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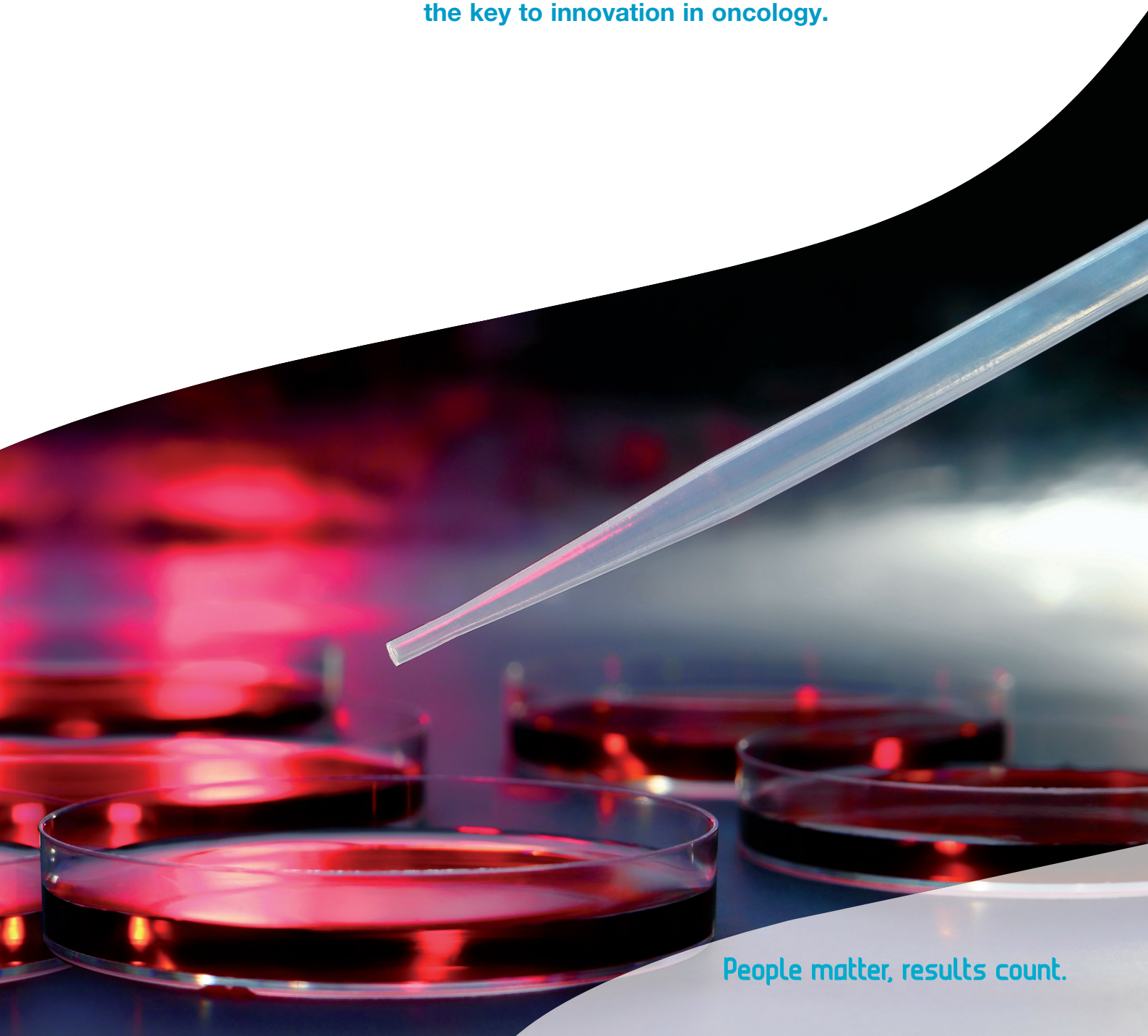
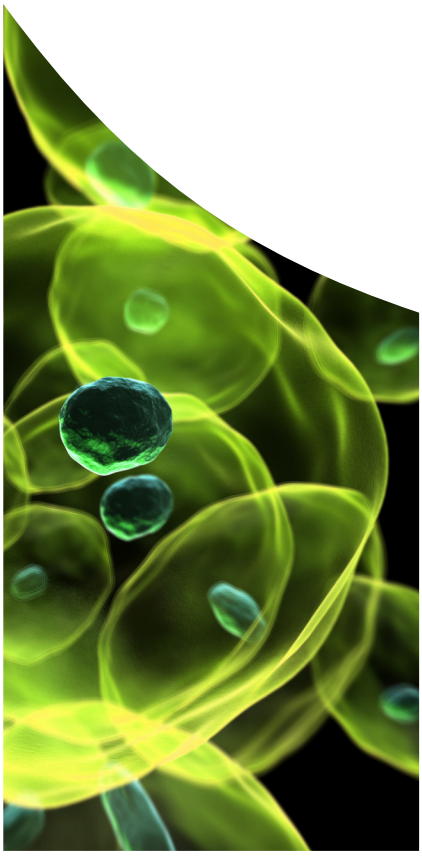
Transforming oncology clinical development

A new alliance between Capgemini and Novo Oncology Associates will facilitate collaboration, the key to innovation in oncology.



People matter, results count.



Given the staggering statistics on cancer rates, there is a renewed emphasis on cancer research and development. More than 1,000 oncology compounds are currently in development and a significant share of the overall industry R&D spend is dedicated to oncology. Historically, the rewards have been big. Blockbuster drugs Avastin, Rituxan, Herceptin and at least seven others each generate more than $1bn in annual global sales.

Growing risks and costs for developers

However, the development risks and costs are substantial, and growing. It is clear that the more we understand the scientific basis of cancer, the more complex it becomes. Two patients with a similar diagnosis and the same treatment may show very different responses and outcomes. A cancer diagnosis – be it lung, breast, colorectal or others – requires an understanding of how that specific disease originates and how it progresses and spreads in the human body.

The trend toward targeted therapies and companion diagnostic tests means that identifying representative clinical trial patients will be even more challenging than it is now, as only a fraction will meet the traditional inclusion/exclusion criteria. That factor will increase development costs, slow time-to-market, and potentially lead to a limited label.

Acceptable oncology clinical trial endpoints appear to be a moving target, often influenced by the varying positions taken by regulatory authorities, medical academics, and patient advocacy organisations. This uncertainty adds a considerable amount of risk and instils a defensive (and costly) posture by the innovator company. Tumour response, progression-free survival, and overall survival are among the intermediate and final endpoints that must be measured, but often they are given different weightings by different authorities.

The recent FDA interest in, and emergence of, combination therapies during clinical trials, similar to the "cocktails" use to treat HIV, also leads to more complex trials, requiring multiple companies to work together in a unique situation. At the same time, a more active, educated, and engaged cancer patient population expects more manageable side effects with cancer treatments of the future.

To complicate matters even further, financial pressures related to private and public payers are challenging reimbursement levels for cancer drugs and treatments. Companies must evaluate the payer perspective, and how they define the value of oncology drugs.

The industry is facing a genuine dilemma as costs skyrocket and reimbursement challenges multiply. Are clinical development programmes designed to deliver incremental improvement in cancer care a thing of the past?

Transformation of oncology clinical development

If they are to achieve continued progress towards a cure for cancer, pharmaceutical and biotechnology companies need to address a central issue: how should oncology clinical development be transformed to manage the risks and costs better?

The right treatment for the right patient

The use of biomarkers to match the most effective treatment with each individual patient will remain the focus in the industry. This remains true despite the reality that having a smaller initial patient population makes it harder to recover development costs. The investment in biomarkers will be justified by the higher price that a more effective drug commands, and by additional product lifecycle opportunities that will boost the revenue potential.

Early decisions on product strategy

Given the significant risks and associated costs of oncology clinical

development, key product strategy and go/no-go decisions need to be made early in development. Doing so requires a deep understanding of a compound's mechanism of action and of future standards of cancer care.

In particular, critical product positioning decisions (such as whether the treatment is first- or second-line, stand-alone or combination) must be made early, and must be based on scientific and commercial insights. Access, reimbursement and other payer issues are key factors in these decisions.

When there are major uncertainties, parallel development of agents within organ-defined patient populations (for example, colon, breast, lung, prostate) may be required to maximise the scope of eligibility for individual patients. More precise targeting of specific agents for individual patients may help minimise clinical trial costs and greatly accelerate the development timeline for these agents.

Redefined endpoints
To accelerate speed to market, companies urgently need intermediate endpoints that accurately reflect global clinical benefit and are acceptable to the regulatory agencies. Developing such early metrics is challenging, in part because of the complexities and variability of the patient care pathways. Further complexity results from the fact that multiple interventions may occur during a given patient's care, as each intervention used may confound the "gold standard" endpoint of survival. Identification of new, valid short-term endpoints that are widely accepted across the industry by investigators, payers and regulators remains a vital, but as yet unmet, need.

An eye on the competition
Understanding competitors' pipelines and critical areas of clinical need are important in developing a clear and certain direction and timeline for product approval. Successful trials will change the standard of care and set a higher bar for efficacy and tolerability.

Speed to market
Once a strategy is set, patient enrolment, trials execution, data analysis and dossier preparation must be managed as a process to be continually optimised. Early involvement of the regulators, and in some situations of payers, will make it possible to prepare for rapid decisions and to determine acceptable data points for approval and reimbursement.

Collaboration for better cancer care

The upcoming wave of product innovation in oncology and the advent of personalised medicine holds an exciting promise: a world with improved cancer care that far exceeds the tedious, incremental progress that has characterised cancer developments until now.

However, rapid improvement of outcomes will require collaboration between stakeholders, including pharmaceutical companies, patient groups, regulators, investigators and payers. This collaboration is the only way to maintain a reasonable balance between accelerating safe access to innovative care and managing the cost of care to a level within societal tolerance.

With this need in mind, Novo Oncology Associates (NOA) and Capgemini Consulting have set up an alliance under which we will jointly help life sciences companies to seize opportunities within the oncology therapeutic area. The alliance will benefit clients by enabling direct and immediate access to academic, government and community practice research.

Life science companies will be able to gain from creative, oncology-specific approaches to solving complex challenges in research, development and commercialisation. Companies will also have access to guidance and direction about oncology drug discovery, early and late stage clinical development and all aspects of the commercialisation of oncology products.

Together, Capgemini Consulting and NOA will help provide practical, specific recommendations and implementation support to help companies succeed in the evolving and complex market that is global oncology.

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