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Defining a Globally Acceptable COA Strategy

Case Study | COA Strategy

Defining a Globally Acceptable COA Strategy for Phase III Dermatology Trials

Background

A biopharmaceutical company preparing for Phase III dermatology trials required confidence that its planned Clinical Outcome Assessment (COA) strategy would meet regulatory and health technology assessment (HTA) expectations across key global markets. With increasing scrutiny of COA measures by regulators, early alignment was critical to support primary and key secondary endpoints in global development.

The Challenge

The client needed evidence that its proposed COA measures would be acceptable to regulatory agencies in the US, Europe, and Asia-Pacific.

Key challenges included:

- What are current regulatory expectations for ClinRO and PRO measures across major agencies?
- How have COA measures been accepted in similar dermatology indications?
- Would the planned COA strategy withstand global regulatory review with minimal modification?

A clear, jurisdiction-specific regulatory landscape assessment was required to de-risk late-stage development.

The Solution

Clarivate delivered a multi component COA regulatory strategy combining landscape analysis, expert input, and qualitative validation.

Key elements included:

Regulatory landscape review:
Assessment of guidance published by the FDA, EMA, and PMDA to establish baseline expectations for COA measure format, content, and meaningful score change.

Competitive and precedent analysis:
Review of dermatology clinical trials to understand historical regulatory acceptance of ClinRO and PRO measures in similar conditions.

Primary qualitative research:
In depth interviews with 40 dermatologists across the US, Canada, Germany, China, and Japan, incorporating concept elicitation and cognitive debriefing to assess content validity and usability of the measures.

Strategic guidance:
Integrated recommendations from Clarivate's COA and Regulatory experts to refine the overall COA strategy.

The Results

Clarivate provided clear evidence that the client's COA strategy could meet global regulatory expectations with targeted refinement.

Outcomes included:

- Confirmation that planned COA measures were broadly aligned with regulatory guidance across regions
- Identification of minor modifications to COA instruments, instructions, and investigator training materials
- Clear guidance on future psychometric validation studies to strengthen regulatory acceptance
- Increased confidence that the COA strategy would support primary and key secondary endpoints in global Phase III trials

This work enabled the client to move forward with a globally aligned COA strategy, reducing regulatory risk and supporting efficient late stage development.

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