



Measurably improve global
clinical research:

How Language Scientific Saved a Sponsor \$1 Million



www.languagescientific.com

CASE STUDY

“Language Scientific’s
rigorous duplicate-
checking process saved
our clinical trial
sponsors over \$1 million,
reducing costs by 45%
while maintaining the
highest translation
accuracy and
compliance standards.”

ACI Clinical





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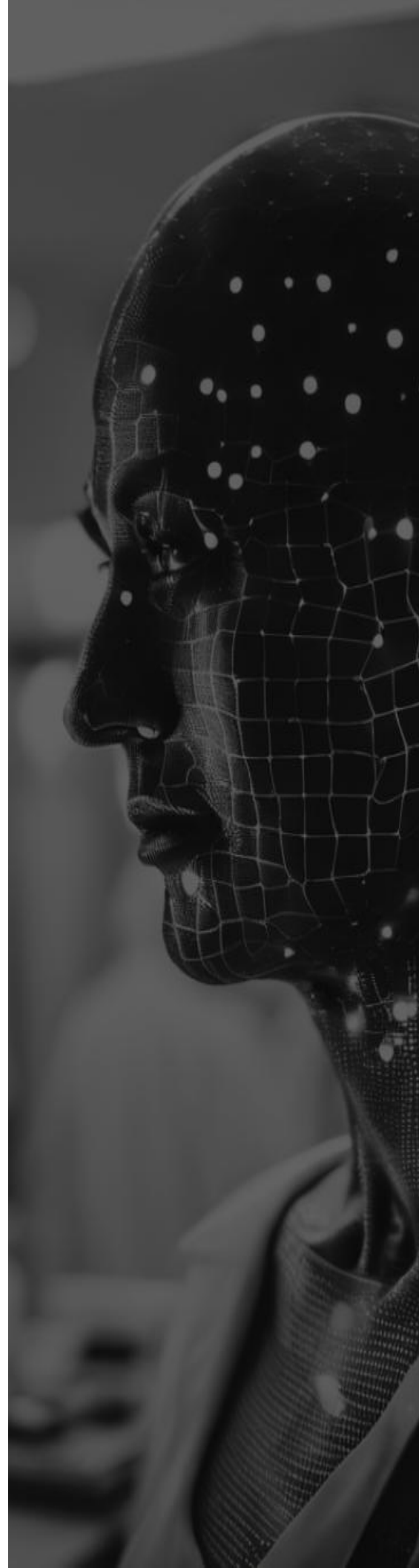
ACI Clinical Overview **Overview**

ACI Clinical was founded in 2001 as a specialty service provider to the clinical research industry. For more than a decade, ACI has specialized in driving best practices in managing Expert Committees that provide oversight to clinical trials, including full-service Endpoint Adjudication Committees, Data Monitoring Committees, and Safety Assessment Committees spanning the globe.

ACI's global network of over 500 expert thought leaders serve as committee members and/or advisors to their clients. They provide bias-free analytics and state-of-the-art decision support technology to enhance trial integrity for regulatory submissions, while ultimately mitigating risks and enabling patient safety.

Since 2018, ACI Clinical has been part of WCG (WIRB-Copernicus Group), the world's leading provider of solutions to biopharmaceutical and medical device companies, CROs, and research institutions.

www.wcgclinical.com



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Summary of **Circumstances and Challenges**

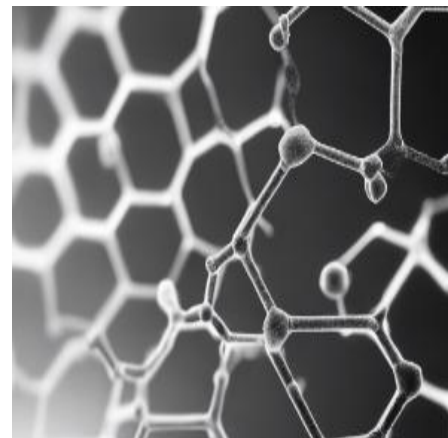
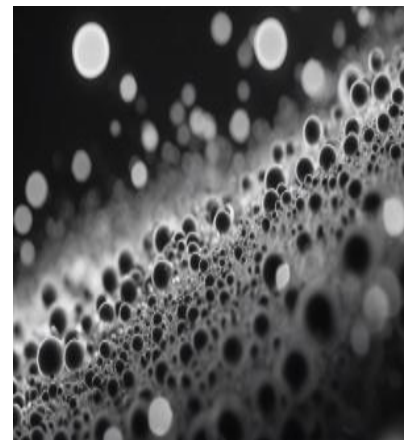
Circumstances

Working within the clinical research industry comes with numerous risks. On the financial end, billions of dollars are spent annually on global clinical trials. An error during a trial can cause significant financial losses. On the other end, human lives are at stake.

Especially when it comes to Endpoint Adjudication, ACI Clinical's global clients require timely, cost effective, high integrity data. With data arriving from numerous global sites, ACI requires unimpeachable translation accuracy of patient clinical data to ensure the safety and efficacy of each clinical trial. This data may include handwritten clinician notes, lab and radiology reports, hospital discharge instructions, autopsy reports as well as other information pertinent to the trial. Accuracy and timely translation of these documents are essential to the overarching timeline of each clinical trial.

Prior to working with Language Scientific, ACI's previous translation service provider had issues meeting their agreed-upon turnaround times, thus negatively impacting the timeline for ACI's end clients.

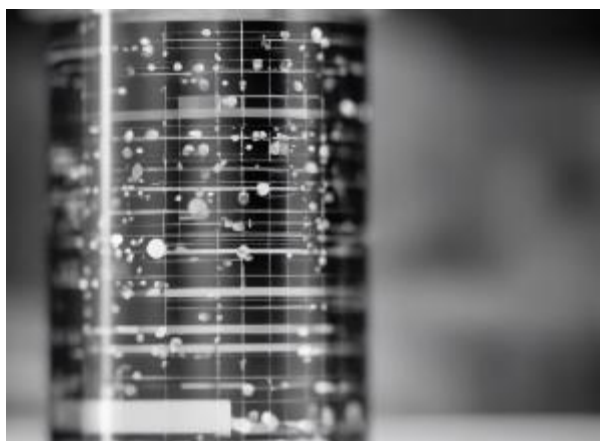
ACI needed to find a way to decrease the turnaround time and cost required to provide high-quality translations of clinical trial materials.





Challenges

ACI faced four challenges to improve language translations for their Endpoint Adjudication clients.



1. Meeting Turnaround Time Requirements

Fast turnarounds of clinical trial results are critical. Some ACI clients needed 24-48 hour turnarounds for time-sensitive trial results, and their previous translation vendors were not able to consistently accommodate this schedule.

2. Translation Accuracy

Quality of translations could not be compromised—even with short turnaround times.

3. Maintaining Trial Integrity

Trial participants need to remain anonymous in all documentation to maintain integrity of the results, protect patient privacy, and meet General Data Protection Regulation (GDPR) requirements.

4. Reducing Cost

ACI sought to reduce their clients overall spend on translation.



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LANGUAGE
SCIENTIFIC

About **Language Scientific**

Language Scientific, Inc. provides specialized clinical, medical, scientific, and technical language services and solutions. Since 1999, Language Scientific has provided high-value services to more than 1,500 clients in the biopharmaceutical, clinical, and medical device space. This value allows clients to realize direct cost savings, improved efficiencies, and reduced time to market.

Language Scientific works at the intersection of science and language. This is our core competence; this is what we do better than anybody else. Our doctors-turned-translators and our expert Project Managers understand the complexities of both technical and linguistic challenges. We provide the most effective, rapid, and customer-focused service in the industry.

Language Scientific is the only translation company with deep industry, regulatory, and language understanding that enables customized, reliable, and timely completion of translations. Clients benefit from Language Scientific's

- flexible and innovative culture,
- patented technology, and
- robust 12-step Quality Methodology.

Best-in-class 24/7/365 language solutions—that's the Language Scientific way.

Science Is Our First Language.

www.languagescientific.com

Solutions For Endpoint Adjudication

Language Scientific applied its specialized know-how toward an Endpoint Adjudication translation process unique to ACI's needs. We were able to develop customized solutions to meet all four challenges that ACI faced.



1. Meeting Turnaround Time Requirements

Language Scientific created software to systemize and enhance the workflow through their specialized business practice group dedicated to handling Adverse Events and Serious Adverse Events (AEs and SAEs), in addition to Endpoint Adjudications. To reduce time spent during project inception, Language Scientific implemented a specialized file submission process through their Client Portal and customizable APIs, helping to save valuable time. Standard procedures for ACI were also created to better assist in meeting expedited turnaround times as well as maintaining a high quality of the translation. These are discussed in the following section.



2. Translation Accuracy

To provide highly accurate translations while meeting tight turnaround times, Language Scientific developed standard procedures for ACI including creation of style guides, Project Manager guides, Project Manager review checklists, delivery checklists and a project auditing process. Alongside these procedures, Language Scientific holds their linguists to some of the

highest standards in the industry. To be considered for an ACI project, a linguist must meet the following requirements:

- Pass Language Scientific's stringent accreditation requirements.
- When required, have advanced degrees pertinent to the subject they are translating; many of the linguists hold medical degrees (typically MD) and undergone training (including Fellowships and clinical experience) in the specific area of medicine most relevant to the document.
- Be a native speaker of the target language of the translation (namely, US English).
- Meet Language Scientific Conflict of Interest and Confidentiality requirements.

In addition, all Language Scientific translation projects follow a 12-step Quality Methodology to ensure accuracy in the final deliverable.



3. Maintaining Trial Integrity

Language Scientific established a unique process of performing multiple QA steps to ensure all patient identifying information (PII) has been fully redacted to ensure patients anonymity to comply with all patient privacy laws. Guidelines for this redaction step were created by Language Scientific and this step was built into the standard process for ACI.

Alongside Language Scientific's redaction of PII information, Language Scientific also adheres to the following ensuring GDPR compliance.

- Utilize a secure translation management system and do not send files for translation via an unsecured email address.
- Language Scientific and all linguists work under Non-Disclosure Agreements.
- Do not utilize open-source machine translation engines such as Google Translate.



4. Reducing Costs by \$1 Million

Language Scientific helped ACI reduce study costs by implementing a unique duplicate checking process. Submissions from global sites requiring translation would often include pages of information previously submitted for translation, sometimes several years prior.

All submissions are scans of original documents, sometimes of poor quality, often with handwritten scribbles in the margins. They include discharge instructions, medical reports, and labs.

Trained Language Scientific specialists compare each submission to all prior submissions to find duplicate pages. Through this process, Language Scientific identifies pages that were either partial or complete duplicates of prior submissions.

If full duplicates are detected, Language Scientific sends the previously translated document back to ACI at no additional cost. If only some pages or parts of a page were translated, Language Scientific re-uses that translation without charge.

ACI also benefited from Language Scientific's customized Client Portal. This secure website allowed ACI to track the status of individual submissions, cost savings, and quality metrics.

This thorough and highly customized approach not only helped save millions of dollars for ACI's customers (clinical trial sponsors) but also greatly reduced overall turnaround times, all while maintaining the highest levels of linguistic accuracy.



Solutions By The Numbers

Sample Clinical Trial Savings #1

	Price	% Savings
Nominal Price	\$2,436,005	
Cost Savings on Duplicate Detection	\$1,098,099	
Final Price	\$1,337,906	45%

Sample Clinical Trial Savings #2

	Price	% Savings
Nominal Price	\$168,149	
Cost Savings on Duplicate Detection	\$143,115	
Final Price	\$25,034	85%

Sample Clinical Trial Savings #3

	Price	% Savings
Nominal Price	\$2,396,163	
Cost Savings on Partial Duplicate Detection	\$762,697	31.8%
Cost Savings on Full Duplicate Detection	\$61,248	2.5%
Final Price	\$1,572,217	34.3%

Conclusion 12



ACI Clinical needed a translation partner that could deliver speed, accuracy, compliance, and cost savings—without compromise. Language Scientific exceeded expectations by implementing a tailored translation workflow, ensuring 99.7% on-time delivery, and establishing a rigorous duplicate-checking process that saved clinical trial sponsors over \$1 million.

By combining expert linguists, advanced technology, and a deep understanding of clinical research requirements, Language Scientific not only streamlined ACI's operations but also safeguarded trial integrity and patient confidentiality.

The result? Faster, more reliable translations, reduced costs, and an unwavering commitment to quality—proving that in the world of clinical trials, precision is everything.

For more information, visit:

www.languagescientific.com