Alt. #4

ALTEN Magazine / 2024

Life Sciences

Clinical trials

When digital becomes critical — P.28

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Content

14

26

40

Synergising disciplines for biotech innovations

01

Cross-disciplinary collaborations drive a broad spectrum of biotech innovations, accelerating medical advancements for safer, more precise treatments. Highlights include: AI-powered CRISPR for gene editing, portable diagnostics through lab-on-a-chip technology, RNA therapies targeting HIV and cancer, bioprinting and tissue engineering for regenerative medicine, and stem cell applications broadening drug testing and disease models. Additionally, predictive modelling boosts drug development efficiency, while personalised medicine customises treatment based on genetic profiles. This collaborative ecosystem forecasts a trend towards strategic mergers and acquisitions, reflecting the impactful transformation of scientific discoveries into clinical and societal benefits.

Integrating emerging technologies into manufacturing

02

AI-enabled intelligent automation and advanced analytics are reshaping pharmaceutical manufacturing, making it agile, eco-friendly, and focused on patients' needs. Real-time data and analytics allow for immediate operational decisions and improvements, addressing supply chain and talent shortages. Digital twins virtually simulate manufacturing facilities to optimise processes and enable predictive maintenance, reducing time to market for drugs. These advances support the shift from traditional batch methods to continuous manufacturing, further enhancing efficiency while cutting waste. Meanwhile, flexible production technologies like single-use bioreactors, modular systems, and 3D printing are advancing personalised medicine by enabling the production of small, tailored drug batches.

Aligning regulations with technological advancements

03

Regulatory evolutions underscore a global shift towards more adaptive and patient-centric frameworks, ensuring safety and efficacy in the face of technological advances. The European Union is debating reforms to tackle potential medicine shortages, to fight antimicrobial resistance, and to improve access to medicines. These discussions are also addressing supply disruptions under new medical device and in vitro diagnostics regulations. In the United States, the Food and Drug Administration is adapting guidelines for digital health and remote data collection, reflecting the sector's shift towards innovative therapies and digital solutions. Additionally, standards like USP <665> are being introduced to ensure quality in pharmaceutical packaging amidst new material technology.

“Our goal is clear: providing tangible results for the clients we support, ultimately making a difference in patients’ lives.”

OLIVIER GRANGER /

EDITORIAL

OLIVIER GRANGER /
INTERNATIONAL MANAGING DIRECTOR — ALTEN

In an era of rapid technological advancement, the life sciences sector is experiencing unprecedented transformations. Recent health crises have emphasised the need for agility in pharmaceutical development, where speed and efficiency are paramount.

At ALTEN, we don't just keep pace with these changes—we shape them. Our innovative solutions drive progress in healthcare, biotechnology, and clinical research worldwide.

— In response to the dynamic demands of the life sciences domain, ALTEN has strategically evolved to provide adaptive and robust solutions. In 2022, we launched a dedicated Life Sciences division, combining our strengths with Aixial, managing CRO activities, and working together with Caduceum for Engineering and Manufacturing. We are now present throughout the entire value chain, from clinical research to post-market surveillance.

— Thanks to this consolidation, we now support over 300 clients, ranging from innovative startups to industry giants. Our goal is clear: providing tangible results for the clients we support, ultimately making a difference in patients' lives.

Since acquiring SDG Group in 2020, specialising in business analytics, data management, AI, and performance management, ALTEN has developed operational and commercial synergies, strengthening our market position and offerings.

— At ALTEN, we prioritise client-focused innovation. Our commitment is demonstrated through initiatives like the Smart Factory 4.0 developed by ALTEN Labs, and through our internal hub of excellence, which fosters a true culture of innovation. With our global technical direction and flexible nearshore and offshore solutions, we provide bespoke, best-in-class support for our client's projects.

ALTEN's expertise in automation, AI, and machine learning, accelerates drug discovery and development, ensuring fast and safe outcomes. Our groundbreaking work in biotechnology and cutting-edge healthcare technologies is central to our operations. Our teams of experts are dedicated to pushing the boundaries of what is possible, positioning us as a key player in the industry.

— As the life sciences sector remains crucial to global healthcare and economic stability, ALTEN will continue to advance, focusing on adaptability, collaboration, and excellence. Over the past 15 years, we have expanded our capabilities, with the aim of becoming a European market leader in the near future and extending our global reach.

Through dedication, innovation, and a shared vision, ALTEN is poised to make a significant impact in the life sciences industry.

We invite you to explore this magazine edition to discover just how we're making this possible. Join us in charting a course towards a brighter and healthier future for all.

Staying ahead — In the ever-changing landscape of life sciences, maintaining a competitive edge requires unwavering commitment to innovation. At ALTEN, we have taken decisive steps to ensure that our Life Sciences division not only meets, but exceeds market expectations.

JONAS MÖLLER /
MANAGING DIRECTOR — AIXIAL GROUP

How ALTEN's Life Sciences Division is Leading the way in Market Innovation

The ALTEN Labs

— A key testament to our commitment is our labs. Established in 2016, these labs were introduced to empower consultants to experiment with pioneering technologies such as big data, artificial intelligence, UI/UX design, SAFe methodology, virtual and augmented reality, and digital twin technology. In 2019, the 11 labs became part of our Innovation Department, intending to offer clients innovative value propositions that integrate engineering and digital expertise with business services.
One of these labs, the Smart Healthcare Program (ALTEN x Aixial), is dedicated to digitising the healthcare system, combining data analysis and artificial intelligence, and conducting the development of cutting-edge IoT technologies. Its goal is to facilitate the development and implementation of virtual/decentralised clinical trials using connected solutions, AI, and real-life data, all while ensuring their reliability and safety.

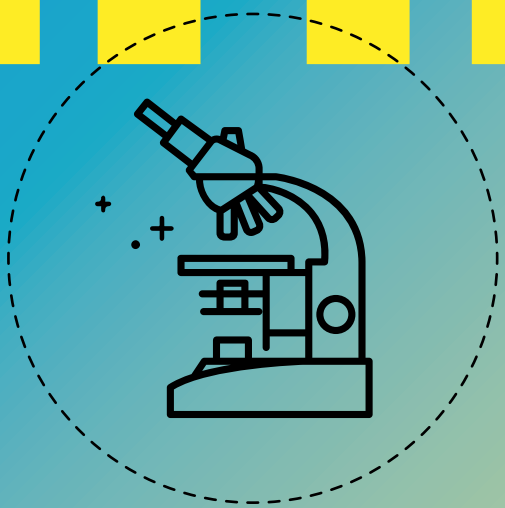
Investing in Artificial Intelligence

— Fully aware of the transformative potential of artificial intelligence in advancing innovation, we have proactively invested in it through SDG, our AI & Data Management specialised subsidiary, to leverage this technology across all sectors, particularly in life sciences. Through this collaboration, we aim to find solutions to reduce the production cycles of documentation, accelerate the time to market for medicines and minimise the human error.

Supporting Manufacturing 4.0

— Drawing from our extensive experience in industries like automotive and aerospace, we have applied the principles of Manufacturing 4.0 to the healthcare sector, addressing areas such as data traceability in the production chain, digital twins, and more. This approach encompasses automation and smart manufacturing (we assist healthcare clients in implementing advanced manufacturing techniques, enhancing efficiency, precision, and scalability) but also cross-industry expertise by leveraging our knowledge from other high-tech industries, enabling us to deliver innovative solutions that are both reliable and cutting edge.

BETTER



Life sciences are the realm of progress. However, innovation in service of patients only truly makes sense when advancements prove robust, free from adverse effects, and ethically impeccable. A subtle equation at the heart of the work carried out by ALTEN.

ENHANCING DATA INTEGRITY IN INDUSTRY 4.0

Turning point — Biopharma manufacturers are encouraged to remain vigilant on Data Integrity (DI). It is crucial for accurate decision-making, ensuring patient safety, and product quality. Recent Food and Drug Administration warnings highlight the critical need for robust data management practices. The challenge of preserving DI becomes even greater as Industry 4.0 advances, characterised by extensive automation and massive data generation. In this digital age, DI is not just a technical necessity but a strategic asset that is pivotal for building trust and driving innovation.

Advanced technologies in smart manufacturing bring significant DI challenges, affecting operational efficiency and competitiveness. High volumes of complex data necessitate sophisticated management to maintain accuracy, where lapses can lead to substantial operational disruptions and financial costs. The need for real-time data processing increases the risk, as speed should not compromise reliability. Additionally, greater data accessibility heightens vulnerability to security breaches, especially in cloud environments. Such breaches can severely impact product quality, delay production, and jeopardise compliance, undermining manufacturer trust and market position.

Strategic approaches to safeguard DI

— Companies must think early about adopting strategies to mitigate DI risks effectively. Based on our expertise and experience at ALTEN, a comprehensive approach is crucial. Establishing robust governance with clear policies is essential for ensuring transparency and regulatory compliance. Utilising frameworks like ALCOA+ (Attribuable, Legible, Contemporaneus, Original, Accurate + Tracability) helps identify risks and uphold compliance, while effective audit trails are imperative for logging data interactions. Building upon this, implementing Electronic Data Management Systems (EDMS) secures data accuracy and storage. Furthermore, continuous training for personnel on the latest DI practices reinforces a culture that prioritises meticulous data handling and transparent, well-documented processes.

Future-proofing DI maintenance

— To further reinforce DI measures, companies must embrace innovative strategies that go beyond conventional approaches. By using advanced predictive analytics, they can detect discrepancies early and take timely corrective actions. Blockchain technology enhances traceability and security, especially in sensitive sectors like clinical trials, by creating immutable records. Additionally, artificial intelligence automates monitoring and compliance of data processes, improving efficiency and reducing human error. The integration of regulatory technology ensures automatic compliance, while concurrently promoting global data integrity standards. This dual approach fosters international uniformity, bolstering industry-wide data governance efforts.

— In light of all this, it is clear that, robust data integrity is crucial to the life sciences sector's commitment to patient safety and regulatory compliance. As Industry 4.0 evolves, maintaining secure and compliant data becomes more complex. By adopting advanced strategies, companies can meet current standards and prepare for future challenges. This continuous commitment to DI serves as a pivotal driver of the industry's enduring success.

Pharmaceuticals manufacturing — By May 2026, manufacturers must comply with the newly released USP<665>* from the United States Pharmacopeia. These guidelines establish strict safety standards for polymeric plastic components used in pharmaceutical production, particularly those in direct contact with products. As the application of single-use technologies from tubing to bioreactors expands, USP<665> addresses the risks of Extractables and Leachables (E&L), enhancing patient safety and drug purity.

CODE NAME USP<665>

Manufacturers are required to rigorously assess and select plastic materials that meet specific safety criteria. This involves evaluating material for chemical resistance, purity, and stability. This stringent selection process may restrict the available materials, potentially leading to higher costs and alterations in supplier relationships.

Manufacturers may also need to overhaul existing production processes. This could include modifying equipment, changing fabrication techniques like molding and extrusion, and implementing new handling procedures to reduce contamination risks. Such modifications require planning, time, and financial resources, impacting production timelines and possibly leading to temporary reductions in manufacturing efficiency.

The guidelines further mandate detailed testing for E&L, requiring manufacturers to develop, validate, and routinely execute solid testing protocols. This implies investments in advanced analytical capabilities and training for technical staff, potentially leading to the creation of dedicated labs for ongoing compliance. Additionally, rigorous quality control measures

refers to Chapter 665 of the USP-NF (United States Pharmacopeia - National Formulary), a publication establishing rigorous quality standards for pharmaceutical products.

are essential, involving tight inspection of materials, process monitoring, and comprehensive testing of final products to ensure compliance with safety standards.

Preparing for change

— Pharmaceutical companies can prepare for USP<665> by adopting a proactive and strategic approach. This includes reviewing and adjusting their current processes and materials, focusing on risk assessment for E&L. They need to identify gaps in compliance, invest in targeted staff training, and collaborate with suppliers to ensure that materials meet new standards. Adopting a risk-based approach helps prioritise efforts when they are most needed.

The transition to USP<665> compliance may present several challenges for manufacturers. Resource limitations could restrict the ability to implement necessary changes swiftly, while a lack of specialised technical expertise could complicate testing and data interpretation. Additionally, managing compliance across intricate supply chains requires strong coordination and communication, ensuring that all suppliers adhere to the new standards.

To support this significant transition, ALTEN offers specialised services to help clients in achieving USP<665> compliance. With our deep expertise in E&L testing, we provide essential resources and knowledge to navigate these complex requirements. By facilitating the early adoption of USP<665> guidelines and delivering strategic support, ALTEN helps its clients stay ahead of regulatory shifts and maintain a competitive edge in the pharmaceutical industry.

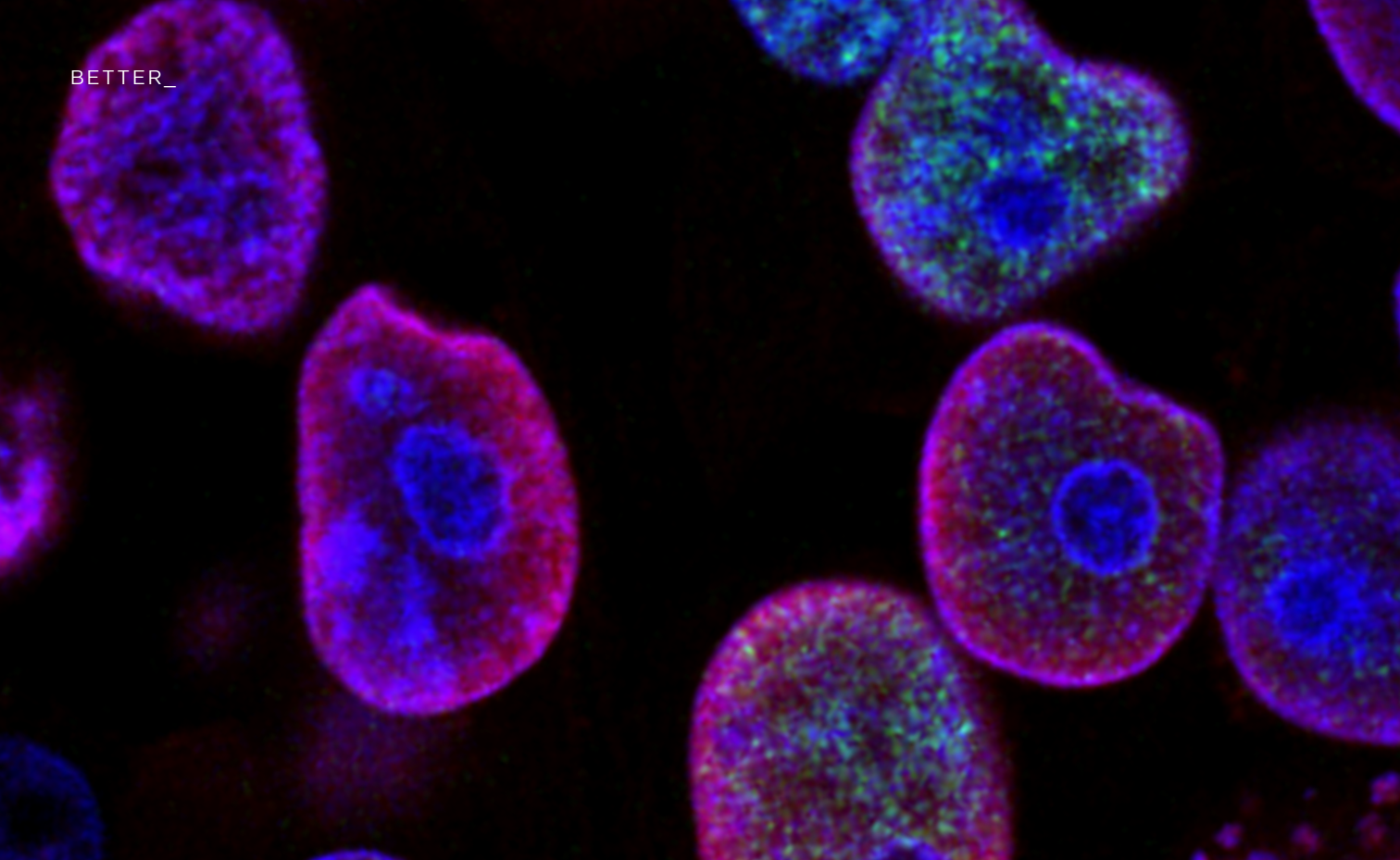
Looking ahead

— USP<665> promises transformative changes across the life sciences industry by establishing higher safety and quality benchmarks. This new standard compels manufacturers to rethink their production processes, encouraging the use of innovative materials and cutting-edge analytical techniques. These advancements are expected to enhance manufacturing robustness, significantly boosting the safety and quality of pharmaceutical products.

Adopting USP<665> goes beyond compliance; it's a strategic opportunity to enhance operational excellence. Companies that proactively embrace these standards can improve compliance and differentiate themselves in the marketplace. This strategic advantage can boost their reputation for quality and reliability, strengthen competitive positioning, and build deeper trust with healthcare professionals and patients.

The successful transition to USP<665> compliance hinges on effective collaboration among various industry stakeholders, including regulatory bodies, material suppliers, and service providers. By working together, these parties can align with the new guidelines, overcome transitional challenges, and share valuable insights. This collaborative approach is essential for promoting continuous improvement and innovation, ultimately improving patient outcomes and streamlining drug manufacturing processes.

— In short, USP<665> advances pharmaceutical manufacturing, enhancing safety and quality while demanding adjustments from manufacturers. Companies must innovate and adapt, investing in new technologies and methods to meet stringent standards and ensure ongoing improvements in product quality and patient safety. Industry-wide collaboration is crucial for successful adaptation. Together, we can transform the challenges of USP<665> into opportunities for growth and advancement, setting new benchmarks for pharmaceutical practices and enhancing global healthcare outcomes.



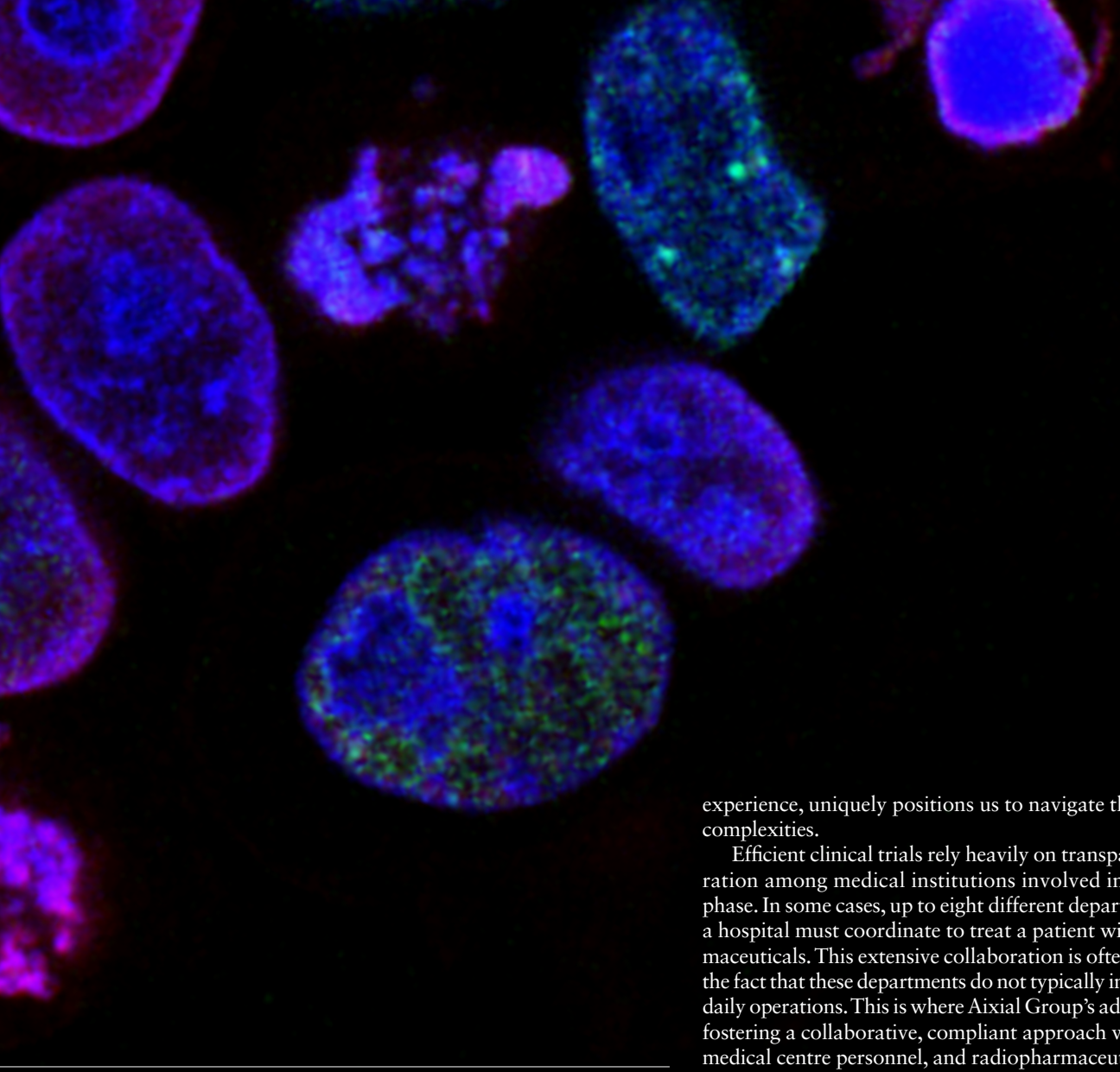
ATOMISING CANCER

Breakthrough
— Radiopharmaceutical therapy represents a novel approach to treating cancer, utilising radioactive atoms to target and destroy malignant cells with precision, without affecting the patient's healthy tissues. A field in which Aixial has emerged as a pioneer.

Radiopharmaceuticals utilise radioactive atoms to precisely target and treat cancer cells. Traditional external beam radiation can indiscriminately damage all cells in its path. Radiopharmaceutical therapy, on the other hand, consists of a radioactive compound binding to a pharmacologically active carrier molecule (tracer), which in turn targets the cancer cells, thus minimising harm to surrounding healthy tissue.

At the unique crossroads of medicine, chemistry, and nuclear physics, radiopharmaceuticals play a crucial role in both diagnostic imaging and targeted therapies. Techniques such as PET and SPECT imaging rely on these compounds (radiodiagnostics) to facilitate early disease detection, leading to improved therapeutic interventions. This method, referred to as radiotherapeutics, enhances treatment effectiveness and ultimately improves patient outcomes.

As the field of science progresses, researchers are optimistic about uncovering more unique receptors in cancer cells, paving the way for even more effective treatments. A growing area of interest is radiotheranostics, a synergy between diagnostics and therapy within the realm of radiopharmaceuticals. Here,



radiotracers used for imaging can be tailored to deliver therapeutic agents directly to malignant cells. This approach, guaranteeing high precision and accuracy, is bolstering the development of individualised medicine tailored to real-time imaging data and patient responses.

Challenges ahead

— However, the journey to reaching the full potential of radiopharmaceutical therapies is not without its challenges. One significant hurdle is guaranteeing the availability of the necessary infrastructure—referring to both equipment and expertise—to administer these innovative treatments. In the United States, many rural areas are distanced from major medical centres, often hundreds of kilometers away. Despite this, even within rural hospitals, there is a pressing need to ensure that adequate personnel, equipment, and safeguards are in place to ensure these therapies are available to patients in need.

Logistics present another significant challenge. Many radiopharmaceuticals have a very short shelf life, with some products expiring just several hours after being manufactured. The expertise of our operational teams, coupled with our extensive experience, uniquely positions us to navigate these logistical complexities.

Efficient clinical trials rely heavily on transparent collaboration among medical institutions involved in the research phase. In some cases, up to eight different departments within a hospital must coordinate to treat a patient with radiopharmaceuticals. This extensive collaboration is often hindered by the fact that these departments do not typically interact in their daily operations. This is where Aixial Group's added value lies: fostering a collaborative, compliant approach with sponsors, medical centre personnel, and radiopharmaceutical suppliers in one of the most highly regulated industries in the world.
As we continue to explore the depths of radiopharmaceutical therapy, the potential for transformative cancer treatments is brighter than ever. With a dedicated focus on collaboration, innovation, and logistics, we are poised to lead the change into this promising future. ⊗

The global market for radiopharmaceuticals is witnessing remarkable growth, valued at over $7.9 billion in 2023. Experts anticipate this market will surge to approximately $21.8 billion by 2033, reflecting a compound annual growth rate exceeding 10%. Aixial's research from 2021 to 2023 indicates a staggering 200% increase in the number of sponsors engaged in the development of radiopharmaceuticals, underscoring the industry's exciting trajectory.

Point of view — The current healthcare landscape is shaped by AI's potential to enhance diagnosis, treatments, and remote care through the leveraging of integrated data—a fabulous opportunity that also comes with ethical and regulatory challenges.

MAURIZIO SANARICO / CHIEF DATA SCIENTIST AND GLOBAL AI ADVISOR — SDG GROUP

AI as a Solution for Healthcare

The Current Scenario

— Many concomitant factors are impacting healthcare systems around the world. We have seen vast improvements with the help of available data from EHR (Electronic Health Record), imaging, and various other factors enabling advanced AI algorithms that provide healthcare practitioners with powerful tools. These tools enhance precision medicine and support preventive actions. On another hand, there are negative factors to be considered, such as the ageing of populations with associated increase of chronicity, budget restrictions, and the scarcity of healthcare personnel and medical doctors.

Opportunity from Artificial Intelligence

— AI tools provide a potential solution to healthcare system challenges by enabling faster and more accurate diagnosis and treatment through the analysis of clinical data, diagnostic images, vital signs, patient symptoms, and available multi-omics and lifestyle summaries. AI can assist physicians by providing personalised treatment recommendations, leading to earlier prescription of therapies and better clinical outcomes. Promoting and establishing sustainable telemedicine and remote monitoring through a "one-to-many" AI model, offers the possibility of treating numerous patients from a distance. This can be carried out through wearable devices or smart sensors.

Moreover, by utilising integrated data effectively, we can reduce the risk of unnecessary hospitalisation, enhance education and training, and employ generative AI to develop training platforms and virtual medical simulations for medical students and health professionals. AI can also be used to assist the population with "human-like" virtual assistants and, ultimately, promote and support medical research thanks to properly organised data.

Data and AI Governance

— All of these functions must be appropriately governed to grant access to the different actors in the right way and format, with particular respect to the General Data Protection Regulation (GDPR) and the criteria of fairness and ethical restrictions put forward by the AI Act. For example, medical doctors should have access to data and understandable AI results for their patients. Research can be improved with access to anonymous data, focusing on the relationships between the variables of any type gathered and made available. Similarly, AI governance involves avoiding biases, misleading results, and addressing other aspects covered in current regulations.

sdg GROUP

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Compliance — In the era of Manufacturing 4.0, the life sciences industry faces unprecedented challenges in validating computerised systems. Their validation is an essential process that ensures compliance with healthcare regulations, such as those enforced by the Food and Drug Administration (FDA) or the European Medicines Agency (EMA). This process is crucial for healthcare companies, as it guarantees that the software and hardware used in the manufacturing of pharmaceutical products, medical devices, and biotechnologies work as intended and present no risk to patient safety.

LILIAN VEYSSEYRE / COMPUTERISED SYSTEMS VALIDATION ENGINEER — CADUCEUM

Computers under examination

“Compared to traditional systems, AI is like a black box, and we have limited knowledge about its inner workings.”

LILIAN VEYSSEYRE /

What is your expertise?
— My expertise is in Computerised System Validation (CSV). It is vital as it represents the digitalised version of the Good Documentation Practices which ensures traceability and reproducibility of production processes, analytical results, and more widely, all data that guarantees patient safety and drug quality.

What are the main trends and challenges within that expertise?
— Digitalised workflows come with many advantages: greater availability of data, easier inspections for authorities, and simplification of processing, all which contribute to the prevention of errors and the improvement of data processing time. The challenges usually lie in the transcription of the user requirements into logical rules and computer code. Data accessibility also implies that data centres have to be adapted, resilient, and penetration-proof as data security is as crucial as data accuracy.

In terms of CSV, how do you see the life sciences industry evolving in the next 10 years?
— I believe that the next challenge for CSV will involve handling Artificial Intelligence. AI generates a large amount of data based on specific prompts. As CSV specialists, our main challenge is to validate the AI, understand how it operates, and how it processes the data and information we provide. Compared to traditional systems, AI is like a black box, and we have limited knowledge about its inner workings.

Some clients are interested in using AI, but there is still a lack of understanding when it comes to validation. Currently, AI is widely used for simple tasks based on prompts. However, as the prompts become more complex, it becomes increasingly difficult for experts to validate, as we currently lack an understanding of how these “black boxes” operate.

Since we are talking about patients’ lives, how can we guarantee better traceability and reliability of their data?
— In terms of data reliability, using open-source code is a good practice, but not always one chosen by companies. They often have proprietary codes and patents in place, in order to ensure patient data remains internal.

Patient safety should always remain a top User Requirement Specifications (URS) priority. In the end, we must always think about how to consider patient data in our requirements.

What can we expect from the Internet of Things and what is its impact on medical interventions?
— It really depends on the devices. We have connected watches, for instance, that can pick up on abnormalities in cardiac rhythm at an early stage. We are seeing devices that are used to automatically dispense medicinal drugs.

With the help of IoT, we can rely on connected devices that indicate whether a drug was dispensed correctly, if any problems were encountered during the intervention, and even the patient’s previous medical record when prescribing medicine.

Trends — The life sciences market is constantly evolving, with technological, regulatory, and economic pressures driving everchanging trends. At ALTEN, these changes continually prompt further developments in a sector where every day counts for patients.

When simple solutions require complex means

BY QUENTIN BIROT / DIRECTOR OF LIFE SCIENCES MANUFACTURING & CLINICAL OPERATIONS — ALTEN

What are the biggest current trends & stakes within the life sciences market?

— The life sciences market is evolving rapidly, coping with constant technological, regulatory, and socio-economic changes. The rise of pressures, R&D costs, and ESG compliance, pushes for innovative strategies to maintain vigorous development while optimising expenses. Consequently, outsourcing to Clinical Research Organisations (CROs) and Contract Development Manufacturing Organisations (CDMOs) is increasingly vital for balancing cost-efficiency with high-quality, innovative outputs. Furthermore, the pandemic exposed supply chain vulnerabilities, prompting Pharma reshoring for resilience, while balancing Medtech's need for global efficiency. AI also revolutionises trials and manufacturing, while blockchain supports data integrity, requiring solid implementation and regulatory adaptation. These advancements facilitate the merging of MedTech and Pharma, which fosters innovative therapies and diagnostics. This convergence enhances patient care and requires integrated technologies and harmonised regulations.

What is ALTEN's perspective?

— ALTEN applies a multidimensional approach to address these trends. In response to economic pressures, Aixial's CRO comprehensive services enhance R&D efficiency, containing costs without sacrificing innovation or quality. Additionally, ALTEN aligns client operations with global ESG standards, boosting compliance and competitiveness. Furthermore, we are well-positioned to address the challenges posed by supply chain vulnerabilities. With a presence in over 30 countries, ALTEN's local embedding near manufacturing and R&D clusters ensures a balance between local production and global operational efficiencies. In terms of digitalisation, ALTEN, together with SDG and Lincoln, uses AI to optimise trials and manufacturing, reducing time to market and improving quality. We ensure secure and transparent data management, leveraging ALCOA+ and blockchain. To address the MedTech and Pharma convergence, ALTEN leverages its engineering roots and strong life sciences expertise to drive innovation at this intersection. Through Aixial, ALTEN enhances patient care with advanced therapies and diagnostics, integrating both fields.

What is our Group's added value?

— ALTEN's added value lies in our comprehensive and tailored approach to meet client needs. We deliver services spanning the entire product lifecycle, from early R&D to regulatory compliance and market release, which ensure seamless project progression. This is complemented by ALTEN's unique glocal synergy. Our global expertise, enhanced by local execution, effectively meets diverse regulatory and market demands. Central to these capabilities is our integrated technical direction, supported by a sturdy delivery framework and centres of excellence. This combination provides tailored solutions and guarantees high-quality standards.

FASTER

Whether we are talking about drug discovery, delivery or working process, it is clear that in life sciences, the time is ripe for acceleration. AI, automation, and advanced analytics change the game in expediting clinical trials, optimising manufacturing processes, and reducing time to market for new therapies. Indeed, it's a race against time in the service of life, and ALTEN is fully committed to it.

LIMS & ELNs: A ROUGH TIME FOR QUALITY DEFECTS

Quality control — To stay competitive, companies are increasingly adopting Laboratory Information Management Systems (LIMS) and Electronic Laboratory Notebooks (ELNs). These platforms and software enhance data accuracy and streamline operations, leading to significant improvements in manufacturing efficiency. By setting new industry standards, LIMS and ELNs empower Quality Control labs (QC labs) with the ability to make rapid, precise, and confident decisions. As a result, they enhance current operations and become crucial in shaping the advanced, digitised lab environments of the future.

LIMS and ELNs play a foundational role in driving efficiency by ensuring laboratories operate at peak performance. These systems enhance data accuracy and streamline decision-making processes in QC, significantly reducing manual data entry errors. This leads to improved reliability and compliance with regulatory standards, which are critical for maintaining product quality. Access to real-time data speeds up decision-making and reduces time to market. This improves responsiveness to quality issues, increasing operational efficiency and reducing costs. Additionally, features such as audit trails and electronic signatures in LIMS and ELNs facilitate compliance, streamline audits, and simplify certifications. This not only strengthens the manufacturer's credibility but also frees up the lab team's time to focus on critical quality control tasks, thus enhancing product consistency and adherence to standards.

Success factors for digitising QC labs

— At ALTEN, key factors for successfully digitising QC lab operations with LIMS and ELNs include defining clear objectives and securing strong executive support. A comprehensive assessment of existing workflows and strict adherence to regulatory standards such as FDA 21 CFR Part 11 are crucial for

LIMS

Laboratory Information Management Systems are software solutions designed to manage and streamline laboratory workflows, data management, and information tracking.

ELNs

Electronic Laboratory Notebooks are digital platforms designed to record, manage, and share laboratory experimental data and observations electronically, replacing traditional paper-based notebooks.

aligning the new systems with lab requirements. Engaging stakeholders from various departments early in the process is essential to ensure that the customised solutions meet diverse needs and integrate seamlessly with existing technologies. The transition process includes meticulous data migration and system validation, reinforced by robust change management and communication strategies. Continuous improvement after implementation ensures that the systems evolve with the lab's needs, maximising return on investment and paving the way towards future advancements in the life sciences industry.

Advancing technologies

— The future of LIMS and ELNs looks bright, driven by advancements in technology such as artificial intelligence and machine learning. These technologies are poised to significantly enhance the predictive capabilities of LIMS and ELNs, enabling proactive optimizations of laboratory workflows. This will not only reduce time to market but also streamline complex processes. Additionally, the shift towards cloud-based solutions will increase scalability, improve data security, and facilitate global collaboration. Integration with the Internet of Things will streamline data collection and analysis, boosting decision-making and operational efficiency. As these technologies evolve, LIMS and ELNs will not only improve efficiency and compliance but also transform QC labs into more strategic high-value assets within the life sciences sector.

— As a matter of fact, the horizon for LIMS and ELNs is setting a dynamic course towards unprecedented operational excellence. These systems are the bedrock of future-ready labs that prioritise innovation and precision. For industries looking to thrive in an ever-competitive and regulatory stringent environment, embracing LIMS and ELNs is not an option—it's a necessity. As we look towards a future where data is king, those tools stand as critical enablers, propelling laboratories into a new era of technological sophistication and strategic capability. Are you ready to embrace this digital revolution? ⊗

Digitalisation — Clinical trials are essential research studies evaluating medical intervention safety and efficacy, with varying designs and phases aimed at understanding treatment effects and patient experiences. Until recently, traditional in-person trials posed challenges such as patient recruitment and regulatory compliance. Innovations like decentralised trials and digital technologies completely change the game and open up a whole new field of solutions. Our expert shares her insights in the field.

ASMA SERIER / DIRECTOR OF THE AIXIAL LAB — AIXIAL GROUP

Clinical trials: when digital becomes critical

What is the status of clinical studies today? What would be the future of it?

— Clinical trials are research studies designed to assess the safety and efficacy of medical interventions on human health outcomes. Trials' design can vary based on what researchers are trying to find out. For example, treatment studies are designed to understand the effects of new medicines or devices, while observational trials are intended to understand patients living with a particular health condition.

Studies are also categorised by phase. Phase I trials represent the first step of research that includes human participants and focuses on safety assessment, Phases II and III evaluate treatment efficacy, while Phase IV entails long-term safety monitoring post-approval.

Until recently, all clinical trials were conducted in person. Volunteers who wished to participate had to travel to a research site, whether it was their local doctor's office or a distant location across the country. These traditional clinical trials posed several challenges related to patient recruitment, resource limitations, intricate protocols, protracted timelines, accurate adverse events reporting, regulatory compliance, geographical diversity, patient inclusivity, and strong data management. Innovations, such as decentralised trials and digital technologies, strive to address these challenges.

The future of clinical trials holds exciting advancements driven by technology and scientific innovation. The most impactful trends include digital transformation (digital

“The life sciences industry is now shifting to Direct to Patient (DTP) models that allow more personalised solutions.”

ASMA SERIER /

endpoints, Patient-Reported Outcome Measures (PROMS), Patient-Reported Experience Measures (PREMS), Artificial Intelligence (AI), and real-world data), precision medicine, decentralisation (remote trials), predictive models, and a focus on ethics and transparency. These advancements aim to make trials faster, more efficient, and better aligned with patient needs.

How can the life sciences industry adopt more patient-centric approaches in clinical studies, and what benefits do they offer in terms of engagement and outcomes?

— Patient-centricity is a key driver of change in the healthcare sector. It means putting patients at the centre of the entire research and development process. The life sciences industry, which used to focus mainly on business-to-business relationships with healthcare providers, buyers, and regulators, is now shifting to Direct to Patient (DTP) models that allow more personalised solutions. This reflects the growing demand of patients, who are no longer passive recipients of medical interventions, but informed consumers who want to be involved in their own care.

Clinical trials that adopt a patient-centric approach aim to align the research and development process with the needs, preferences, and values of patients. By engaging patients as partners in the design, operations and dissemination of clinical trials, those approaches can reduce the burden on patients and/or their relatives, improving the participation and retention of volunteers, as well as the relevance and generalisability of the results. They can also enhance the quality and efficiency of clinical trials by improving adherence and facilitating recruitment. Moreover, patient-centric approaches can build trust and transparency between researchers and patients, which can lead to better communication and collaboration.

How do you foresee emerging technologies, such as artificial intelligence, impacting the design and execution of clinical studies in the life sciences industry?

— AI has emerged as a transformative technology with tremendous potential in the field of clinical studies, particularly in patient identification and recruitment. Thus, solutions such as Natural Language Processing (NLP) can be leveraged to analyse electronic health records data, streamlining the identification of potential trial participants. This not only accelerates recruitment but also lightens the workload for trial teams. Additionally, machine learning has proven useful in detecting unsual patterns within health datasets, genomic, imaging data, and more. Thus, AI is likely to contribute to earlier diagnosis, particularly in the context of rare diseases which can potentially lead to improved patient outcomes and prognosis. Its applications in healthcare are endless, including automation of several tasks, from administrative workflow to clinical documentation and patient monitoring.

Recently, in silico trials have emerged and gained momentum. By leveraging computer simulations and modelling, virtual participant groups can be created to mirror real-world cohorts and predict outcomes. In silico trials can also help

“Explainable AI (xAI) or attention models, have the potential to transform many aspects of healthcare.”

ASMA SERIER / DIRECTOR OF THE AIXIAL LAB — AIXIAL GROUP

optimise trial design, by identifying optimal doses, duration, and targeted population for new interventions while assessing their potential adverse events or interactions.

Despite several AI deployment challenges in the health sector (such as ethical concerns, data privacy, data security, possible biases, etc.), advances in computational techniques, like explainable AI (xAI) or attention models, have the potential to transform many aspects of healthcare, enabling a future that is more personalised, precise, and predictive.

How could we effectively leverage the growing volume of patient-generated data and Real-Word Data (RWD) through digital tools to generate Real-World Evidence (RWE)?

— Real-World Data is collected from sources outside of randomised controlled trials, such as electronic health records, claims databases, registries, and mobile/connected devices. RWE is the clinical evidence derived from the analysis and interpretation of RWD. RWE can provide valuable information about the effectiveness, safety, and value of medical interventions in real-world settings and populations, with a growing importance amongst stakeholders.

Despite the expectations, RWD poses significant challenges and limitations, such as data quality, validity, reliability, representativeness, interoperability, privacy, and security. Several national and regional initiatives are working to create a common framework for RWD collection, management, and use. For example, the Food and Drug Administration (FDA) in the US supports using RWD for regulatory purposes. The European Medicines Agency (EMA) in Europe advocates for RWD in drug evaluation, and the European Health Data Space (EHDS) initiative aims to unify health data across EU member states. At a global level, organisations like the International Society for Pharmaceutical Engineering (ISPE) and the Observational Health Data Sciences and Informatics (OHDSI) promote RWD harmonisation worldwide. By establishing common standards, ensuring data quality, and fostering international collaboration, we can maximise the impact of RWD and AI in improving patient care, advancing medical research, and enabling informed decision-making. Moreover, the volume and complexity of such data poses additional challenges for their analysis and interpretation. AI-based solutions and blockchain could help overcome some of these hurdles and enable the generation of high-quality evidence to support regulatory and reimbursement decisions.

What role do you see technology playing in optimising data ingestion throughout the entire patient healthcare professional journey?

— As previously said, RWD, which is generated by various sources such as sensors, electronic health records, medical claims, registries, wearables and social media, has attracted a lot of attention and raised high expectations for modern decision-making. However, there is a gap between the hype and the reality of RWD, particularly related to the large volume and the heterogeneity of data, the lack of structure and standardisation, and the difficulty of interpretation which limits the usability. AI-based solutions can help overcoming some of these obsatcles. We also need to continue data standardisation and harmonisation efforts at every layer to ensure interoperability and comparability across different data sources and formats. Indeed, one of the key factors for improving the quality and impact of RWD is fostering interdisciplinary collaboration among all the relevant stakeholders, researchers, clinicians, regulators, payers, and patients.


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Interview —

1

2

MATILDE THYE KVEIBORG [1] / DIRECTOR OF MEDICAL WRITING AND **TANJA JENSEN** [2] /SENIOR MEDICAL WRITER, AIXIAL GROUP

Writings with molecules and standards as main characters

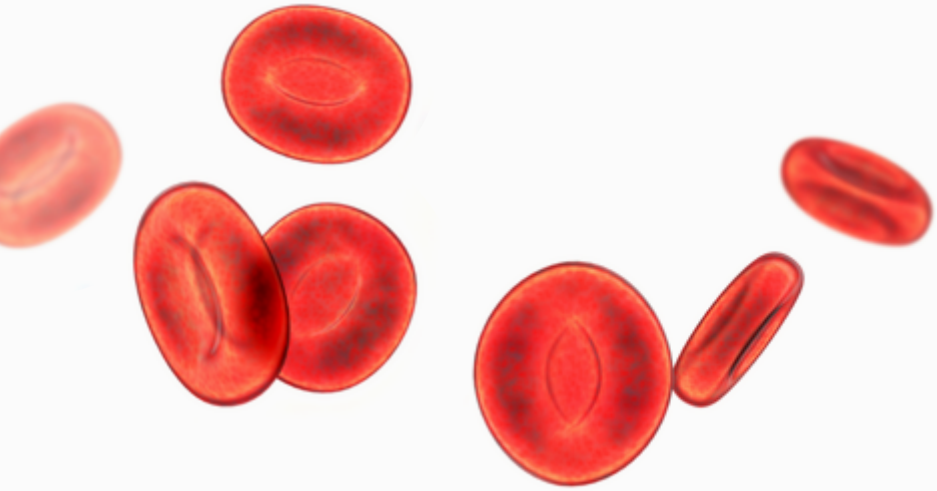
What does your department do?
Matilde — The medical writer role is broad, with the key responsibility to design and deliver fit-for-purpose documents that communicate highly complex information clearly and concisely. We handle various types of documents, including typical regulatory documentation, such as protocols for clinical studies, clinical study reports, and investigators' brochures. Additionally, we prepare scientific publications and occasionally assist with marketing materials or Standard Operating Procedure writing. All of our team members come from scientific backgrounds – having obtained PhDs, and some even postdoctoral experience. In addition to our strong scientific foundation, we have dedicated many years to gaining insights into what effective communication is when it comes to drug development. And this means that we have some tricks up our sleeve that can help accelerate clinical development by optimising the regulatory documents that we send to the authorities.

What does Aixial Group offer that sets you apart?
Matilde — I would say it is our extensive experience that sets us apart from other Clinical Research Organisations – particularly with the high complexity and strategic document types, and then our great teamwork. We often work with a cross-functional team of experts representing various skill areas. In such a team, the medical writer role is crucial in helping to facilitate document progress, ensuring clarity in messaging and understanding how the different pieces of information interconnect. Additionally, medical writers can assist in guiding the sponsor's flow of thought, mapping out the path to their conclusions. A medical writer can therefore help pave the way towards documentation that is both compliant and concise, while also aiding the reader's understanding and interpretation of data.

At what stage of clinical development is it best to engage in as a medical writer?
Tanja — I would say very early, as it is crucial to consider how the writing will align with downstream documents. With a comprehensive strategy in place, a medical writer can discern how each piece of information connects with subsequent documents where specific questions must be addressed. For instance, when preparing a protocol, there are many advantages, considering the clinical study report and subsequent scientific publications, (e.g., to ensure regulatory compliance and coverage of necessary aspects for publication in high-impact journals).

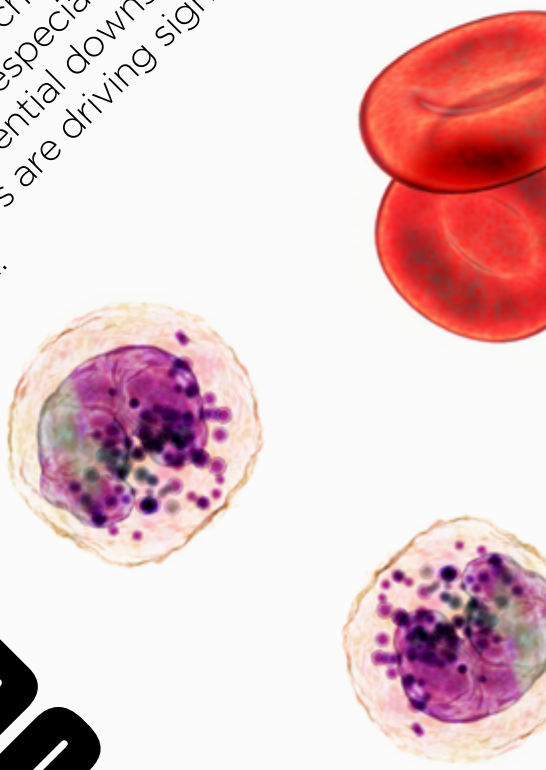
What are the most common problems you, as a medical writer, help clients overcome?
Tanja — Excessive length, incomplete content, and especially poor explanation of rationale are the most frequently encountered issues related to document quality. Particularly, poor explanation of the rationale has the greatest impact on document quality according to regulators. As medical writers, we know how to overcome these issues and prepare high-quality documents. Based on extensive experience, we understand what needs to be done and how to accomplish it. We have our tips and tricks to help our clients achieve the approvals they need.

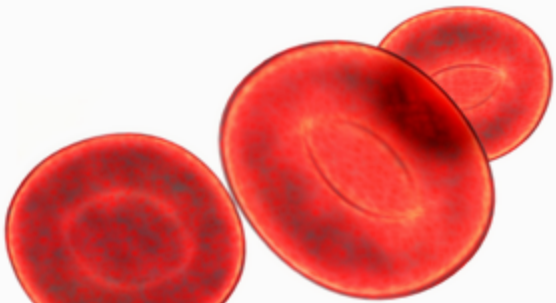
What are the most important things to consider as a medical writer in the early stages of protocol development?
Tanja — It's all about a long-term strategy involving stakeholders. This entails understanding the end goal, whether it's a medicinal product or a device. To ensure consistency, medical writers facilitate important discussions and glean insights from stakeholders into comprehensive writing, all while navigating the nuances of their unique language.

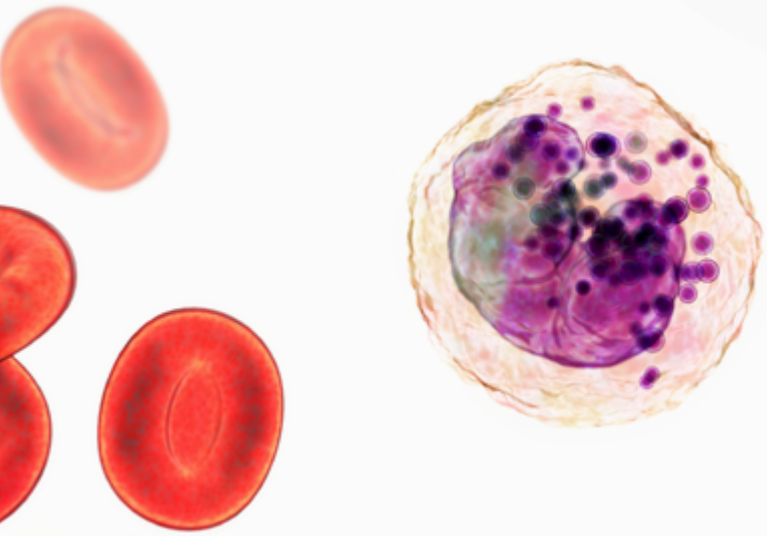


CARs AT A CROSSROADS

Safety and clinical activity — Cell and Gene Therapies (CGTs) are transformative, offering potential cures with a single dose. Despite challenges in logistics, safety, and cost, their benefits, especially in CAR-T immunotherapy, outweigh the potential downsides. As innovation continues, CGTs are driving significant growth in the medical field.







A revolutionary approach within a complex landscape

— Cell and Gene Therapies (CGTs) are a class of drugs with immense potential. They are used to prevent and treat diseases and can go as far as curing them with just a single dose.

As promising as CGTs present themselves, their successful administration faces challenges in multiple areas, such as logistics, communication, long-term safety, cost of manufacturing, and accessibility.

- Medical teams must coordinate smoothly across multiple contributors such as apheresis clinics, specialised shipping vendors, therapy manufacturers, chemotherapy teams, and post-treatment care providers.
- Decision-making involving the patient's care requires greater reactivity, adaptability, and a higher level of input from external parties. From cell extraction to reinfusion, there are many steps, stakeholders, and external factors to be considered.
- CGTs are still considered to be a recent scientific advancement. Much remains unknown about their long-term effects on patients, such as the possible passing down of mutations to next generations, or the adverse effect on immune system response. This is why CGTs may take longer to research, approve, and adopt.
- These therapeutic agents are also expensive to manufacture and to administer, further limiting their accessibility.

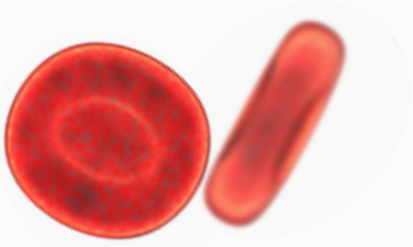
Nonetheless, the medical community and clinical development industry acknowledges that the revolutionary benefits of CGT outweigh the risks. The market size and growth are clear evidence of this, worth $18.12 billion in 2023 and expected to reach $117.46 billion by 2034.

A closer look into CAR-T therapy

— One of the most clinically and commercially advanced embodiments of CGTs is Chimeric Antigen Receptor T (CAR-T) cellular immunotherapy. CAR-T therapy is a personalised cancer treatment, also known as precision medicine. This treatment utilises specific information about the patient and their tumour to provide the most suitable approach. By using the patient's own immune system to fight the disease, fewer treatment cycles can be expected, potentially reducing harmful side effects and damage to healthy cells.

CAR-T therapy involves collecting the patient's white blood cells (T cells) and then genetically engineering them in the laboratory to produce receptors (called Chimeric Antigen Receptors, or CAR) on their surface. The T cells used to create CAR-T cells can either come from the patient (autologous) or other sources (allogeneic). The generated CAR-T cells are then infused back into the patient where they will recognise and bind to cancer cells more efficiently.

— In the future, we can expect next-generation CAR-T therapies to encompass additional tumour types, particularly in solid tumours. Recent research has focused on expanding the approach to utilising donor T-cells or other immune cells, such as Natural Killer (NK) cells, which would in turn reduce the side effects of CAR-T products. With each advancement, we can expect to increase CAR-T therapy's accessibility, reaching larger groups of patients and widening the range of diseases it can treat.



Paradigm shift — In the life sciences industry, deviation management is a crucial activity that must be mastered to comply with good practices. A deviation, or an unplanned event that diverges from an established standard in a GxP environment, requires thorough resolution and documentation. Yet, an overemphasis on immediate fixes can overlook the opportunity for significant quality improvements and operational excellence. Recognising this gap, ALTEN has developed a functional service model designed to transform deviation management from a quality issue into a proactive operational asset.

DEVIATING

DEVIATIONS

Traditional deviation management often traps companies into focusing on quick fixes for immediate quality issues, leading to a host of challenges. This approach tends to divert resources away from strategic objectives aimed at long-term improvement and compliance, making it difficult for companies to maintain a consistent focus on quality and operational excellence. Additionally, the fluctuating number and the unpredictable nature of deviations can overburden in-house resources, leading to peaks that create backlogs and bottlenecks that hinder effective management. Furthermore, this variability could expose a knowledge gap in handling specific deviations or in the overall process of managing deviations. This complicates the identification of the root causes and implementation of effective corrective actions. This reactive stance also impacts a company's readiness for regulatory inspections, as a lack of continuous improvement and proactive quality culture can leave gaps in compliance and operational integrity.

The impact of ALTEN's deviation management functional service: a measurable success

— In this context, ALTEN introduced a functional service model that redefines the essence of deviation management. The model quickly proved effective through a pilot project, where a team of five deviation coordinators demonstrated its strengths early on. Within a couple of months, the team started to deliver deviations ready to be closed, and by the third month, operated autonomously. This early success was driven by strategically capitalising on knowledge, boosting the model's capacity and sustainability. This approach enabled clients to focus on core activities, offering adaptability and access to an extensive expert network. Following the pilot's success, the model gained recognition by several life sciences clients and expanded rapidly. Since then, over 200 consultants have collaborated on various projects and contributed to the closure of more than 4500 deviations. This growth led to the establishment of a Belgian center of excellence, now a global hub for sharing best practices and expertise.

The ALTEN model: a critical breakthrough

— Historically, the Belgian consultancy industry has relied on the time-material model for technical support, placing consultants under client supervision to meet specific needs. While effective to a point, this model often led to inefficiencies, focusing more on filling roles than on enhancing performance and knowledge management. ALTEN's technical direction identified an opportunity to rethink this approach, resulting in the creation of the deviation management functional service model. This model marks a significant leap from the status quo by emphasising performance and outcome-driven results. This model shifts consultant management and performance monitoring to ALTEN, enhancing expertise and efficiency while decreasing reliance on individual client process knowledge through structured knowledge management. It offers high flexibility in resource allocation and includes efficient turnover management for consistent support. Additionally, ALTEN now oversees consultant training to ensure a standardised understanding of deviation management across the team.

— In summary, ALTEN reshaped deviation management, turning challenges into strategic assets for better quality. With our expansion into Corrective Action & Preventive Action (CAPA) and Change Controls since 2023, we've significantly extended our reach. Our strategy goes beyond creating a generic expertise hub; we leverage ALTEN's extensive global network to establish specialised hubs that enable profound synergies within the same client across different countries. This initiative will optimise interconnectivity and efficiency, transforming how multinational clients manage deviations worldwide.

Talents — The world of life sciences is vast and constantly evolving. It's not enough to follow trends: you have to anticipate them, and to do that you need to bring together the best specialists. At ALTEN Group, Stéphane Thérèse is well aware of this.

Training and upskilling are part of our genes

STÉPHANE THÉRÈSE /
DIVISION DIRECTOR — AIXIAL GROUP

What kind of profiles do we have today within the life sciences sector at ALTEN?
— We have a broad range of profiles within our life sciences division. Our teams include pharmacists, doctors, engineers, scientists, biologists, and the list goes on. This diversity is not just a strength, but the trademark of our unique market position. Historically, we have strong engineering DNA, but today, this wide array of expertise allows us to tackle challenges from multiple angles, making us a strong challenger in the market.

How do you keep up with the training and career development of your talents while respecting this diversity of profiles?
— We have a 360° approach when it comes to training and development. We participate in many external conferences, promote knowledge sharing through communities, and together with the Group, we are enhancing our training offerings. Career-wise, we also conduct transparent talent reviews and maintain a detailed profile mapping to accelerate our consultants' growth.

Do you see new roles emerging? How can we envision the life sciences market within the next years?
— Life sciences is an ever-evolving industry. We are in the first stages of the next technological advancements, especially in AI. Due to the healthcare industry becoming more and more global, we can expect many new opportunities and developments for our people abroad within the next years. Studies tell us that 85% of the jobs in 2030 do not exist yet. However, we know that the new landscape will be 100% linked to AI and technology. I believe that we already have the qualified experts, and that they will need to grow and adapt to keep pace with the upcoming changes.

How does ALTEN anticipate these changes to keep on responding to clients' needs?
— Our DNA is not simply knowing how to react to changes; but rather to anticipate and shape them. By making strategic investments and maintaining close relationships with our clients, we ensure that we can meet their expectations. In-house, we are starting to develop training programs focused on AI and other emerging technologies. In Belgium for example, we developed the Masterclass program to train students and offer them their first opportunity within the industry. Externally, we partner with top-tier universities, developing scientific programs. These initiatives allow us to identify young talents and play a role in shaping their careers, as it is paramount to stay connected to the next generation of talents.

STRONGER

For an organisation, strength is not an end in itself, but a basic necessity for survival. Nowhere is this clearer than in life sciences. ALTEN's approach is to gather and cultivate the best talents and, thanks to technology, give them the time to concentrate on high-value tasks and generate reliable results.

Career paths — ALTEN's women and men are the driving force behind our business. Our Group's ability to develop and promote the best talents available is fundamental in enabling us to meet our customers' needs. Over the past years, we have made concerted efforts to counter certain widely held stereotypes and misconceptions in order to encourage engineering vocations among young women. Elizabeth Sydney and Jana Lejaeghere are the perfect illustration of this.

Women driving change in Life Sciences

ELIZABETH SYDNEY /
RESEARCH ENGINEER AT ALTEN SWEDEN

Born in Nigeria, then having moved to Gothenburg as a teenager, Elizabeth Sydney decided to pursue her higher education in the United States, where she obtained her Chemistry degree at California State University, Long Beach. During her years of study, she carried out two years of research in electrochemistry. Today, Elizabeth holds the position of Research Engineer in the Life Sciences division at ALTEN Sweden.

What does building Tomorrow's world mean?
— "To me, building Tomorrow's world means making and enforcing decisions that'll make the world easier and better for the next generations. There has been a huge development in terms of sustainability in the latest and upcoming innovations, and I think that will make a positive impact in building tomorrow's world.
AI will definitely have an impact, with the speed and rate it's being implemented."

JANA LEJAEGHERE /
QA ENGINEER AT ALTEN BELGIUM

**After having studied at the University of Antwerp, enriching her background in pharmaceutical sciences, Jana decided that rather than working in a pharmacy, she would opt for industry. She was hired to join ALTEN's consultant team just after graduating, representing her first job experience.
"As a consultant for ALTEN," says Jana, "I work in quality assurance. I'm there to vouch for the patient's life and trust." Jana is currently working on an innovative treatment for a type of blood cancer called multiple myeloma – involving quite the unique process.**

Does your work inspire you to become a better person and professional?
— "Because of the products we're working on and the patients we're working for, I've had the chance to work on very rare diseases, like a growth hormone, vaccines, or cancer treatments. You really feel the connection with the patients, even though you're never in direct contact with them. You know that you're working for a purpose: to help people and save lives. That's what helps you get through the day and what makes your job feel important."

“I strive for excellence in every project I take on, bold enough to stand behind my decisions, I work on building trust with my colleagues and managers, curious enough to always ask for different projects, and resilient in any task I’m given. In finding a job, it is crucial for me that there is always room for professional development, while also attaining a good work-life balance.”

ELIZABETH SYDNEY /

“We take the patient’s blood and then we reprogram the white blood cells to attack cancer cells instead of other things. So basically, we build a patient’s own defence system against cancer, which is remarkable. The technology is very advanced and is potentially also a way to treat many other cancers. And we’re putting that out in the world right now. That’s amazing!”

JANA LEJAEGHERE /

CUTTING EDGE

Cancer care — Elekta Esprit, a Gamma Knife® stereotactic radiosurgery system, revolutionises cancer care. It is used for curing targets in the brain, such as tumours, vascular malformations, or functional disorders, with high precision. No wonder it has been awarded.

On the occasion of the Red Dot Award Ceremony in June 2023, together with members of his team, Peter von Zweigbergk travelled to Germany to accept an award in the "Product Design" category for the Radiosurgery System Elekta Esprit, a Gamma Knife® stereotactic radiosurgery (SRS) system used in cancer care. Its design stands out for its sleek, minimalist aesthetic that shifts focus from the machine to the user. The system integrates sophisticated technology with a user-friendly interface, making complex treatments more accessible and efficient. By prioritising ease of use and patient comfort, Elekta Esprit significantly improves the treatment experience. "It's great to receive international recognition and an award for all the work put into the project! Especially when it comes to the Red Dot Design Award, as it's a very renowned and esteemed prize in the industry."

"The most fulfilling reward in Med-Tech product development is witnessing the final product actively transforming the lives of patients."

PETER VON ZWEIGBERGK /
SENIOR INDUSTRIAL DESIGNER & DESIGN MANAGER — ALTEN SWEDEN

Working as a designer at a Neuro Department

— Peter works as a Senior Industrial Designer on an assignment in Elekta's neuro department, focusing on delivering design solutions in all phases of the product development process. He believes in facilitating collaboration by establishing clear and comprehensive objectives for both aesthetics and functionality. It is essential to consider what values we aim to convey through the product and how we want customers and patients to perceive it. Deliberating on these aspects enhances the team's decision-making process. This approach fosters unwavering cooperation, inspiring all stakeholders to exert additional effort in crafting something more cohesive and polished.

Individuals across various levels must be fully engaged to be successful in achieving synergy and innovation, and in establishing cohesive product development and optimisation across all stages, from conception to market release. This includes a product management and marketing team, responsible for strategy and sales alignment; an engineering team, ensuring high-end solution delivery; NPI managers, maintaining supplier communication; release engineers, overseeing project realisation, and a service team, providing essential feedback.

The challenge and the outcome

— The challenge and complexity of MedTech products lies within striking a delicate balance between finding the right scope while simultaneously pushing for a product that makes a significant impact. On the one hand, there's a need to ensure that the product remains manageable in terms of size, complexity, and resources required for development. On the other hand, there's a relentless drive to innovate and create solutions that truly transform healthcare and improve patient outcomes.

Achieving this balance requires careful navigation through regulatory requirements, technological advancements, supplier need times, and user needs.

"The most fulfilling reward in MedTech product development is witnessing the final product in action, actively transforming the lives of patients," concludes Peter. "It's an indescribable feeling to see something you've contributed to make a tangible difference in someone's health and well-being."

Next-gen pharma solutions — Rui Campos is emblematic of what ALTEN has to offer in terms of career development. Initially an automation expert and now a life sciences leader, he tells us here about his career path.

Advance science, and one's career at the same time

Reflecting on my progression at ALTEN, from a novice in life sciences to a leader in technical management, I have continuously evolved through learning and leading. Every role has been a critical step forward, building on the last to enhance not only my skills but also the capabilities of our team. Throughout this journey, my focus has been on leveraging technology to deliver positive and impactful changes.

Joining ALTEN marked a pivotal transition in my career. With a solid background in automation and practical experience in the water and oil & gas industries, I was well-prepared to tackle the new challenges of the life sciences sector—an exciting and dynamic field. My initial role at ALTEN tapped into my automation expertise but also marked my entrance into pharmaceuticals. This position provided a sturdy foundation to build upon my interests and skills in an innovative and effective environment.

As a consultant, one of my first significant challenges was to automate equipment for the development of a COVID-19 medication. This project was not only critical due to its potential global health impact but also served as a focal point in my career. It sharpened my skills in Industry 4.0 and Good Manufacturing Practices, deeply immersing me in the pharmaceutical industry's unique challenges. This experience set the stage for my career progression, emphasising the critical impact of our work on healthcare.

Progressing from Consultant to Team Leader, I took on the role of mentoring new consultants. This part of my journey was about guiding their development, instilling a culture focused on innovation, teamwork, and consistently elevating standards of excellence. Today, I hold the position of Technical Unit Manager, where I oversee broader strategic initiatives and lead larger teams. In this role, I've led projects aimed at enhancing operational efficiency, such as the introduction of advanced automation systems that streamline production processes and improve data accuracy and accessibility.

Looking ahead, I'm excited by the potential integration of Artificial Intelligence (AI) in our operations. AI is set to revolutionise our approach of predictive maintenance and drug manufacturing. As we embrace these technologies, my focus will be placed on fostering innovation and guiding our team towards new possibilities.

Interview —

CHERYL DALGADO /
PROJECT DIRECTOR — ALTEN CANADA

Crafting the future of Life Sciences

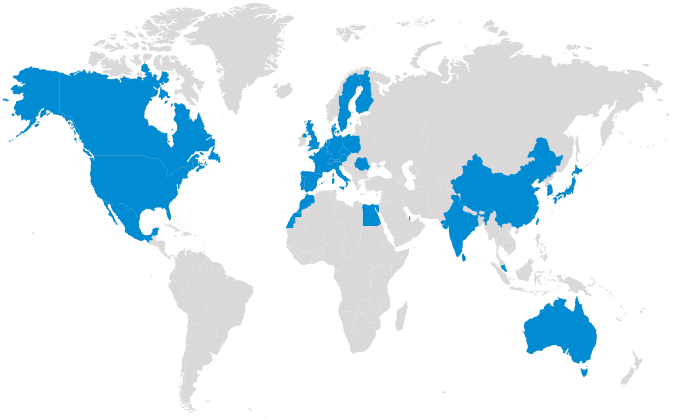
What has inspired you to pursue a career in life sciences?
— During my undergraduate studies at McGill University, I discovered the world of microbiology & immunology. I was fascinated with disease causing bacteria and viruses, and their impact on society. It wasn't until my graduate work at University of Guelph that I realised the impact I could have on patients. I spent 4 years studying bacteria that caused chronic kidney infections. I realised I wanted to do more to help patients. My first job in the workforce was with Baxter Healthcare (Alliston, Ontario). One of the first mentors in my career reminded me of the importance of Good Manufacturing Practices, and how my actions in the pharmaceutical industry can impact patients. While I started my career in Manufacturing, I quickly moved to quality control & compliance roles, where I could apply my background in microbiology. My desire to solve problems and lead teams (all in the spirit of patient safety) brings me great satisfaction.

What was your vision when you decided to join ALTEN?
— I have 25 years of pharmaceutical experience in sterility assurance, quality control, compliance, batch release, and project management. I was inspired by the opportunity to use my experience to provide technical direction to consultants working in the ALTEN team. Throughout my career, I have always enjoyed sharing my knowledge. I want to provide guidance and leadership to people who are starting out in their career, or people who want to learn how the industry works. I was also motivated by the opportunity to reconnect with my large network of colleagues. Many of my former colleagues are now clients!

What are you looking to achieve in the life sciences industry through your current Project Director role?
— ALTEN offers managed services, which is a concept a lot of our clients are not familiar with. As a Project Director, I'm excited to share ALTEN's way of working with prospective clients, and more importantly, how I can support consultants from a technical standpoint should they choose to pursue ALTEN's services.
Often, clients overlook that when they transition to managed services, the Project Director will personally work with ALTEN's Business Managers and Recruiters to identify the right talent for the role.
Once the project begins, ALTEN's full management system is deployed for our client's benefit. My role is to continue supporting the consultants in their work to ensure deliverables are achieved and to stay in contact with our clients to ensure they are satisfied with the support they are receiving.
This management system is what differentiates ALTEN from other consulting companies and I am excited to be a part of this new way of working.

What are some challenges that you are facing in this industry, and how are you navigating them?
— Pharmaceutical companies must comply with various regulations, from clinical trial requirements to manufacturing and distribution standards. Keeping up with these standards can be a challenge for many companies.
They are faced with resource constraints and in some cases, an inexperienced workforce. These difficulties provide us with the opportunity to work with such clients. ALTEN consultants can support client business needs without impacting constraints on full time employee headcount.

ALTEN AROUND THE WORLD



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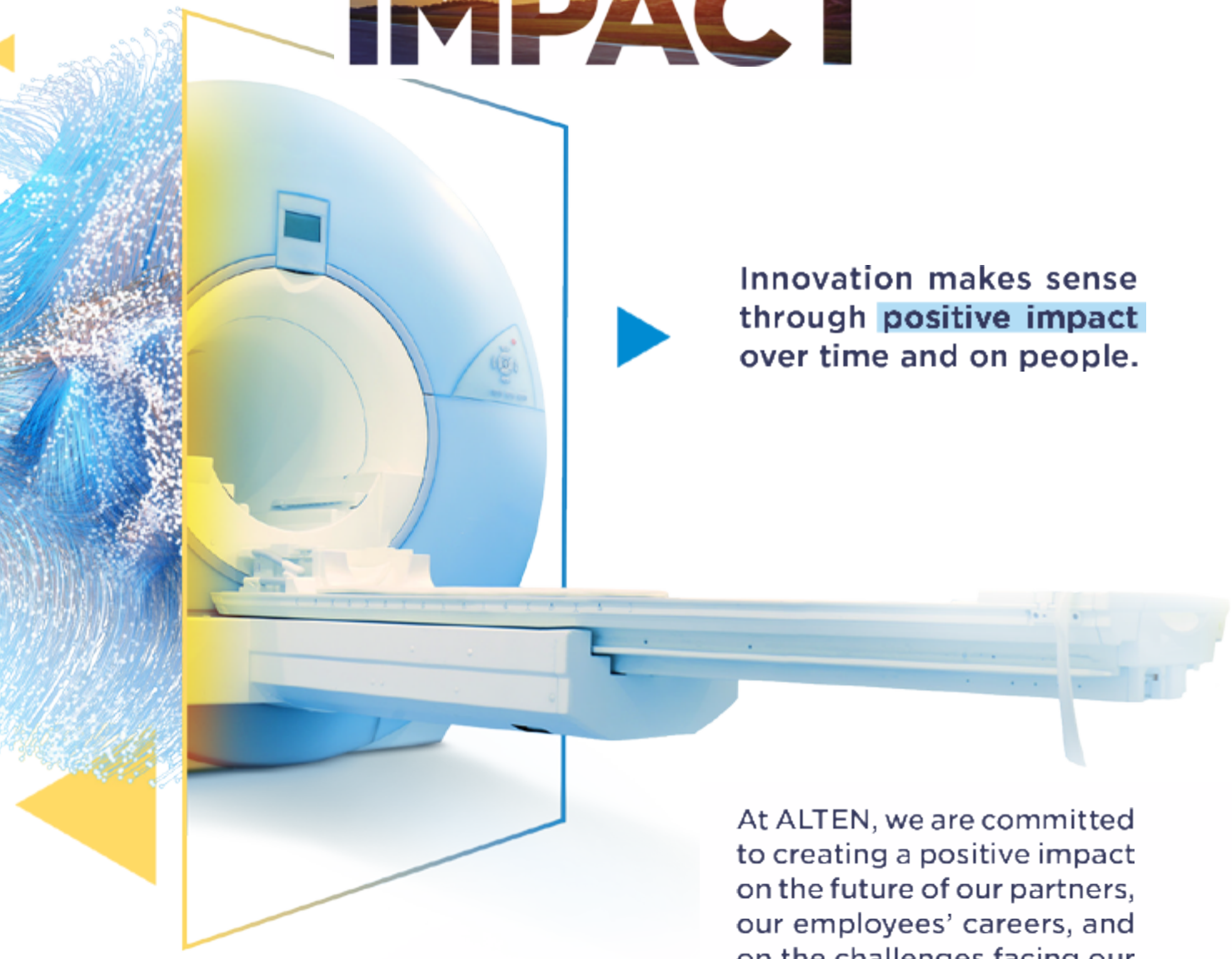
CREATE IMPACT



Innovation makes sense through **positive impact** over time and on people.

At ALTEN, we are committed to creating a positive impact on the future of our partners, our employees' careers, and on the challenges facing our society and the environment.

We are home to those committed to have a positive impact.

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