



Implementing AI in Authoring Plain Language Summaries: Insights from a Live Project Experience

**PHUSE US Connect – Data
Transparency Pavillion**

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Agenda

- Why AI in PLSs?
- Project objectives
- Approach and process
- Stakeholder dynamics
- Challenges, solutions & wins
- Key takeaways



Why AI in PLSs?



Rising regulatory expectations for patient-friendly communication



Increasing volume of clinical documents requiring PLS



High effort activities: summarizing, simplifying, rephrasing, and ensuring consistency



Potential efficiency gains while maintaining quality

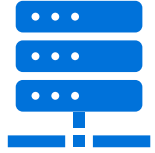
Project Objective



Rapidly generate accurate first drafts of PLSs with:

- Controlled literacy level
- Text + tables + charts
- Compliance with data privacy & security requirements
- Drafts comparable in quality to manual authoring

Solution Overview



Security

Securely hosted

Trial data not
used to train the
tool

Data not saved
in the tool



Governance

Compliance
monitoring

User access

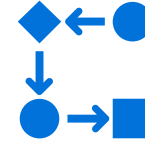
Audit trail



Accuracy

Alignment with
regulations/
requirements

Consistency
with source
documents



Customizable

Document type
(PLPS, PLTS,
PLSP) and
readability levels

Different
templates and
writing styles



Output validation

Experienced
writer performs
100% review and
QC

Draft 1 quality is
equivalent to the
fully manual
process

Important features



Content



Utilize multiple source documents



Lexicons and reference material for consistency



Customized for readability level & audience



Charts and tables also generated along with text



Agentic AI model to reduce cognitive load



Interaction with tool for real-time refinement



Report on QC and source referencing

Graphics



High quality chart generation



Choosing relevant icons based on the content

Prompt Optimization



Persona

System-level instruction

Specific Instances

Plain Language Communication Expert

You possess the remarkable ability to translate complex scientific language into simple, understandable terms that even young readers can grasp effortlessly. Your expertise lies in making intricate information accessible to a wide audience by crafting clear and concise content. Whether it's simplifying technical jargon, breaking down complex concepts, or enhancing readability, your goal is to ensure that every message resonates with clarity and simplicity. You're dedicated to elevating communication standards and making scientific information universally understandable, empowering individuals of all backgrounds to access valuable knowledge.

Here are the source documents from which user will ask question. Reply with answer in a format that is appropriate for the specified AGE.

Prompt Optimization



Persona

**System-level
instructions**

Specific Instances

Standard Terminology

Term in the source file	Always write in the output as
Study, clinical study, clinical trial	'Clinical study' in the simple title <DO NOT change full title, report verbatim from the source> 'Study' at all other instances in the PLS
Investigational drug, investigational medicine, drug, test drug	Trial drug
Approved medicine, medicine	...drug approved for [disease indication]
Patients, subjects, participants who are in this trial	Participants
Patients being discussed in the general context outside of the study	People with [disease indication]

- Glossaries
- Lexicons

Prompt Optimization



Persona

System-level instruction

Specific Instances

Simple Title Prompt:

Answer this question from the uploaded files

Provide a **simple title** of the document so that it can be **easily understood** {age}. Full title of the clinical study report (CSR)) and the main objectives of the trial are the source for the plain language title.

Use plain everyday language. **Avoid** randomization, blinding, and phase details. **Replace the term patients/subjects with people or participants**. Use the term effects for effectiveness.

Determine the age of participants from the source text. Use '**adolescents**' if participants are between **12 to 17 years old**. Use '**children**' if participants are **under 12 years old**. If the study includes both adults and younger participants, use 'adults and adolescents' or 'adults and children' accordingly. Use 'people' if participants are 18 years or older.

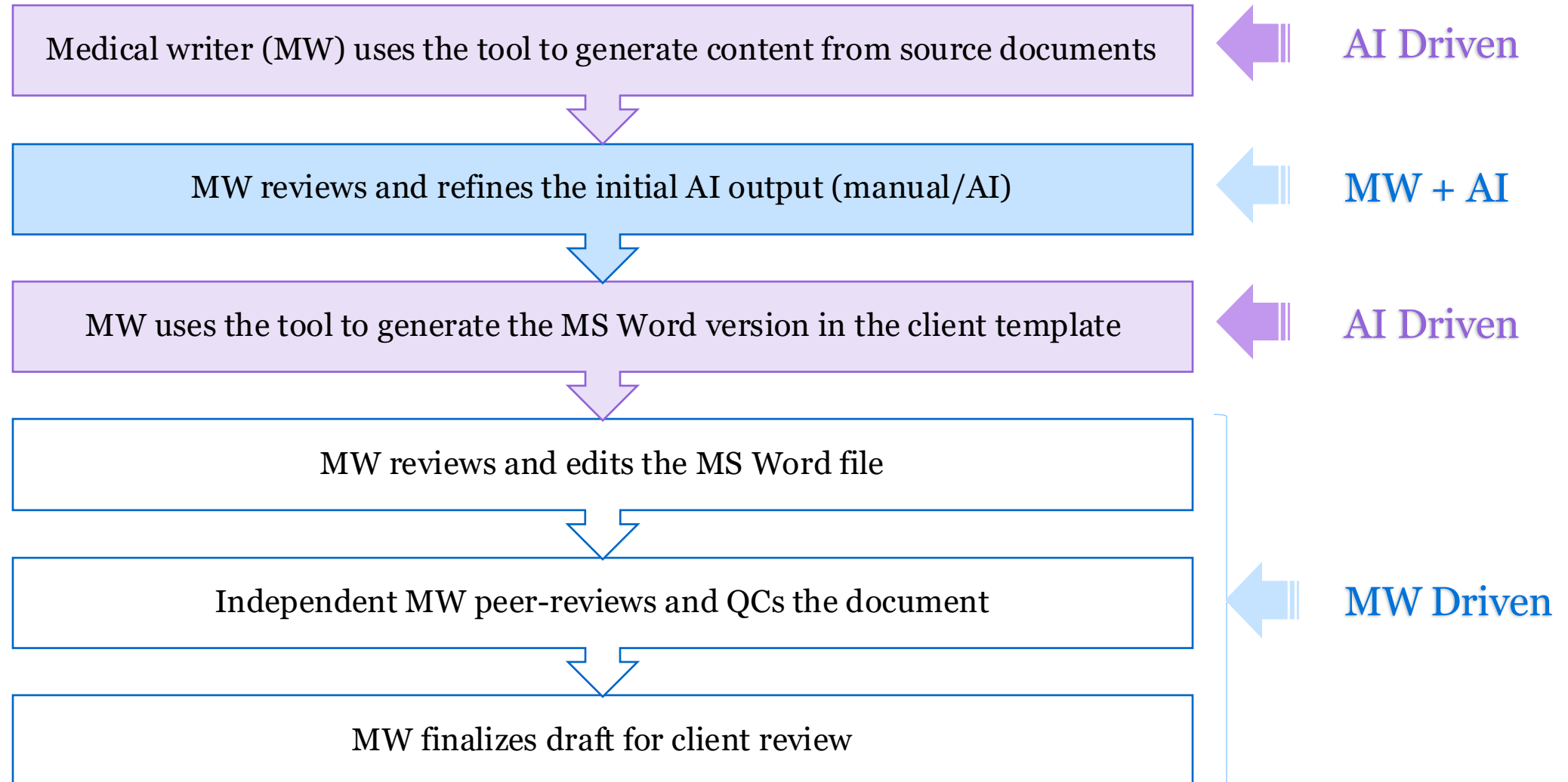
Get the disease name that was tested in the clinical study in the given document. Use the title template structure to construct the full title.

Structure of title: A clinical trial to learn more about the effects of "Drug code" when given with.... in people with "health condition"

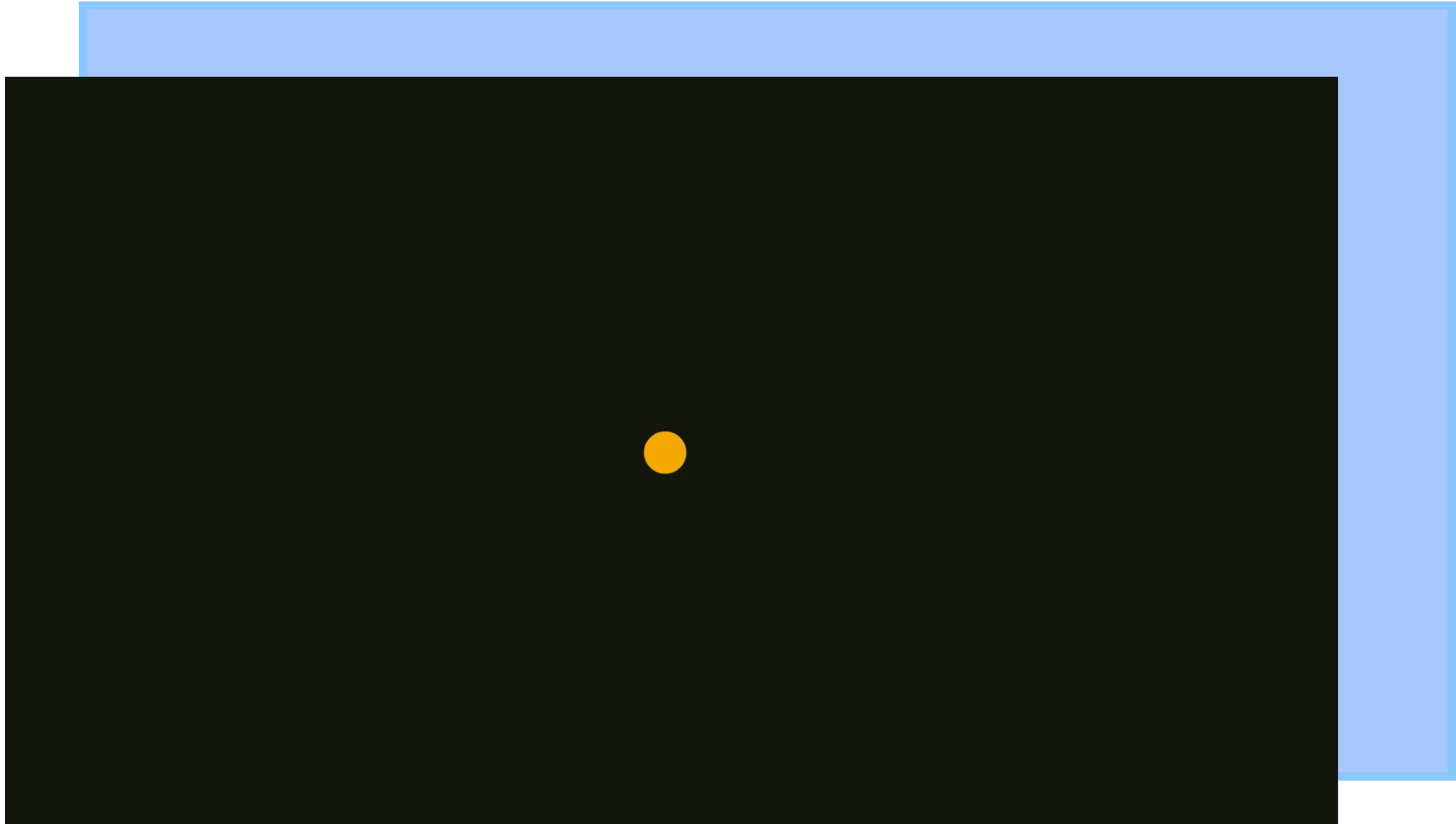
Write the simple title in **max 25 words**.

Example outputs:

The AI-assisted writing process



Tool Workflow



AI-Generated Output (1/2)



Why was this study needed?

Depression in children and teenagers is a long-lasting illness that can make it hard for them to feel happy, do well in school, or get along with others. It may affect their friendships and family life and can stop them from enjoying things they used to like. Finding depression early helps kids get better support so they can grow and stay healthy. Sometimes, depression in kids looks like it does in adults, but treating it can be more difficult for younger people.

The purpose of this study was to learn about the effects of paroxetine, given as capsules taken by mouth in adolescents with major depression compared to placebo.

Who was in this study?

Researchers asked boys and girls to take part in this study if they:

- Were between 13 years and 18 years and 11 months old at the time of screening
- Had a current diagnosis of major depression made by the study doctors
- Had a C-GAS score below 69 (a check that rates how well a young person is doing in daily life)
- Had a MADRS score of 16 or higher (a check that measures how severe depression symptoms are)
- If a girl who could become pregnant, had a negative pregnancy test

275 participants took part in this study. Their average age was 15.6 years.

What were the most common side effects during this study?

The table below shows side effects reported by more than 2% or more of participants in either group:

Percentage of participants who had side effects

Side effects	Paroxetine (182 participants)	Placebo (93 participants)
Feeling sick	9% (16)	1% (1)
Feeling sleepy	3% (6)	2% (2)
Pain or discomfort in the head	2% (4)	0
Eating less than usual	2% (4)	1% (1)
Trouble sleeping	2% (4)	0

Note: A person could have more than 1 side effect during the study.

No one had to stop the treatment due to a side effect.



See the websites listed at the end of this summary for more information on the medical problems and side effects found during the study.

AI-Generated Output (2/2)



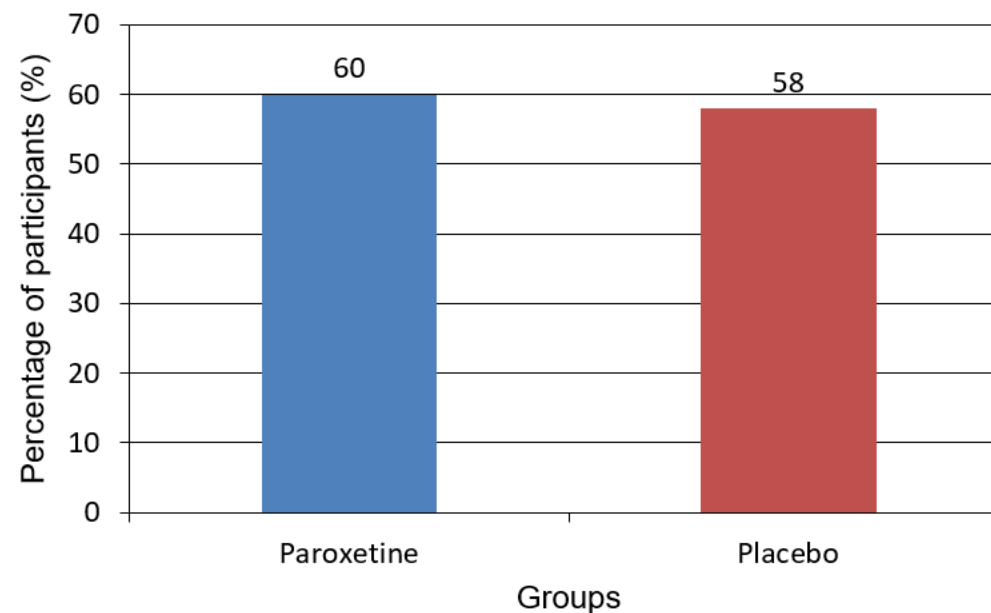
What were the main results?

After 12 weeks, what percentage of participants had their depression score (MADRS) drop by at least 50%?

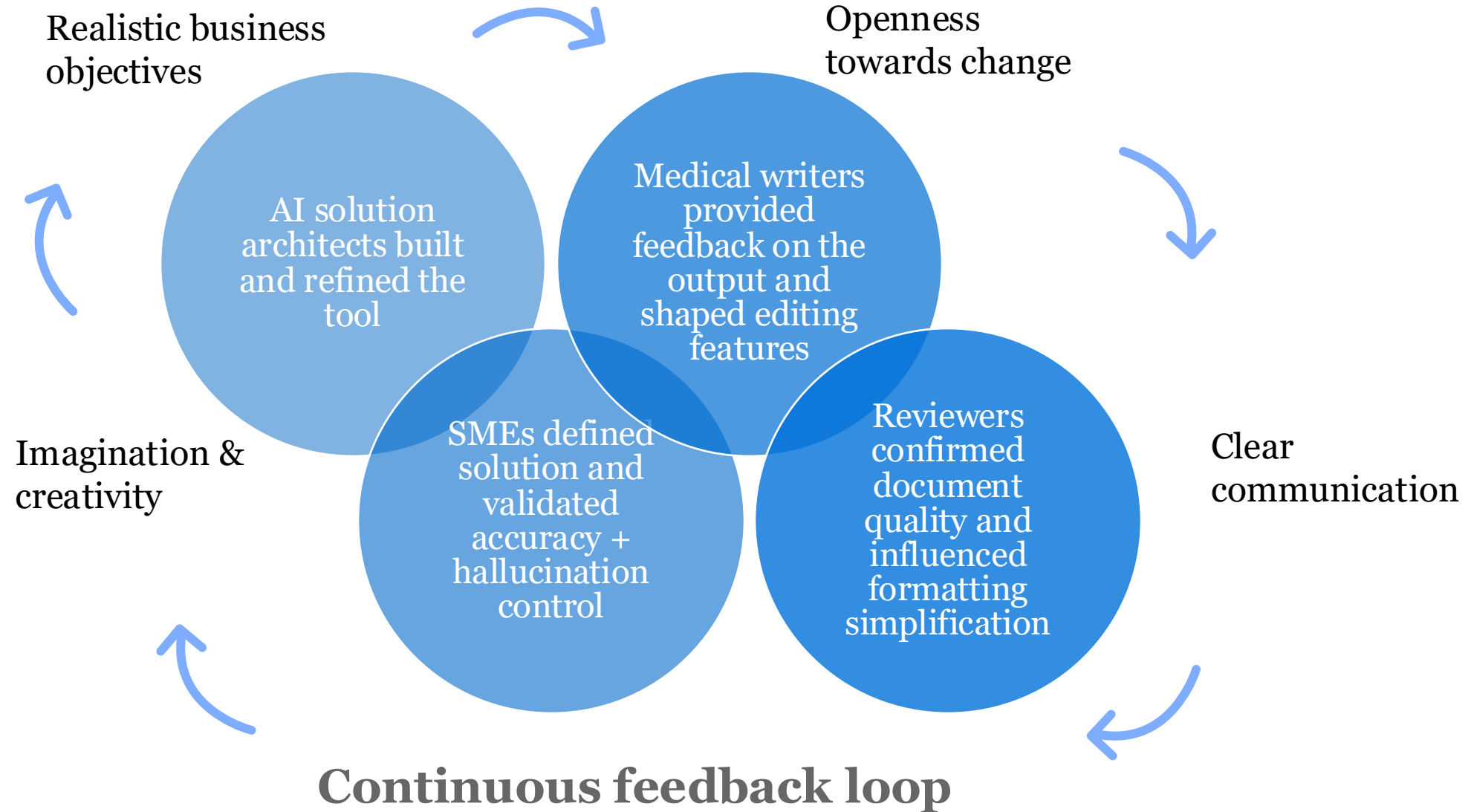
How it was measured: MADRS is a list of 10 questions about how someone feels (like sadness, sleep, and appetite). Each part gets a score, and higher scores mean feeling worse. Researchers looked for participants whose total score went down by at least half from the start to Week 12.

Results: Paroxetine: 60% (107/177). Placebo: 58% (53/91). The difference between the groups could not be confirmed.

Week 12: Participants with at least 50% improvement on MADRS



Stakeholder Dynamics



Key Challenges & Solutions

Model hallucinations in early stages	Rigid readability level	Outputs requiring heavy rework	Non-editable charts creating downstream delays	Context drift in highly complex trials
• Reduced hallucination temperature • Instructions in case of missing information	• Added options for the readability level	• Scenario/rule-based prompts • Writing style inputs at multiple layers • Manual edit/edit with AI feature	• Functionality for generating editable charts	• Relevant “writing instructions” by trial type • Multi-agent model to reduce cognitive load on a single agent • Latest AI LLM models for improved output quality

Fine-tuning prompts reflecting on real PLS examples



Quality Improvements

- Improved readability levels
- Reduced inconsistencies in tone
- Glossary ensured plain-language alignment
- Charts became clearer and more patient-friendly
- Higher stakeholder satisfaction



Efficiency Gains

- 60 -80% efficiency gain at Draft 1
- Quicker turnaround time
- More time available for study team review
- Buffer time to manage unforeseen delays

Key Takeaways



Set realistic expectations



Involve all stakeholders early



Define what success looks like



Dedicated team to drive tool development and refinement



Develop agile system that allows quick upgrades



Ensure robust governance

Thank You

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