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Making clinical research crystal clear

CLINICAL TRIAL TRANSPARENCY SERVICES

End-to-end Services

- National and international clinical trial registry services
- Redaction and anonymisation services
- Plain language summary (PLS) services
- Transparency compliance monitoring
- Transparency regulatory consulting

Best-in-Class CTT Services

Clinical Trial Registry Services

- Protocol registration
- Clinical trial record data entry and maintenance support for registries
- Results disclosure
- XML generation for safety data
- Protocol and SAP redaction
- Liaising with regulatory/registry points of contact

Redaction and Anonymisation

Services supporting:

- EMA Policy 0070, EMA Policy 0043, HC PRCI, Japan PMDA, BfARM
- EU-CTR 536/2014
- Voluntary data sharing
- Protocol and SAP redaction for ClinicalTrials.gov

Other Services

- Plain language summaries for protocols and results
- Clinical trial transparency compliance and consistency check for national and international registries
- Transparency regulatory consulting and advisory support (e.g. gap assessment, process development and update, training)

Over **40 years** of cumulative team experience in CTT

1000s of CTT deliverables completed

Deep understanding of current and emerging global regulatory requirements

Significant contributions to industry forums and the development of policies

Our Mission

To help customers improve the lives of patients by providing services recognised for quality, value, and collaboration

Contact us:

info@krystelis.com

www.krystelis.com

Pooja Phogat
Co-founder & Co-CEO
+91-9810 889208

Stuart Donald
Co-founder & Co-CEO
+44-7806 565974

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Redaction and Anonymisation Services

An expert solution for all your anonymisation requirements

...led by our subject matter experts

- Over **40 years** of combined experience in successfully delivering redaction and anonymisation services
- Experience of submitting over **100 packages** on various regulatory portals (as per EMA Policy 0070, 0043, Health Canada PRCI, PMDA, BfArM), **over 100** voluntary data sharing submissions and redaction of **over 500** documents as per NIH Final Rule and EU-CTR requirements
- Effective, **efficient, customised** solutions for timely and successful publication to the applicable regulatory portal

Our differentiators...

- Strong domain knowledge
- Technology-enabled solutions
- End-to-end process support
- 100% compliance with timelines
- 'Right-First-Time' Quality
- Strong project execution

Redaction and Anonymisation Services

Anonymisation of Documents for Health Canada PRCI & EMA Policy 0070

- Support throughout, including **regulatory authority meetings**
- Development of the **Anonymisation Plan**
- **Risk-based Approach** to redaction and/or transformation
- Preparation of **Anonymisation Report**, and **Justification Table**
- Assessment of regulator's comments, providing justifications and updating documents

Anonymisation of Documents for European Clinical Trial Regulation

- Assessment of documents for commercially confidential information (CCI)
- Redaction and/or transformation of **Part I and Part II documents**
- Redaction of documents available in **English and other languages**
- Support with **gap-analysis** - preparation of **'disclosure-ready'** documents

Anonymisation of Documents for Other Policies and Regulations

- Review and updates of documents requested under **EMA Policy 0043**
- Redaction of documents under **BfArM (Germany) and PMDA (Japan)**
- Redaction of protocol & statistical analysis plan under **NIH Final Rule**
- Support for **voluntary data sharing**

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Support for European Clinical Trial Regulation 536/2014

ABOUT US
WHO WE ARE

Krystelis provides specialised clinical transparency services to the global pharmaceutical industry

OUR WORK
WHAT WE DO

We help our clients achieve regulatory compliance through our efficient processes, 'Right First Time' quality, and highly collaborative approach

REGULATORY CONSULTING

GAP ANALYSIS & IMPLEMENTATION PLAN

TRAINING SUPPORT

REDACTION & ANONYMISATION

PLAIN LANGUAGE SUMMARIES

ADMINISTRATIVE SUPPORT

For more information visit:
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EU Clinical Trial Regulation Requirements

EU-CTR 536/2014 improves the transparency of clinical trial data, allowing public access to trial information through the Clinical Trial Information System (CTIS). Krystelis offers services to enable sponsors to meet their EU-CTR-related obligations.

Connect with us for your requirements for:

Consulting Services

- Gap analysis and implementation planning
- Preparation of standard processes (SOPs, Work Instructions, Process Maps)
- Advice on the regulation

Training Support

- Training on trial transparency (e.g. redaction of PPD and CCI), and associated guidelines, policies, and recommendations
- Training support for lay language requirements

Operational Services

- Redaction and/or anonymisation of Part I/Part II submission documents, and clinical study reports
- Preparation of lay language protocol synopses and results summaries
- Medical writing and document QC
- Protocol registration on regional platforms
- Translation of documents

Administrative Services

- CTIS user management
- CTIS data entry
- Dissemination of lay summaries

Project Management

- Dedicated project manager to coordinate EU-CTR activities
- Project dashboard and execution tracker
- Collation of Part I and Part II dossiers ("For Publication" and "Not for Publication")
- RFI and notification tracking

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Plain Language Services

We can meet all your plain language requirements

- Plain language writing
- Health literacy review
- Translation and dissemination
- Patient panel review (user testing)
- Graphic and video formats
- Advisory services

We develop all types of plain language material

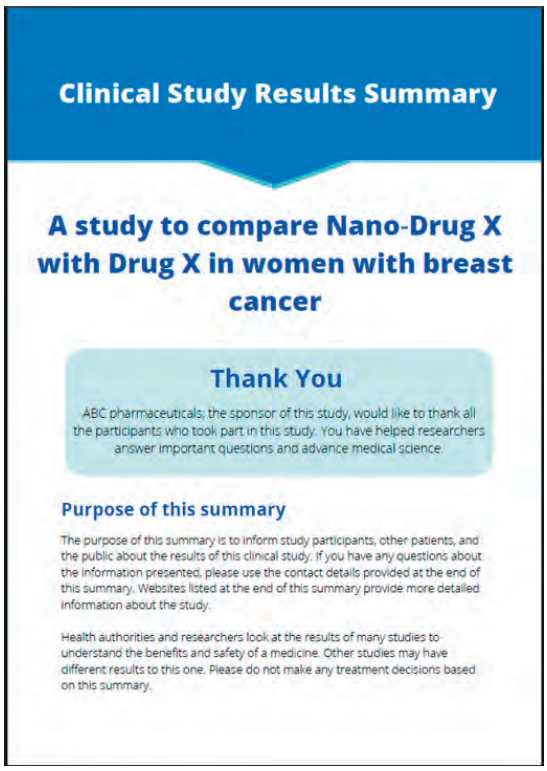
- ✓ Informed consent documents (ICDs)
- ✓ Trial consent element documents (TCEDs)
- ✓ Plain language protocol synopses
- ✓ Plain language summaries (PLSs) for clinical trial results
- ✓ Plain language summaries of publications (PLSPs)
- ✓ Patient information leaflets
- ✓ Patient recruitment material
- ✓ Public health education material

We provide world-class plain language services which are based on:

- Our deep understanding of the complexity of public health communication
- Our ability to explain complex scientific content in plain English accurately
- Social listening to understand how patients and public discuss health topics
- Engagement with patient partners to better understand disease areas

We help you select the right plain language format for your audiences

Traditional PDF | Interactive PDF | Video | Comic


Clinical Study Results Summary

A study to compare Nano-Drug X with Drug X in women with breast cancer

Thank You

ABC pharmaceuticals, the sponsor of this study, would like to thank all the participants who took part in this study. You have helped researchers answer important questions and advance medical science.

Purpose of this summary

The purpose of this summary is to inform study participants, other patients, and the public about the results of this clinical study. If you have any questions about the information presented, please use the contact details provided at the end of this summary. Websites listed at the end of this summary provide more detailed information about the study.

Health authorities and researchers look at the results of many studies to understand the benefits and safety of a medicine. Other studies may have different results to this one. Please do not make any treatment decisions based on this summary.

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Writing Services

Expert solutions for all your writing requirements

- Regulatory writing
- Safety writing
- Publications
- Marketing authorisation application submissions
- Medical communications
- Disclosure writing

Over **75 years** of cumulative experience in writing services

Effectively conveying key messages to **diverse audiences**

Knowledgeable across **therapeutic areas** and **all phases** of clinical development

Exceptional **communication** and **project management** skills

Our differentiators

- Proactivity
- Deep understanding of current and emerging regulations
- Strength of communication
- Quality review by an independent team
- Flexible and responsive resourcing model
- Processes optimised for each project using our own or customer's SOPs

Writing, Editorial, & Quality Review Supported for:

Regulatory Writing

- Protocols and Amendments
- Clinical Study Reports
- Investigators' Brochures
- Informed Consent Documents
- Narratives
- DSURs
- Briefing Packages

Marketing Authorisation

- Clinical and Non-clinical Overview
- Clinical and Non-clinical Summary
- Summary of Clinical Biopharmaceutics
- Summary of Clinical Pharmacology
- Summary of Clinical Efficacy
- Summary of Clinical Safety

Publication Writing

- Manuscripts
- Systematic Literature Reviews
- Conference Abstracts and Posters

Medical Communications

- Product Monographs and Labels
- Patient Information Leaflets
- Medical Affairs Slide Decks
- eLearning Content Creation (e.g. Training Modules, Educational Materials)
- 2-D/3-D Animations and Videos

Safety Writing

- Regulatory Responses
- Periodic Benefit Risk Evaluation Reports (PBRERs)
- Top-line Summaries
- Literature Searches for PBRERs and DSURs

Disclosure Writing

- Protocol Registrations
- Results Disclosure
- Public Disclosure Synopses
- Redacted Protocols and SAPs
- Plain Language Summaries
- Redaction and Anonymisation

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Quality Review Services

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Expert solutions for all your requirements...

- Stand-alone document Quality Review services for all document types (including redaction packages)
- 100% data verification
- Internal consistency checks
- Editorial and formatting review

... led by our experienced subject matter experts

Over **75 years** of combined experience in clinical research

Extensive experience across **diverse document types**

Effective, **multi-tiered approach** for quality enhancement

Exceptional **communication** and **project management** skills

Our differentiators

- Quality control (QC) checklists for all document types
- Rapid turnaround of urgent requests
- All QC findings are clearly documented
- QC KPIs drive consistent, high quality output
- Flexible and scalable resourcing model

Quality Review Services

Quality Review

- **QC Process:** uses document-specific checklists, all findings are annotated
- **QC Assessment and Data Check:** validates results, statements, and conclusions
- **Content Consistency:** checks within and across documents in a submission
- **QC Change Verification:** all findings are verified by a second QC specialist

Editorial Review

- **Template Consistency:** checks against template requirements
- **Abbreviation Inclusion:** checks all abbreviations and acronyms
- **Spelling, Grammar and Punctuation:** checks for US or UK English, grammar usage, and consistent use of punctuation
- **Referencing & Appendices:** checks referencing style and accuracy

Formatting Review

Formatting checks including:

- Fonts, paragraph spaces, page numbering, margins
- Consistency in heading levels
- Table and figure headings, legends, footnotes, endnotes
- Text alignment, numbered/bulleted lists
- Header and footer accuracy and placement

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