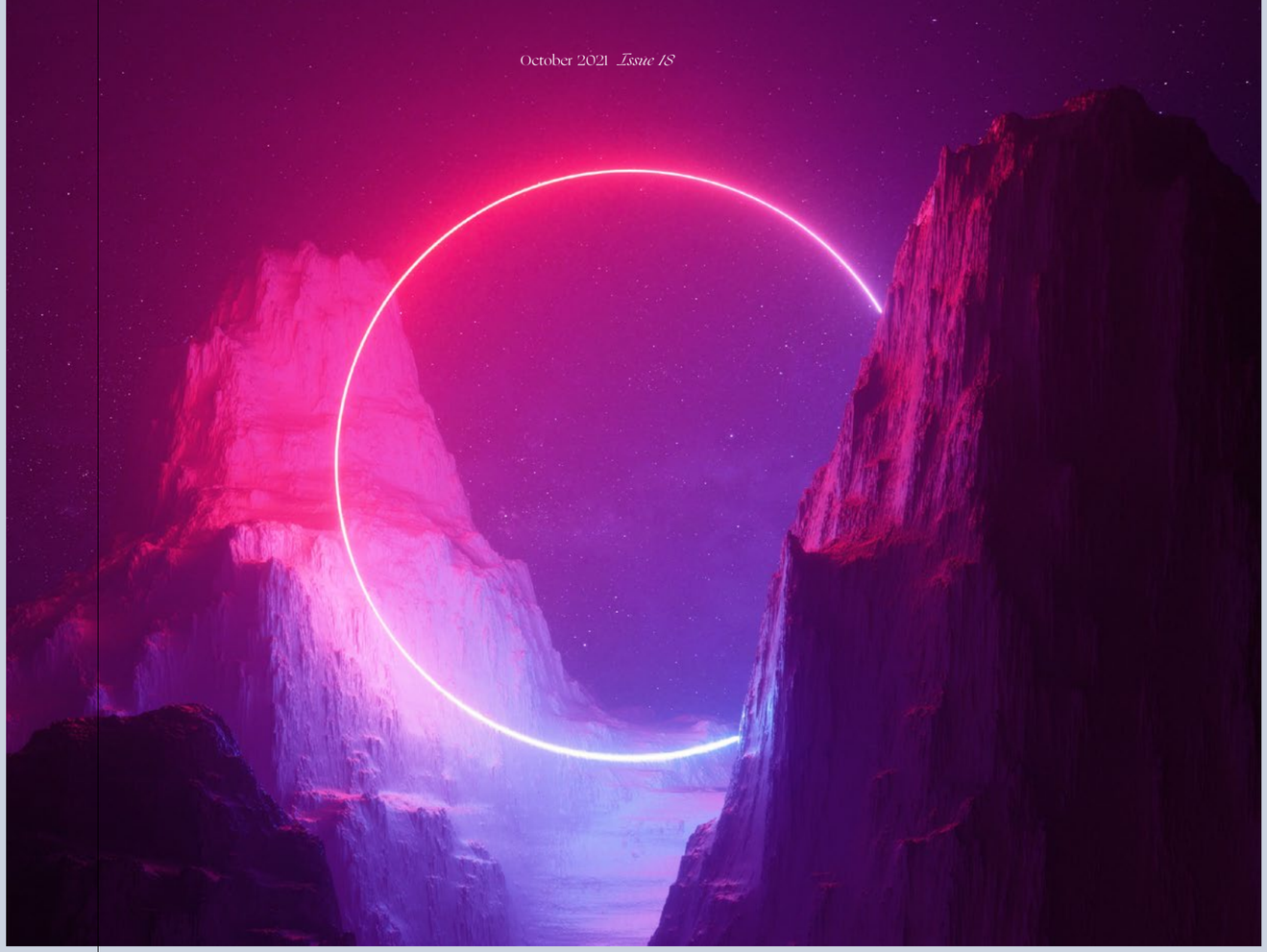
Cabozantinib: An FDA-approved MET inhibitor that targets a broad range of tumours, this medication has yet to get the green light as a MET inhibitor in Canada, where it is currently approved only for renal cell and hepatocellular carcinoma.

Physicians, for their part, face the challenges of navigating this patchwork testing landscape and explaining the tests to patients with different levels of health literacy. Recent Canadian consensus guidelines on biomarker testing and treatment may help doctors treating pediatric patients with NTRK fusion cancer,[30] but significant gaps still exist. This leaves many patients shouldering a large portion of the access load, forcing some to resort to private options to finance their tests.

A natural fit for patient support programs

Patient support programs (PSPs) originated to fill gaps in the care of patients on specialty pharmaceuticals. As such, they have a built-in flexibility that could be harnessed to facilitate companion diagnostics for cancer.

Some pharma companies are moving in this direction. Bayer Canada's Fast TRK program provides centralized NTRK gene fusion testing to patients, free of charge, in partnership with LifeLabs and Kingston Health Services.[31] In a similar



"Why aren't we using the latest technology to try and identify cancer at its *inception*?"

Dr. Azra Raza, oncologist

vein, Roche subsidiary Foundation Medicine has partnered with a Canadian PSP provider to test eligible patients for 325 genes using NGS techniques.[32] As an example of the program's value, a test involving a patient with lung adenocarcinoma was able to identify an EGFR mutation, a dozen other mutations, as well as disease-relevant genes without any concerning mutations.[33] Called FoundationNavigate, the program also helps doctors enrol patients, who in turn receive assistance with reimbursement navigation. Projecting into the future, one can envision an open-access PSP, subsidized by a consortium of pharmaceutical companies or perhaps by governments, devoted to navigation and execution of companion diagnostics. An area to watch.

A HOLISTIC VISION

In tandem with the revolution in cancer diagnostics, clinical trials are finding new ways to evaluate the success of a drug. While overall survival remains the gold standard, evolving endpoints such as pathological response, metastasis-free survival, and time to treatment failure may have more clinical significance in particular scenarios.[34] For example, one-year survival carries the greatest significance in cancers with a poor prognosis, while event-free survival can help tease out events of interest such as metastases or fractures.[34]

Patient-reported outcome measures (PROMs), meanwhile, will take on added importance as cancer shifts toward a chronic disease. As US-based clinician Atul Awande noted in his book *Being Mortal*, "medical care should focus on well-being rather than survival," and PROMs put well-being at the forefront.[35] Building on this theme, the authors of a 2019 commentary in Nature Reviews Drug Discovery noted the opportunity to reconsider traditional approaches to health technology assessment and put more emphasis on PROMs.[36] In their view, failing to do so could lead assessors to undervalue new treatments.

Insights from PROMs can inform the development of next-generation drugs that give patients what they most value beyond merely surviving. From a systems perspective, PROMS also serve as a rich source of real-world evidence (RWE), which in turn can play into reimbursement decisions. In line with this vision, Dr. Parneet Cheema, Medical Director of Oncology at William Osler Health System in Toronto, is spearheading a multicentre observational study called PALEOS that will collect data on patients with lung cancers associated with speific gene mutations.[37] If all goes according to plan, the data could help support outcomes-based agreements (OBAs) that facilitate access to precision medicines.

Not to be discounted, real-world trials can help achieve equitable representation in outcomes data. Elderly patients, who represent roughly two-thirds of cancer cases, comprise only 20 to 30% of oncology trial subjects, and women accounted for only 38% of participants in trials that led to cancer drug approvals in 2018.[38] The impact of gender and ethnicity on biomarker mutation status makes it especially important to correct such imbalances.[38]

Full circle

For all its power, research alone won't solve the cancer treatment puzzle: a complete circle of care begins with screening. We know that it works: breast cancer mortality drops by 21% in women aged 50 to 69 who undergo regular mammographic screening,[39] and a US study linked half of the decline in mortality from colorectal cancer between 1975 and 2000 to screening programs.[40]

That said, we have yet to figure out the optimal level of population-level screening: broad screening carries the risk of overdiagnosis and unnecessary interventions, while restricted screening can lead to missed diagnoses and delayed treatment. Perhaps the answer lies in better screening, as advocated by Azra Raza, a professor of medicine at Columbia University. "Why aren't we using the latest technology to try and identify cancer at its inception?" she says.[41] She anticipates that future technology will enable us "to find the earlier footprints of cancers, and that along with that revolution will come better treatment options."

Most current screening programs in Canada cover breast, colorectal, and cervical cancer. Ontario and B.C. have lung cancer screening programs in place, and a pilot project in Quebec is offering lung CT scans to people aged 50 years or older.[42] Concerns about the potential harms of prostate cancer screening, which include overdiagnosis and overtreatment, have led some jurisdictions to opt out of population-level screening for this type of cancer.[43]

Instead of piecemeal genomic testing, some experts recommend testing the whole genome, which could do double duty as a screening tool and treatment decision aid for patients with existing cancers. "There are too many biomarkers to do individual tests anymore," notes Nathan Pennell, a medical oncologist at the Taussig Cancer Institute. "It costs a lot more to do multiple tests and bill for each individually than it does to do one [whole genome] NGS test… NGS should absolutely be the standard of care."[38]

Sequencing the whole genome used to cost millions, but companies are now offering the service for a few thousand dollars,[29] bringing Dr. Pennell's vision into the realm of possibility. Even so, as life expectancy continues to increase for cancer patients, with some patients remaining on targeted therapies for decades, costs are bound to rise.

This radical shift in cancer treatment philosophy raises uncomfortable questions: how many new drugs can the health system bear? How good do they need to be to justify their costs? How to ensure equitable access to these drugs across a country as spread out as Canada? Are these therapies providing the outcomes that patients want? Our country needs a plan. In the meantime, patients can take their cue from GBM survivor Ted Taylor, who urges patients to arm themselves with information, get tested, and play an active role in their own treatment. "Research and become your best advocate," he says.

One way or another, things are about to get more interesting. It's never a good time to get cancer, but today's patients have life-changing options that never existed before – and they keep getting better. Stay tuned.

Bringing Oncology Treatment Down to Earth

Real-world evidence can accelerate access to life-saving medications – but as Dr. Parneet Cheema explains, it has to be the right kind

As Medical Director of Oncology at William Osler Health System, Dr. Cheema leads the first-of-its-kind immuno-therapy program at the institution. A medical oncologist with a worldwide reputation, Dr. Cheema is also an assistant professor at the University of Toronto's Faculty of Medicine. Dr. Cheema and her team are currently recruiting subjects for the Pan-Canadian Lung Cancer Observational Study (PALEOS), a multicentre observational study that will collect data on patients with specific subtypes of lung cancer in Canada. Here, Dr. Cheema explains how we can use real-world evidence (RWE) to greater advantage.

You do a lot of work in lung cancer. Can you tell us how the medical understanding of this form of cancer has evolved?

We used to think of lung cancer as one disease, but we know about numerous subtypes. So we're looking at many different diseases, some of them with orphan-type status, all under the non-small-cell lung cancer (NSCLC) umbrella.

"We're looking at many different subtypes of lung cancer, some of them with orphan-type status."

What is standing in the way of value-based or outcomes-based agreements (OBAs) for lung cancer medications?

Historically, the evidence collected from databases hasn't consistently panned out in clinical trials, which has led to a bit of skepticism about RWE. So first and foremost, we need to create the infrastructure to generate high-quality RWE that can supplement clinical trial data rather than just generate hypotheses.

Can you give us an example in which RWE and OBAs might have helped obtain a listing?

There is a targeted therapy for a form of NSCLC called BRAF V600E. It's a combination of two medications, dabrafenib and trametinib. The pCODR expert review committee (pERC) initially recommended against listing it because of the limited evidence from clinical trials. But it's impossible to conduct a large trial for such a small slice of the NSCLC pie – there simply aren't enough patients. As it was, it took 14 months to enroll 59 patients from 9 countries in a phase 2 trial, which did show a benefit. pCODR also maintained there were other treatment options for NSCLC patients, essentially lumping this subtype together with several others. At the time, this decision was a big step back for precision medicine. The drug did eventually get a positive recommendation, but the lag time between NOC and listing exceeded three years. That's a long time for patients to wait.

To flip the question around, has RWE ever actually helped expedite a listing of a lung cancer treatment?

Yes. There is a medication called crizotinib that targets a lung cancer subtype called ROS1-positive NSCLC. It's a rare subtype, with only 250 cases per year in Canada. A small phase 2 trial showed a clinical benefit. In this case, pERC considered not only the trial results but input from a group of clinicians. I was part of this group, and we submitted our observations that the medication had a durable response and improved patients' quality of life. pERC went on to recommend a listing. Which begs the question: what constitutes good RWE? What can we actually submit? We still don't have clarity on these questions.

"We should always keep sight of what we're trying to accomplish with outcomes-based agreements: *facilitating patients' access to life-saving drugs.*"

There are so many avenues to getting RWE. Where do we start?

We should remember that "the data is with the patient." The patients who come to my clinic, sitting in front of me – those are the patients who can give us good RWE. We also need RWE from patients treated in the community, as patients in academic centres don't represent the entirety of the affected population.

You've explained the "where." What about the "how"?

We need mechanisms to enroll patients in a data collection pathway. And we need to keep it simple. Right now it's a bit of a mess for clinicians. We barely have time to write orders for our patients, so how are we going to find the time to collect all this extra data, not to mention data on historical controls? We need help with this, ideally from both industry and government.

So how would you advise industry and government to proceed with respect to RWE?

My plea to government and industry is this: please invest in long-term solutions as opposed to one-off RWE studies, which are costly, hard to run, and subject to bias. Invest in an infrastructure that includes clinical coordinators and mechanisms to collect prospective data, which is critical for clinician buy-in. Invest in databases with the capability to transfer data easily between sites and to integrate AI capabilities.

What can we do to help patients get on board?

We may need campaigns to communicate the value of participating in registries and databases and to address concerns about privacy. We need to make it easy for patients to provide consent and to include patients from all socio-economic groups. In Ontario, we're getting a jump on this with PALEOS.

Tell us more about PALEOS. What type of data will the study collect?

As I mentioned earlier, lung cancer has so many subtypes that we can't get enough patients to conduct clinical trials with sufficient power. PALEOS is designed to fill this gap by generating real-world data on natural history, treatment patterns, and outcomes in relation to lung cancer subtypes, using both retrospective and prospective methods. To reflect the diversity of Canadian patients, we are recruiting from both academic and community cancer settings. We have funding for clinical coordinators and data analysis support. We will provide centralized education to ensure all sites are entering prospective data the same way, so we can generate standardized variables that can be used by health technology assessors.

How can we get moving on using RWE to support OBAs?

We clinicians can't produce RWE unless our patients can access the medication being evaluated. Industry can help with this, with the understanding that we provide RWE in return. From a regulatory perspective, it would make sense for pharma companies to include an RWE generation plan with their pCODR submission. The plan should address clinical uncertainty about a drug, so the data is strong enough to support an OBA. And we should always keep sight of what we're trying to accomplish with OBAs: facilitating patients' access to life-saving drugs.

NEXT-LEVEL TESTING[44]

Clinicians need to know the status of several gene mutations to optimally treat NSCLC patients, making timely biomarker testing a necessity. Dr. Cheema was part of an expert consensus group that convened in 2020 to create recommendations for biomarker testing. The panel recommended that all patients with nonsquamous NSCLC, regardless of stage, should undergo comprehensive reflex biomarker testing at diagnosis with targeted next-generation sequencing. "That's a big jump from just testing for the EGFR mutation, which is what we used to do," says Dr. Cheema. "Precision medicine keeps on getting more precise."

On the reading *list*

Cancer care in Canada: A disrupted system needing disruptive innovation

A review of precision medicine companion diagnostics in Canada: Are we there yet?

How my 2020 summer health crisis left me grateful for past money and life decisions

UBC's Dr. Poul Sorensen: Bringing a new cancer drug to market

Tumour agnostic treatments and the future of specialized medicine

A global first: New technology brings faster diagnosis to cancer patients

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