LIONBRIDGE

AI AND LANGUAGE STRATEGY IN LIFE SCIENCES

WHAT YOU NEED TO KNOW

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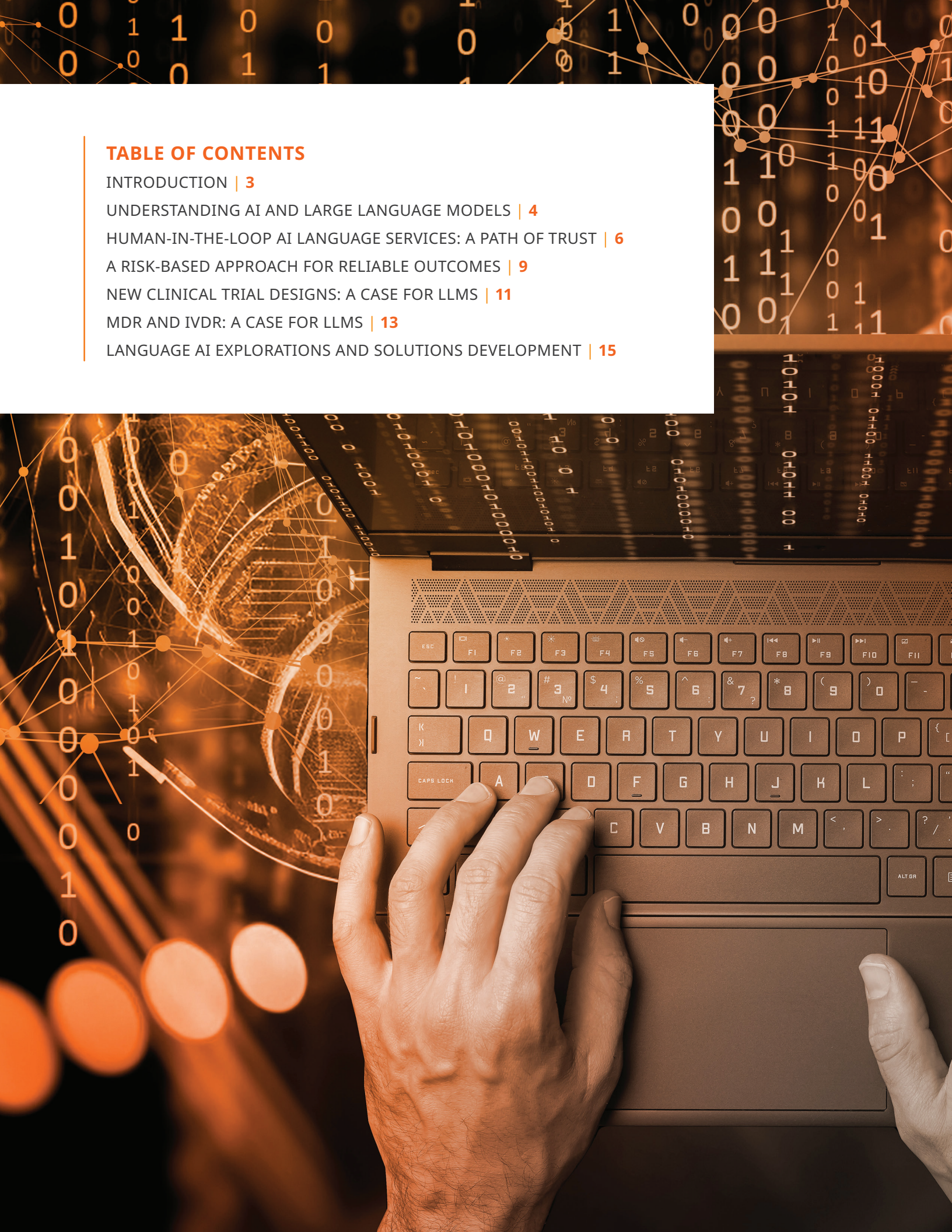

IS AI TELLING YOU WHAT TO DO? OR, ARE YOU TELLING AI WHAT TO DO?

Deploying Artificial Intelligence (AI) successfully hinges on control and trust. While control is familiar in the regulated realm of life sciences, trust must be earned and substantiated by data. This is especially true of AI and Large Language Models (LLMs).

Generative AI and LLMs are emerging technologies, and many companies have adopted a wait-and-see approach. Such caution is appropriate in a regulated industry where lives are at stake. However, AI is developing rapidly and shows tremendous promise in some applications. Doing nothing places organizations at a competitive disadvantage. We at Lionbridge are advising life sciences customers to balance caution with openness to innovation. We also believe that trust can be built around LLMs regarding language outcomes, especially if the Life Sciences industry starts reconsidering its approach to language strategy.

In this eBook, we'll bridge the trust gap and clarify some potential applications of large language models to produce reliable, suitable language outcomes for Life Sciences.

As a Language Services Provider (LSP), Lionbridge is deeply impacted by the evolution of LLMs and how they're reshaping and challenging the language services industry.

Customers look to us for guidance on where and how LLMs and Machine Translation (MT) can be utilized for cost-efficiencies — without compromising language quality and compliance. Since language is inherently contextual and complex, our recommendation in this eBook is to start by focusing on the expected language outcomes and context of use. Then, you can design your AI language strategy based on your product pipeline or corporate business objectives.

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UNDERSTANDING AI AND LARGE LANGUAGE MODELS

AI encompasses a broad spectrum of potential applications and numerous advanced tools that can mimic human intelligence. Navigating through the hyped-up "breakthrough" rhetoric on AI and understanding its tangible value can be challenging. The following four definitions may help demystify the subject.

1. Artificial Intelligence (AI) is a branch of computer science that focuses on creating systems capable of performing tasks that typically require human intelligence. AI systems can be based on rules or trained on large data sets. Tasks can include understanding:

   - Natural language
   - Problem-solving
   - Patterns
   - Decision-making

2. Generative AI (GenAI) is an AI system or technology that generates new content, often text and/or images, based on prompts and extensive multimodal training. It determines the most plausible output that appears to have been human-generated.

3. Large Language Models (LLMs) are a type of generative AI that focuses on language. They're trained on a massive dataset of text and software code. LLMs have several capabilities, including:

   - Summarizing
   - Translating
   - Predicting
   - Generating text from knowledge gained from massive databases

4. A prompt is a starting point or textual input provided to an LLM or AI system to generate a specific response or content. Prompt engineering is the task of developing effective prompts. As an LSP, Lionbridge has embraced generative AI technology to help customers augment their business content. LLMs have grabbed the attention of most industries, including the Life Sciences industry, even though it's traditionally slow to adopt new technologies for regulated content.

   LLMs have enormous potential to change how the industry works and bring therapeutic interventions and healthcare solutions to the world.

GENERAL BENEFITS OF LLMS

The current Neural Machine Translation (NMT) paradigm is ending.
A new paradigm will replace it, likely based on LLMs.

As this development materializes, you can expect the following outcomes:

- **Reduced translation costs.**
- **Greater productivity and the ability to generate content at greater scale.**
- **Improved translation quality — text that appears to have been written by a human.**
- **Enhanced customer experience.**
- **New opportunities to enter more markets.**

HUMAN-IN-THE-LOOP AI LANGUAGE SERVICES: A PATH OF TRUST

Consistency is key for successfully developing therapeutic interventions and obtaining predictable health outcomes. It's also a primary challenge for the LLM application at scale, as LLMs are trained on an extensive corpus across multiple domains. Any AI use case applied to translation or language modifications of regulated content must ensure consistency and reliability in language outcomes. This requires:

- Human intervention
- Fine-tuning of LLMs
- Prompt engineering skills
- Ability to review automated, domain-specific output.

Additionally, their implementation must fit into enterprise-level compliance structures to unlock LLM's scale, efficiencies, and other benefits.

The industry currently tends to be cautious towards LLMs, possibly because regulators have yet to provide consolidated industry guidance on AI. Understandably, concerns around LLMs in the Biopharmaceutical and MedTech industries are particularly salient, as patient safety, data integrity, and bioethical principles are at stake.

The path forward for the Life Sciences domain is finding the right balance between automation and human intervention for building trust and confidence in LLM-derived language outcomes. This isn't easy in a highly regulated industry that demands high-quality output under increasingly tight and unpredictable regulatory timelines. In addition, LLMs have yet to achieve ISO-compliant translations.

For Lionbridge, this challenge is familiar. Neural machine translation (NMT), considered a precursor technology to generative AI, has served life sciences customers at scale for years.

Because we applied the same cautionary principles, insisting on human post-editing for all regulated content, NMT has consistently delivered savings to those customers without losing quality. We're ready to embark on the same journey with the next generation of tools.

USE CASES OF LLMS IN LIFE SCIENCES LANGUAGE SERVICES

Short term, the most obvious use case for LLMs is language translation. This area of great opportunity involves large volumes of content, multiple languages, and challenging regulatory timelines. The opportunity applies to most new medicines and medical devices requiring:

- Significant data to substantiate the efficacy and safety of the products
- High volumes of documentation to demonstrate compliance
- Mandatory, regular reporting to ensure transparency and safety surveillance
- Short regulatory review windows and submissions across multiple territories

As LLMs advance, other use cases can become standard service offerings where multilingual content must be generated, summarized, or modified for specific purpose and context of use.

Examples of such use cases are:

- Transforming scientific language content into plain language content for public disclosure, investor relations, instructions, or information intended for non-technical users, patients, and other intended audiences.
- Summarizing research results or scientific protocols into medical or plain language intended for regulators, trial participants, patients, users, ethical research boards, and other intended audiences.
- Creating new multilingual content directly from the source to speed up content creation and translation. This usage can help meet strict regulatory or other business-critical timelines.
- Assessing quality output of Machine-Translated (MT) content to identify subpar quality segments.
- Automatic post-editing/re-translating MT segments identified as subpar quality to save time.
- Adapting content migrated from paper-based data capture to electronic data capture, e.g., for Patient Reported Outcomes (PROs to ePROs or COAs to eCOAs).

The summation of research results carries a risk of potentially biased selection, of which outcomes to present, and a risk of misleading the reader on performance or safety claims related to the medicine. Also, different results may be generated across different validation tests on LLM output at this early stage of LLM adoption. For these reasons, regulators may never accept fully automated results summaries. Therefore, the value-add of LLMs in this use case is primarily to optimize the summation process, not to replace the human.

HOW HUMANS HELP WHEN MACHINES FALL SHORT

Despite remarkable progress in generative AI and LLM technology, having a human in the loop during AI translation and other language workflows is crucial. LLMs enhance translation efficiency and cost-effectiveness. However, they can't be entirely trusted to operate without supervision for most high-risk or regulated content types. Neither can they run independently, making human intervention indispensable. One critical issue with LLMs is their tendency to produce "hallucinations," which affect their reliability. Hallucination is the generation of content that is irrelevant, made up, or inconsistent with input data. Humans help bridge the AI trust gap, while machines enable humans to work more efficiently and provide more ingenuity than ever. Contributions of both AI and humans will produce the language outcomes you need.

3 CHALLENGES OF LLMS AND HOW A HUMAN-IN-THE-LOOP MODEL HELPS

1. ACHIEVING CONSISTENCY

How LLMs Fall Short
LLM technology performs best when a prompt is limited to a few hundred words, requiring users to split up large, complex prompts. This constraint often results in chunks of inconsistent language output. It creates challenges, for example, when translating a regulatory filing or summarizing a several-hundred-page clinical trial report into a 10-page result summary.

How Humans Help
A human reviewer can review an entire automated output to ensure language consistency, formatting adherence, terminology requirements, and any regulatory-mandated information to be included.

Additionally, context window limitations can be mitigated by an expert-led approach to prompt engineering, whereby inputs and outputs are continuously refined in response to dynamic performance and quality parameters.

2. LEVERAGING LINGUISTIC ASSETS

How LLMs Fall Short
LLMs don't inherently have Translation Memories (TMs), glossaries, or terminologies. These must be layered in, using a series of prompts to ensure your desired glossary, terminology, and voice.

How Humans Help
People trained to perform this work infuse multiple glossaries and instructions per project type into a series of prompts for a consistent voice or terminology. Terminology in life sciences may include the following accommodations for health literacy levels or technical knowledge of the intended users:

- Regulatory terminology
- Disease-specific terminologies
- Product-specific glossaries
- Different tones of voice or style

For this reason, linguists with life sciences experience must help guide setup of appropriate terminologies.

3. GENERATING PROMPTS

How LLMs Fall Short
People generate prompts, not LLMs. An LLM cannot generate effective prompts, an initial step and critical requirement for effective performance and language outcomes.

How Humans Help
Skilled prompt engineers can develop prompt templates, automate prompt recycling, and execute post-processing prompts for an optimal workflow. Much documentation in life sciences has specific, pre-defined structures, purposes, and content requirements because it is regulated and controlled, e.g., via harmonized GxP standards. Prompt templates can thus be set up for repeat content types across the product pipeline and the product lifecycle.

A RISK-BASED APPROACH FOR RELIABLE OUTCOMES

AI tools are revolutionizing the drug development landscape by providing innovative approaches to streamline and enhance the research process.

They can improve clinical trial conduct by:

- Optimizing trial participant selection
- Enhancing trial monitoring
- Improving data collection
- Management and analysis of data

AI may also assist in designing unconventional trials, such as decentralized clinical trials (DCTs), and trials incorporating real-world data (RWD) extracted from electronic health records (EHRs), medical claims, or other sources. These AI technology applications not only boost the efficiency of clinical trials, but also create opportunities for more personalized patient experiences, ushering the clinical trial industry closer to an era of precision medicine.

Using generative AI technologies to replace or enhance human tasks in developing and marketing medicines or medical technologies requires risk management and controls. Regulators will expect the Life Sciences industry to implement a risk-based approach to developing, deploying, and monitoring AI technologies. The ultimate goal will be to proactively help implement proper controls for the specific context of AI usage and influence.

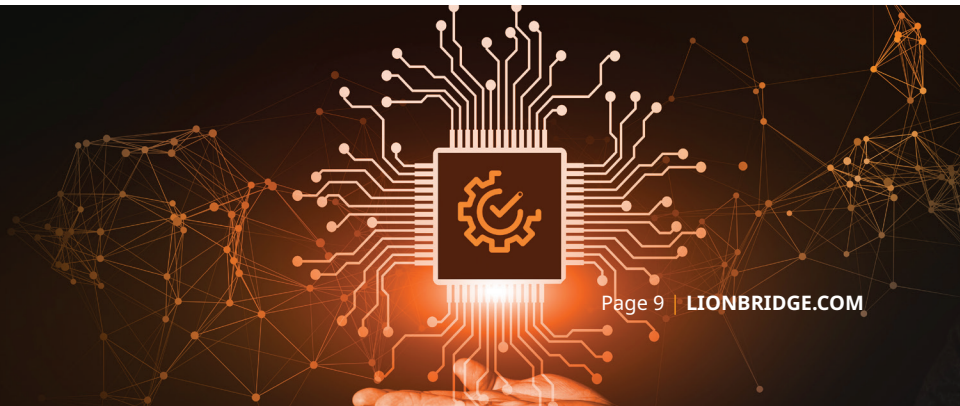
BENEFIT-RISK APPROACH FOR SUCCESSFUL IMPLEMENTATION

To regulators, the cornerstone of developing and evaluating medicines is their benefit-risk profile and the public health's general protection and advancement. These priorities also apply to AI usage, just like other technologies that have penetrated drug and device development (such as electronic data capture).

We recommend adopting a similar benefit-risk principle for use cases leveraging LLMs, and a cross-functional language strategy is set up to determine which content types, product types, intended uses, and languages are suitable for LLMs.

The influence of language on global health outcomes tends to be vastly undervalued — except when it fails to deliver. This approach leaves the industry in a reactive mode of operation and procuring language services in a siloed fashion without visibility of the benefits and risks of LLMs.

However, with the opportunities emerging within Large Language Models, the industry should be compelled to think strategically about language services and outcomes.



BENEFIT-RISK BASED APPROACH TO LANGUAGE SERVICES AND LLMs

CONTROLS

Language Strategy | Quality/Workflow Controls
Human-in-the-loop Controls | Risk Management Controls

POTENTIAL BENEFITS

Cost-savings that increase with volumes and end-to-end lifecycle translations.

Speed to accommodate time pressure and accelerating regulatory procedures.

Agility to accommodate mid-trial changes in new and complex trial designs.

Scale to support larger multinational clinical trials in multiple countries.

Relieve burden of staff by automation of repeatable tasks or workflows.

Language consistency that supports correct product usage, messaging, claims, and results communication.

POTENTIAL RISKS

Harm/hazards to users and patients due to poor language outcomes originated in ineffective prompts, "hallucinations," or lack of proper human-in-the-loop model.

Unintended/harmful influence on clinical decisions or diagnoses.

Negative impact on data integrity/reliability with incorrect/poor translations or summations.

Rejections in regulatory reviews or approval procedures caused by LLM application without rationales or controls.

Unintended or failed language outcomes when context of use is ignored.

Disclosure of Protected Information (personal/proprietary)

RELIABLE LANGUAGE OUTCOMES

NEW CLINICAL TRIAL DESIGNS: A CASE FOR LLMS

Over the past decade, biomedical technology has undergone a massive revolution, leading to innovative breakthrough treatments. Simultaneously, concerns are growing over the development cycle and escalating drug development costs. New trial designs have emerged to tackle cost and time concerns and other modern drug development challenges. These designs include variations of master protocols containing more sub-studies and adaptive trial designs that enable planned adjustments during protocol execution.

While conventional designs remain the standard, newer trial designs infuse flexibility and efficiency, accelerate patient enrollment, and reduce research costs. However, they also present new challenges for planning, organization, and statistical analyses.

Conventional trial designs, characterized by randomized, double-blind comparisons of parallel treatment groups, have long been the gold standard for generating reliable and robust clinical data. However, their inherent limitations have been increasingly scrutinized. These limitations include long execution phases, high costs, and requirements for extensive sample sizes.

Master or Main protocols, classified as either basket, umbrella, or platform trials, are overarching protocols with more sub-studies. These protocols represent a paradigm shift for sponsors, regulators, and patients alike. The protocols enable parallel testing of multiple therapies and/or diseases under the same clinical infrastructure. Implementing a multinational trial protocol is both time and resource-intensive. As a result, a master protocol can deliver significant efficiencies in trial execution when its sub-studies share aspects such as:

- Site selection
- Patient screening
- Data management
- Ethical or monitoring committees

Adaptive trials, another modern trial design, allow for modifications during the trial execution based on accumulated data from trial participants. Such changes must be pre-defined. They require interim analyses during the trial to allow for mid-trial adaptations, such as sample size adjustments or discontinuation of specific doses. Adaptive trial designs offer high flexibility and can reduce timeline, costs, and number of patients exposed in a clinical drug development program.

THE PROSPECTS OF LLMS WITHIN NEW TRIAL DESIGNS

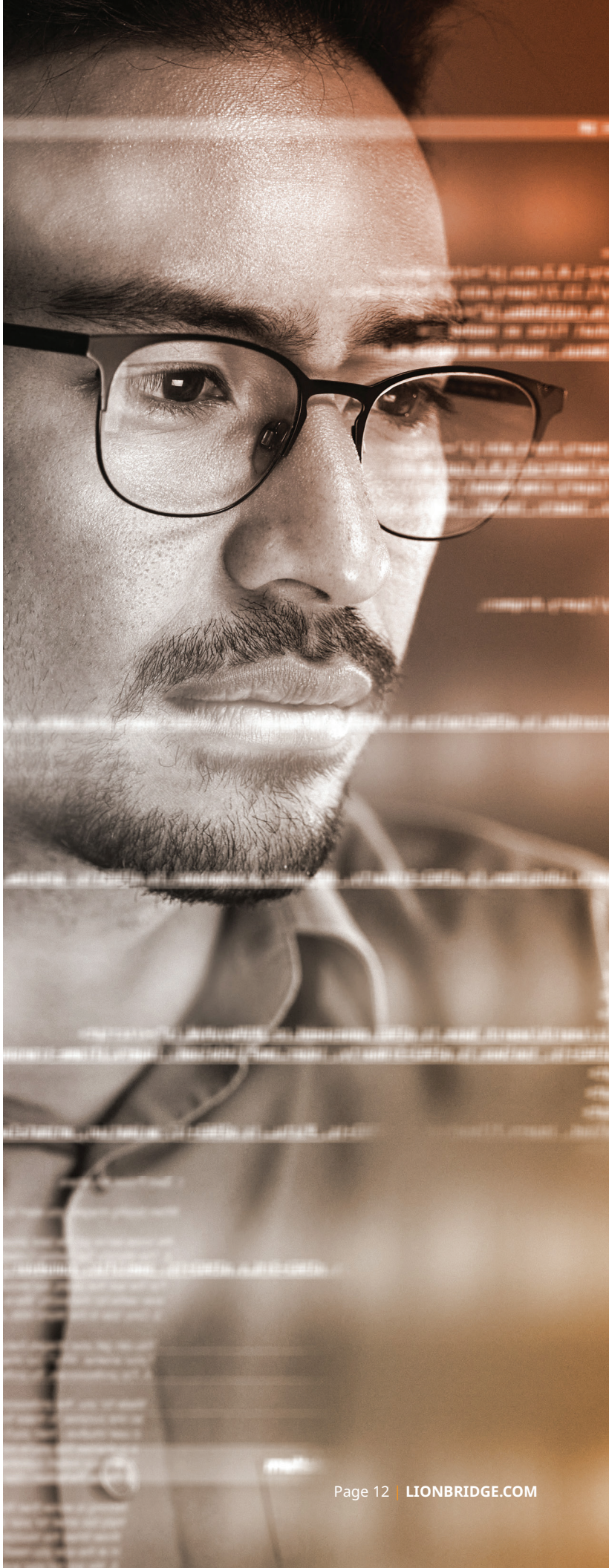
LLMs present an exciting opportunity for new trial designs, as they are designed to drive efficiencies, speed, and consistency in language outcomes.

If planned from the protocol development stage and implemented with appropriate controls and human interventions, LLMs have great potential to support the preparation and efficient execution of new trial designs.

Main or master protocols may require high submission content volumes during initial clinical trial applications (CTAs) and CTA amendments because multiple sub-studies are submitted under the same protocol. Thus, translation efficiency and speed may become critical in preparing all multilingual documents for simultaneous submission and review under the same protocol. LLMs may even bypass the source language step for some repeat content types across the sub-studies and directly create multilingual documents in all protocol languages.

Adaptive trial designs may undergo multiple changes during trial conduct, necessitating new or repeated translations within stringent deadlines. With their speed and efficiency benefits, LLMs can facilitate the agile execution intended with these adaptive trial designs and meet the language needs of large multinational programs.

The key to adding value with LLMs is identifying how language aspects are managed for the concerned trial design — up front and preferably during protocol development.



MDR AND IVDR: A CASE FOR LLMS

AI has great potential within medical technologies. It can help drive decisions and improvements in diagnostic procedures. Or AI can find hidden trends in data for the benefit of patients. Clinical decision support software and diagnostic image enhancement analytics are often highlighted in promising AI narratives on medical technologies. Just like in drug development, AI has the potential to alleviate the burdens of manual processes, clinical trial execution, submission procedures, or regulatory reporting, to name a few. It can help MedTech companies work faster and smarter across the full product lifecycle, from R&D to operations, to regulatory submissions, marketing, sales, and customer support.

Notably, recent and ongoing regulatory reforms in the EU, including the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR), present opportunities to leverage LLMs in the MedTech industry.

The stricter performance, safety, and transparency requirements under these new regulations and shorter regulatory review windows present a challenge to medical device manufacturers. Increasing volumes of content must be created, translated, summarized, and updated —sometimes for both professional and non-professional audiences. Part of this content must be validated by Notified Bodies and/or publicly disclosed on Eudamed (the centralized European database used to collect information about medical devices and their manufacturers). In addition, the EU has 24 official languages and a multilingual policy, meaning that specific reports must be available in all languages of member states where a device is sold.

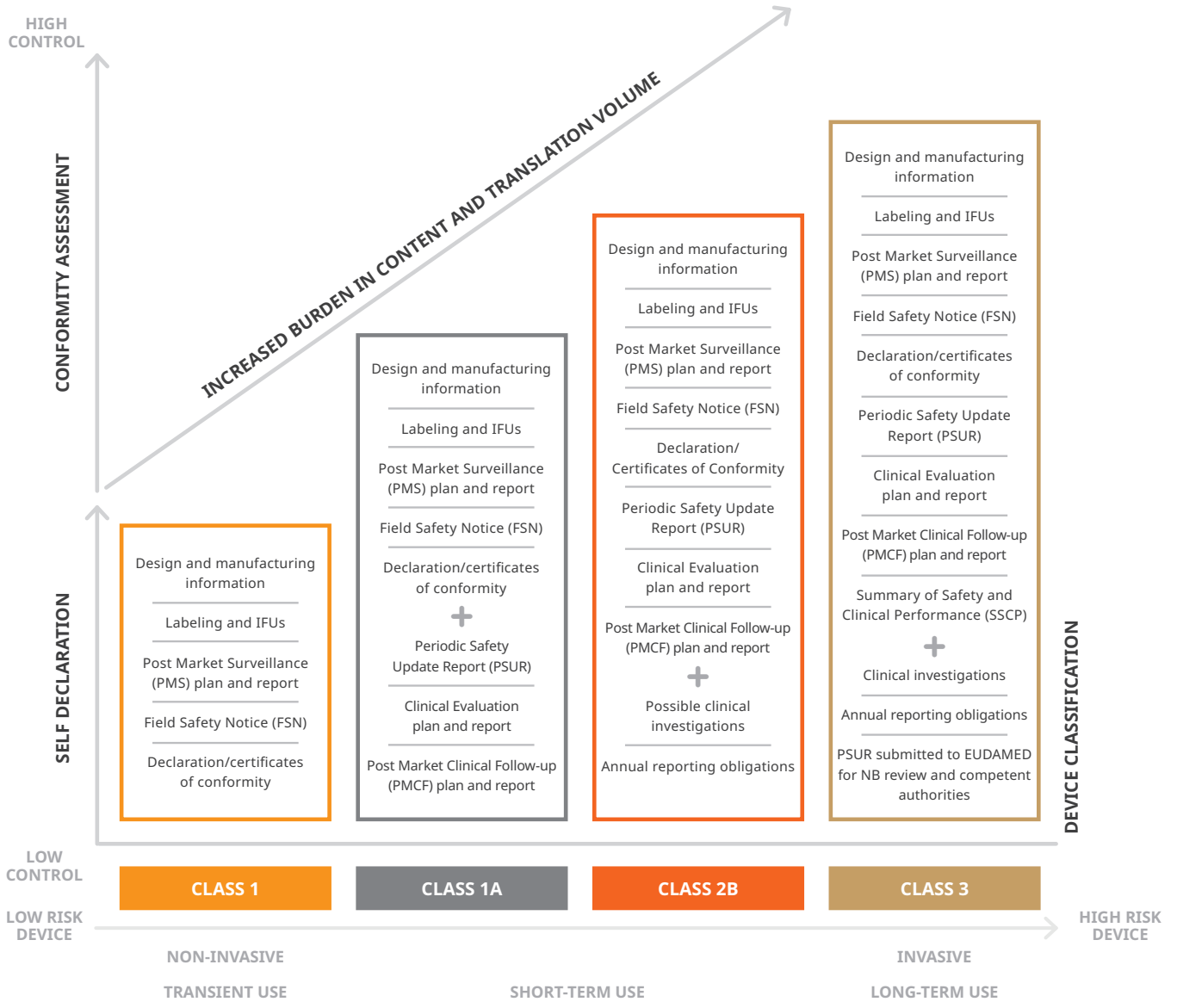
With the intense and ongoing pressure to conform to the new EU framework for medical devices and In Vitro Diagnostic medical devices, implementing language strategies that incorporate LLMs may be overwhelming. However, strategic leadership can be outsourced to a Language Services Provider. An LSP can help navigate language technologies and content strategies while manufacturers provide the necessary expertise on their products and intended uses.

To meet the MDR and IVDR language requirements and harness the full value of LLMs, we recommend manufacturers establish a language strategy for the entire lifecycle of their devices. Or, better yet, for the entire product portfolio. Such strategy can be designed based on the device risk profile, intended uses, content types involved, and intended audiences.

Mapping the content will help determine the appropriate level of LLMs and the extent of a human-in-the-loop required during translations and/or other language services.

RISK CLASSIFICATION DRIVES CONTENT AND TRANSLATION VOLUMES UNDER EU MDR

REGULATORY REQUIREMENTS



LANGUAGE AI EXPLORATIONS AND SOLUTIONS DEVELOPMENT

Language is a prerequisite for global research results and medical intervention marketing, and Large Language Models will deeply enhance language services. These technologies have the potential to optimize language workflows and assets. They can also generate and process new content across languages, audiences, and intended uses.

Language Services Providers (LSPs), like Lionbridge, are rapidly exploring and developing AI use cases in parallel and partnership with the industry. The volume of information and content in the Life Sciences industry is substantial and growing, with content types ranging from regulated to non-regulated content and medical to plain language styles. AI is transforming the language services industry and how it may support future health outcomes by using LLMs in fusion with other language resources.

LLMs have the potential for generating or "remixing" new content intended for specific audiences or markets, with or without traditional source file dependency. With the proper instructions and input, an LLM can produce different content types in various styles, adjusted to appeal to specific audiences or media. However, since we process business-critical and sensitive content for our customers, LSPs must also manage risks and build trustworthy solutions.

To achieve this goal, Lionbridge continuously seeks a deep understanding of our customers' content and products, regulatory requirements, and intended uses. Our strong relationships and expertise within the Life Sciences industry make us uniquely positioned to be a trusted partner in exploring and implementing AI-powered language solutions. We've also dedicated significant resources to developing a robust, trustworthy suite of AI-focused services. To date, Lionbridge has served over 500 customers with customized AI solutions. We've even created our own TRUST framework, which is comprised of 5 key measures.

TRUST

TRANSPARENCY

You'll have access to updates on your project and data every step of the way.

RELIABILITY

Lionbridge will be there to handle your solution and your data. After decades of strong business, we're not going anywhere.

USEFULNESS

We only offer you solutions that you need, no extraneous steps or costs.

SAFETY

Feel confident knowing we have multiple security walls to protect your data.

TIMELINESS

Lionbridge will always deliver your AI projects on time, never late.

DISCOVER AI-POWERED LIFE SCIENCES LANGUAGE SOLUTIONS FROM LIONBRIDGE

Ready to explore secure, innovative AI solutions for your pharmaceutical or medical device activities? Partner with Lionbridge to benefit from our teams of AI and Life Science experts. With our AI mastery, TRUST framework, and decades of Life Sciences industry expertise, you can depend on us to meet language or content needs at any stage of your process.

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ABOUT LIONBRIDGE

Lionbridge partners with brands to break barriers and build bridges all over the world. For over 25 years, we have helped companies connect with their global customers and employees by delivering translation and localization solutions in 350+ languages. Through our world-class platform, we orchestrate a network of passionate experts across the globe who partner with brands to create culturally rich experiences. Relentless in our love of linguistics, we use the best of human and machine intelligence to forge understanding that resonates with our customers' clients. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 24 countries.

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