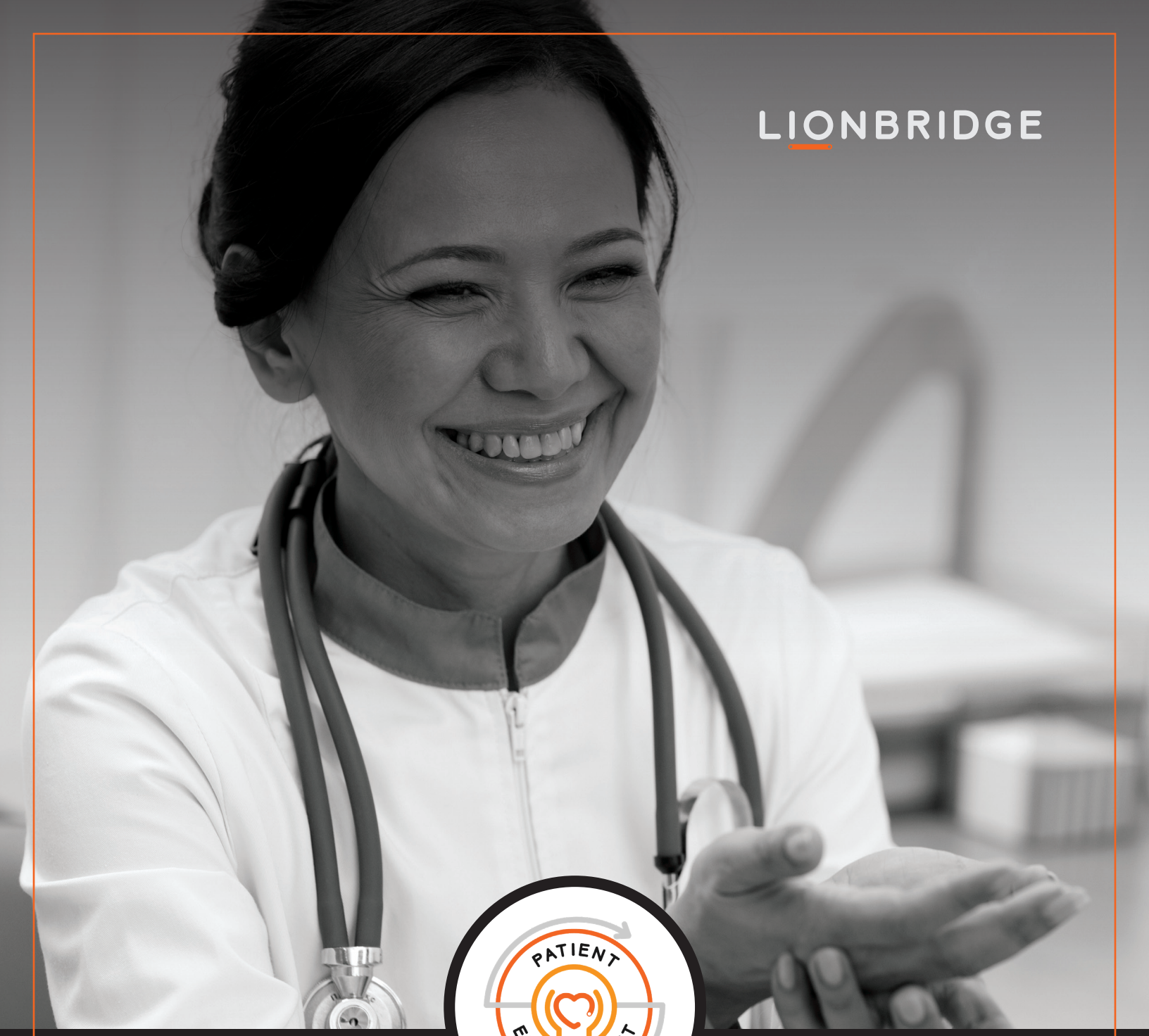

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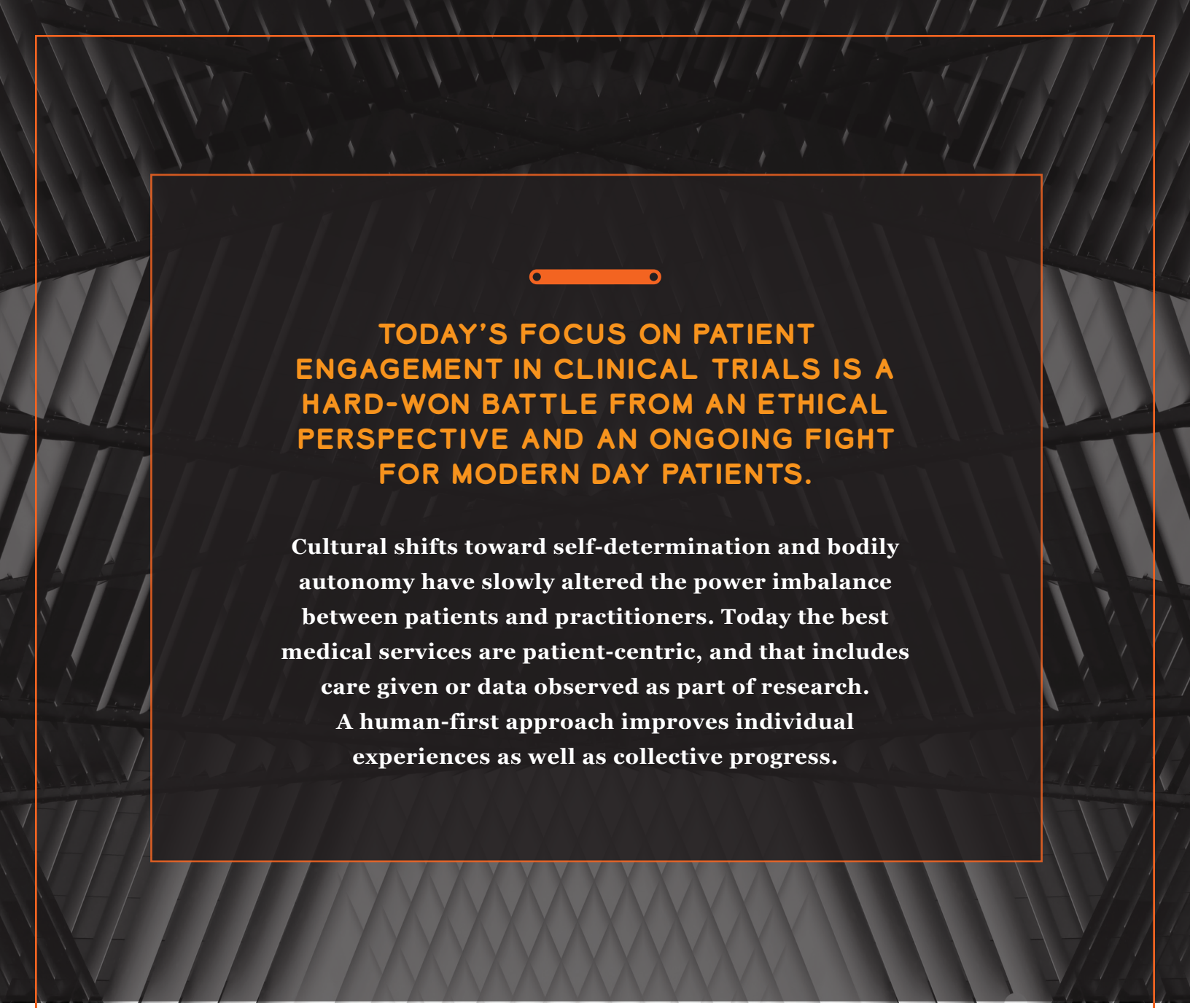
LISTEN TO LEARN: PATIENT ENGAGEMENT IN THE PAST, PRESENT AND FUTURE



TODAY'S FOCUS ON PATIENT ENGAGEMENT IN CLINICAL TRIALS IS A HARD-WON BATTLE FROM AN ETHICAL PERSPECTIVE AND AN ONGOING FIGHT FOR MODERN DAY PATIENTS.

Cultural shifts toward self-determination and bodily autonomy have slowly altered the power imbalance between patients and practitioners. Today the best medical services are patient-centric, and that includes care given or data observed as part of research. A human-first approach improves individual experiences as well as collective progress.

HOW DID SCIENCE MOVE FROM "RESEARCH SUBJECT" TO "PATIENT PARTNER"?

Prior to the mid-late 1900s, institutional paternalism often allowed doctors and researchers to study and practice on human subjects without requiring thorough communication between the medical expert and the patient. The history of research before informed consent was required was grim. Participants were lied to; parents were blackmailed. Researchers targeted racial and ethnic minorities, as well as the elderly, those with disabilities and the poor. By singling out marginalized groups, scientists reduced the likelihood that any complaints, even if registered, would not be recognized by medical, scientific or legal authorities.

THE UGLY TRUTH THAT TRIGGERED BIOETHICAL RESEARCH AND INFORMED CONSENT

Pia Windelov

Bioethical misconduct in clinical research has historically included lack of consent, deception, withholding information or treatment, coercion and undue influence or exploitation of vulnerable groups.

From 1932 to 1972, the U.S. Public Health Service lied to 600 Black American men in the infamous Tuskegee Study. About two-thirds of the group had syphilis, but researchers kept this diagnosis secret. When penicillin became the recommended treatment of syphilis in 1947, these men still were not offered treatment. The study continued—despite multiple attempts by dissenters and whistleblowers—until an Associated Press reporter exposed the study.

In the Willowbrook hepatitis study from the 1950s to 1970, young children with intellectual disabilities were deliberately exposed to hepatitis virus from their infected peers. Some of the children had also been given an unproven vaccine. What passed for a consent form was a short paragraph that did not contain details of the study.

In the 1960s, live cancer cells were injected into the bloodstreams of patients with dementia unable to give consent to the experiment. In the 1970s San Antonio contraceptive study, 700 low-income Mexican-American women were enrolled into a study to determine side effects of a contraceptive pill. The women were not informed that half of the study participants would receive a placebo which led to unplanned pregnancies during the study.

A more recent example of bioethical misconduct is the Poly Implant Prothese (PIP) breast implant scandal. In 2012, French authorities arrested PIP founder Jean-Claude Mas because the company had been selling implant in 65 countries with industrial grade silicone instead of the more expensive medical grade version.

The implants ruptured at double the industry average and caused inflammation and scarring. This scandal triggered the new E.U. Medical Device Regulation.

Stories such as these give testimony to why informed consent and bioethical conduct are critical to medical research and progress.

Luckily, a strong push for transparent clinical research and disclosure of research results has boosted the focus on patients and the value of patient input. As a result, patients are increasingly becoming active contributors in the medical community through various patient engagement initiatives.

MEET PIA WINDELOV

Pia brings over 15 years' experience in R&D in the pharmaceutical, CRO and MedTech sectors. Reach out here to learn more about how Lionbridge experts can simplify and accelerate your projects.

PATIENT ENGAGEMENT TIMELINE

Major events in patient engagement history show much progress, although unethical research still sometimes plagues the industry. Here are some of the most pivotal moments in the movement to focus on the patient as a whole person.

1914

Schloendorff v. Society of New York Hospitals ruled that surgery on a patient without consent constituted battery after a surgeon removed an abdominal tumor without informing the patient first.

1947

Judges create the Nuremberg Code while trying Nazi doctors for WWII atrocities.

1951

A Johns Hopkins doctor removes a sample of cervical cancer cells from Henrietta Lacks without her consent. The resulting HeLa cell line is still used extensively in research.

1957

The Salgo case introduced the term "informed consent" after a patient claimed he was not told of the potential paralysis risks to a surgery he underwent.

1964

The Helsinki Declaration expands upon concepts in the Nuremberg Code and emphasizes ethics reviews as well as informed consent documents and forms.

1972

Tuskegee Study ends.

1979

The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research issues the Belmont Report, which highlights respect, beneficence and justice.

1981

The U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) adopt regulations that evolve into the Federal Policy for the Protection of Human Subjects, better known as the Common Rule.

1991

FDA creates the Patient Representative Program to formalize patient involvement in decision-making processes by the agency.

1996

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) issues the Good Clinical Practices (GCP) guidelines.

2010

Congress enacts the Patient Protection and Affordable Care Act (PPACA).

Moving Medicine Faster

Proper translations of the Informed Consent Form are a constant need for trial administrators. The original text needs to be translated into target languages for IRB and Ethics Committee reviews. One Clinical Research Organization (CRO) was frustrated with their translation provider for a turnaround time of up to four days. They began using Lionbridge for hundreds of documents a week. **Lionbridge established a dedicated resource pool, workflow and tech configuration to cut that time in half.**

What is informed consent?

Before we get into the history of patient activism in clinical trials and the medical field at large, let's define a core value of the concept: informed consent.

THE KEY ELEMENTS OF INFORMED CONSENT

Emphasis on voluntary nature of participation

Clinical Research Organizations are required to clarify that patients are not required to take part in the study nor are they required to continue with the study until it ends.

Explanation of medical condition or variable under observation

Whether participants are volunteering to receive treatments (or placebos) or simply proffer data from daily questionnaires, they should all understand what ailments or symptoms the study is tracking.

In-depth parameters of the study

How long will the study last? Where are study visits? What are study procedures?

Description of potential adverse effects—and benefits

Consent is not truly informed until participants understand what could go wrong if they take part. A reasonable risk analysis should be available for all potential participants. If recruits may also benefit from taking part, this should be explained as well.

Alternatives to trials or study participation

Patients who are interested in a research study should be advised of their options if they choose not to participate. This includes options for treatment or resources to cope with a health issue prompting participation.

> *"The reasonable person concept ... asks researchers to include what reasonable people in the same or similar circumstances would want to or need to know. The use of the reasonable person standard to guide drafting of the consent form does not obviate the obligation to respond to the distinct circumstances, preferences, and needs of individual participants; the opportunity for each participant to ask questions that can take into account that person's own distinct medical history, background, values and personality remains an important part of the consent process."*
>
> Secretary's Advisory Committee on Human Research Protections, an expert panel serving the HHS

THE LANGUAGE OF PATIENT ENGAGEMENT

Even the words "patient engagement" have a complex political history. Not terribly long ago, patient participants were referred to only as "subjects," the passive targets of analysis by academics and medical professionals.

Patient advocates and a growing belief in bodily autonomy regarding medical procedures formed the root of today's human-centric trial design. Peer support groups and community activists in the early days of cancer research and treatment (in the 1950s) and HIV/AIDS awareness (1980s) were robust models for future patient involvement in their own healthcare outcomes.

Communication is at the root of patient engagement, as it is the foundation for understanding. Potential study participants need to be able to comprehend what exactly they are signing up for. That means using clear, concise vocabulary in a language they can easily understand.

Why Patient Engagement Matters

In addition to meeting the obvious moral imperative, increasing patient engagement positively impacts clinical studies by producing more accurate and in-depth data and increasing participant retention. Lowering the burden to trial participation is an obvious way to increase patient retention.

However, researchers without the lived patient experience may miss elements that seem obvious to patients themselves. Focus groups or even mock trial run-throughs can catch these difficulties before they are cemented into study procedures. The more engaged participants are in a particular study, the better the data they will provide. If they understand the intention of a study and are encouraged to communicate with staff, they will be more likely to give useful responses.

And that will naturally lead to better outcomes. Engaged patients are more likely to adhere to a prescribed regimen, which in late-stage trials means not just better data but, if a treatment works, better health outcomes for the participants. Patient engagement is a winning proposition for participants, CROs and scientists alike. How, then, do we work this element into trial creation?

> *"I see a lot of efforts in communicating in plain language across all patient-facing information—in writing, videos or cartoons. I really like that sponsors want to...reach out directly to children. It's an amazing way to empower children because communicating directly to children at their level of understanding also builds trust in the child that (s)he is able to manage the situation. It must be well-balanced, of course, but being a child with a disease and maybe taking part in a trial is not a minor thing."*
>
> Lotte Klim
> EUPATI Fellow

> We should start with the people and design the use of solutions, services, and technologies around the people involved and the quality of data required from the study.
>
> Bruce Hellman, CEO, uMotif

Study Design with Patient Engagement in Mind

The concept of patient centricity is parallel to the individualist approach to today's trend for personalizing and customizing buyer journeys. The logic is the same: design with the user in mind and everyone benefits. But how exactly do you do that?

The first step is to gather information from your patient clients. If you're designing an app to replace paper questionnaires, that may mean something as technical as examining current phone use patterns. It requires asking open-ended questions: What do you enjoy most about the tools you currently use? What do you wish health tech knew about your condition? What symptoms do you notice but not explicitly track?

You can pair this with market research, naturally, and test various versions of your technology or services on small groups. If you're a sponsor requesting daily connection, test every step of the way from installation to ease of use to submission. A diverse focus group of people without specific medical or scientific backgrounds will help you avoid making jumps in logic that might confuse a layperson.

Clear terminology is only accessible when presented in a language the reader understands. The E.U.'s language requirements within Clinical Trial Regulations explicitly state that "Prior to obtaining informed consent, the potential subject should receive information in a prior interview in a language which is easily understood by him or her."

At Lionbridge, we are dedicated to helping our partners move into the future while building patient centricity into every element of our work. Together, we can build a better clinical trial experience for everyone involved.

GET IN TOUCH

Learn more about how Lionbridge can help engage patients and enhance their experience by clicking here.

About Lionbridge

Lionbridge partners with brands to break barriers and build bridges all over the world. For 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' customers. Based in Waltham, Massachusetts, Lionbridge maintains solution centers in 23 countries.

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