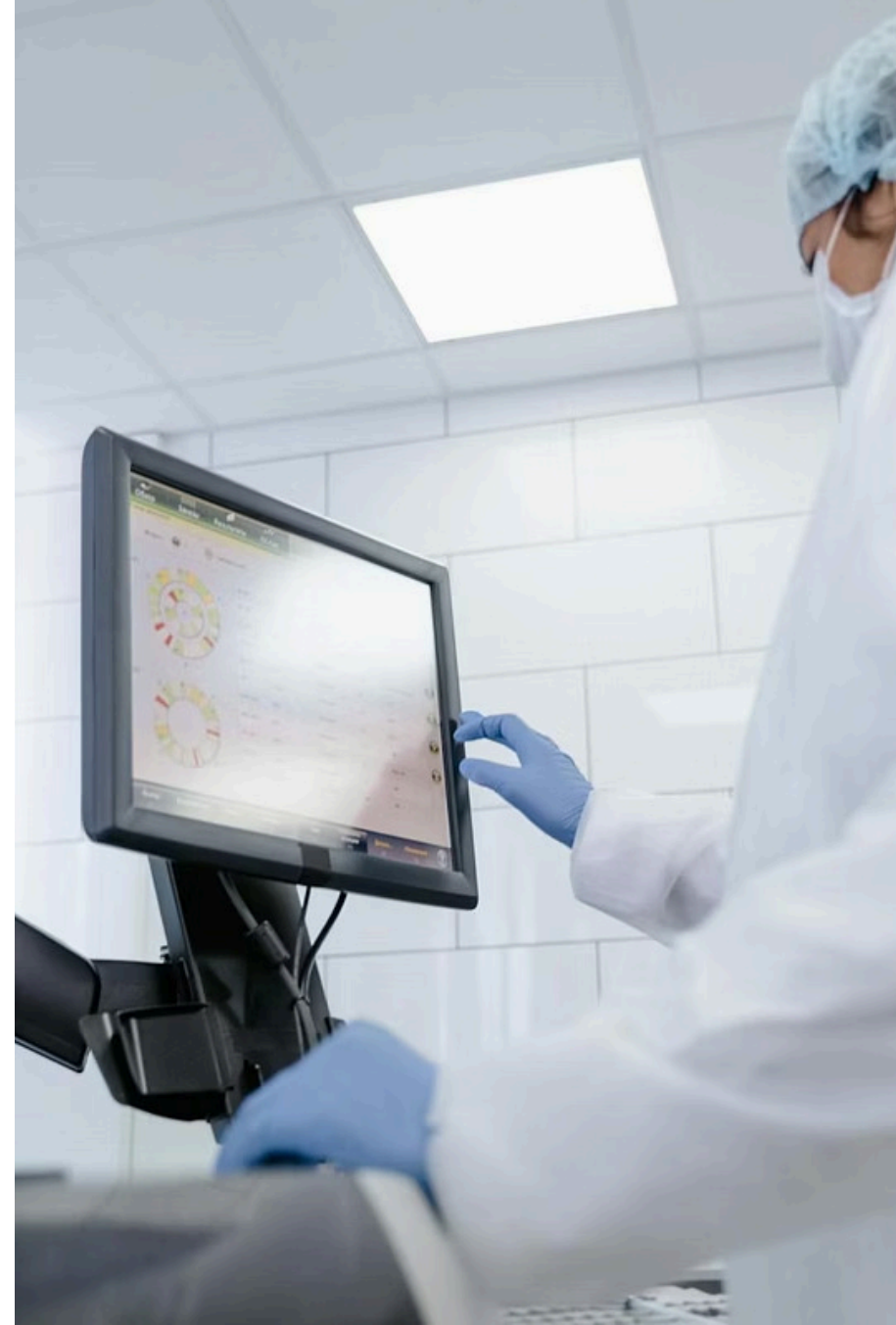


ILLUSTRATIVE SCENARIO – REPRESENTATIVE OF WORKSHOP OUTCOMES | MAKENI BENT DIGITAL CONSULTING

## First-In-Class, First-Time Launcher

How a biopharma team built a messaging architecture for a disease category that didn't exist yet





## THE CHALLENGE

# No Category to Push Against. No Prescriber Habit to Redirect.

Launching a first-in-class therapy is a fundamentally different problem than launching into an established category. The brand must build the **category argument** and the **product argument** simultaneously – in language that brand, medical affairs, legal, and regulatory can all defend.

For this emerging biopharma, it was their first launch. The clock was already running:

- Medical affairs had been operating in scientific communication mode for three years
- Brand had been hired six months before launch
- Legal was reviewing promotional materials for the first time

### The Starting Conditions

No shared vocabulary. No agreed claims hierarchy.

**Fourteen weeks** until the first MLR submission.

# Three Departments. Three Frames of Reference. Zero Common Foundation.

## Medical Affairs

Defaulted to the **clinical trial narrative** – efficacy data, endpoints, statistical significance. Fluent in science, but not yet in promotional language.

## Brand

Defaulted to **emotional positioning** – patient stories, aspirational copy, campaign-ready language. Compelling, but not yet scientifically defensible.

## Legal / Regulatory

Defaulted to the **risk frame** – what couldn't be said, what needed qualification, what required a citation. Protective, but not directional.

- ❏ Without a shared messaging architecture, first-in-class launches fragment by default. Each function optimizes for its own frame – and the launch message fractures before a single asset is written.

# Deployed 12 Weeks Before First MLR Submission

The Launch Messaging Alignment Workshop produced **three foundational outputs** in two days – each designed to serve a different function while locking them into a single shared frame.

1

## Core Brand Message

Scientifically defensible for medical affairs.  
Promotionally executable for brand. Cleared the dual-audience bar before MLR review began.

2

## Claims Hierarchy

A pre-approved framework giving legal and regulatory a structured basis to evaluate every downstream asset – consistently and efficiently.

3

## Shared Vocabulary Document

The internal style guide for all content, across all channels. One source of truth for terminology, tone, and claim-level language.

*Deployed early enough to shape content creation. Late enough that the team had clinical data to work from.*

RESULTS

# Zero Structural Objections at First MLR Submission

**2 days**

## To Full Stakeholder Alignment

Core brand message approved by all four stakeholder groups – after **4 months** of informal, inconclusive negotiation.

**0**

## Structural MLR Objections

First MLR submission cleared without structural objections. Minor sourcing edits only – no message-level revisions required.

**0**

## Channel Inconsistencies Flagged

Sales training, HCP promotional, and digital assets passed compliance review with zero channel-to-channel inconsistency flagged.

- ☐ **Launch executed on schedule.** No messaging-related delays. No last-minute structural revisions to core claims. The architecture held across every asset and every channel.

# Without an Established Category, Every Stakeholder Defaults to Their Own Frame

First-in-class launches fail on messaging for a specific and predictable reason. There is no prior category language to anchor the team. In the absence of a shared frame:

- Medical affairs writes to the clinical trial narrative
- Brand writes to the emotional positioning
- Legal writes to the risk frame

Each function is doing its job correctly — but the outputs are structurally incompatible.

## The Resolution

The workshop gives all three functions a **shared frame** — established before anyone begins creating content in their own language.

Alignment is not a negotiation that happens after content is drafted. It is an architecture decision that must happen before.



# When Launch Teams Find Their Through

**Makeni Bent Digital Consulting** helps pharmaceutical brand, medical affairs, legal, and regulatory teams reach messaging alignment before content creation begins.

Our flagship offering – the **Launch Messaging Alignment Workshop** – compresses months of iterative misalignment into two focused days. The result is a single, defensible messaging architecture that every function can execute from, independently and consistently.

Designed specifically for first-in-class and first-launch scenarios where no prior category infrastructure exists.

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## Messaging Architecture

One shared framework across brand, medical affairs, and legal/regulatory



## Two-Day Delivery

Months of iterative misalignment resolved in a structured two-day workshop



## MLR-Ready Outputs

Claims hierarchy and shared vocabulary document ready for immediate deployment