Craft Science Inc.

Top 10 Pitfalls That Delay PAAB Approval

Practical guidance for brand, medical, and agency teams

PAAB's review timelines are predictable; the *number of rounds* is not. Many delays come from avoidable issues in the way pieces are planned, referenced, and submitted, not from PAAB "being difficult." The list below focuses on common problem patterns and how to avoid them, consistent with PAAB's own submission guidance and tips.

1. Weak or missing references for key claims

The pitfall

Headline or key visual claims are not clearly supported by high-quality, primary references, or they rely on abstracts, pooled post-hoc analyses, or non-Canadian data without proper context.

Why it delays you

Reviewers must question, downgrade, or reject claims, leading to major re-writes and new data searches mid-review.

How to avoid it

- Anchor major claims in "gold-standard" trials and the Product Monograph wherever possible.
- Use RWE and secondary analyses as supportive, not primary, evidence and disclose limitations clearly.

2. Claims that drift beyond the Product Monograph

The pitfall

Efficacy, safety, or positioning statements imply broader indications, populations, comparators, or outcomes than those supported in the PM.

Why it delays you

PAAB must request revisions to bring content back within indication and PM language, often changing headlines, visuals, and key messages.

How to avoid it

- Map each claim explicitly to PM sections and key trials before creative development.
- Flag any necessary nuance (e.g., subgroup findings) early so they're framed cautiously and contextually.

3. Unclear positioning versus competitors

⚠ The pitfall

Comparative claims (direct or implied) lack robust head-to-head data or use indirect comparisons that are not presented with appropriate caution.

Why it delays you

Reviewers challenge the basis for superiority or non-inferiority, triggering multiple iterations on wording, graphs, and footnotes.

✓ How to avoid it

- Reserve strong comparative language for situations with direct, well-designed comparative data.
- Where only indirect or network meta-analysis exists, present it cautiously, with clear limitations and without promotional over-reach.

4. Poor integration of RWE

⚠ The pitfall

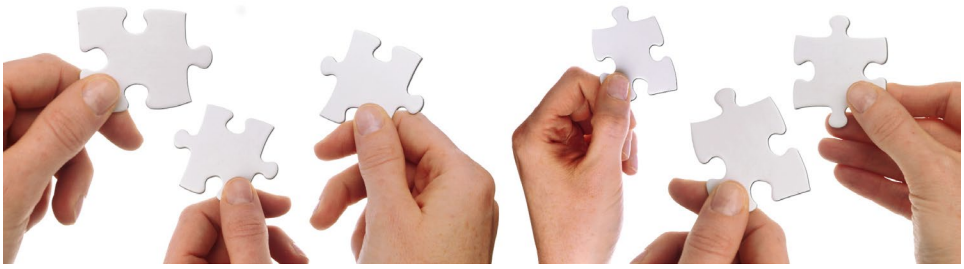
RWE is treated like RCT data, used to support strong benefit claims, with limitations underplayed or formatting not aligned with PAAB's RWE guidance (e.g., no RWE box, missing icon or disclaimer).

Why it delays you

PAAB requests reformats, additional caveats, or removal of RWE-based claims, leading to substantial layout and messaging changes.

✓ How to avoid it

- Use RWE as supplementary context, not as the sole basis for major claims.[6][9]
- Follow the RWE formatting principles (boxed, icon, explanatory text, limitations disclosed) from the outset, not as an afterthought.



5. Imbalanced risk–benefit presentation

The pitfall

Benefits are prominent and concrete, while risks, contraindications, and monitoring requirements are minimized, buried, or missing.

Why it delays you

PAAB requires rebalancing: adding fair balance, moving or resizing safety text, and sometimes softening benefit language.

How to avoid it

- Ensure fair balance is present, legible, and proportionate to the strength of benefit claims.
- Plan space for safety and limitations from the first mock-up—don't treat balance as "copy we'll squeeze in later."

6. Incomplete or non-standard submission packages

The pitfall

Core elements (final PM, references, annotated copy, previous related approvals, cover letter context) are missing or incomplete when the eFile is submitted.

Why it delays you

PAAB may have to pause review, request missing materials, or spend extra time reconstructing context from scratch.

How to avoid it

- Use PAAB's submission checklist every time, especially for multi-piece campaigns.
- Clearly annotate where each claim is supported, and how pieces in a series relate to prior approvals.

7. Treating each APS in a campaign as if it lives alone

⚠ The pitfall

Series or families of advertising pieces are developed with inconsistent claims, references, or positioning, without a clear “parent” piece or message hierarchy.

Why it delays you

PAAB must query discrepancies between pieces, extending reviews and sometimes reopening prior files.

✔ How to avoid it

- Establish a master claim/reference grid and a “parent” APS that anchors the series.
- Indicate in the cover letter how each child piece relates to the parent file (e.g., 60% shared copy, same core claims).

8. Late or fragmented responses to PAAB letters

⚠ The pitfall

Response letters arrive late, address only some comments, or introduce new material and claims without explanation.

Why it delays you

Each incomplete or unclear response can effectively restart parts of the review, stretching timelines across multiple rounds.

✔ How to avoid it

- Consolidate internal feedback and respond to each PAAB point clearly, one by one.
- Avoid adding new claims mid-review unless absolutely necessary. If you do, explain the rationale and supporting data explicitly.

9. Misalignment between brand, medical, and agency

The pitfall

Brand, medical affairs, and agency partners are not aligned on risk tolerance, key messages, or evidence strategy before submission, so disagreements surface only after PAAB feedback arrives.

Why it delays you

Internal re-debating of strategy between rounds leads to re-briefs, re-writes, and shifting instructions to creative and medical writing teams.

How to avoid it

- Align on a clear evidence-based messaging strategy and risk posture before creative development.
- Use a pre-PAAB internal review that includes both medical and regulatory perspectives, not just brand.

10. Underestimating layout and design implications

The pitfall

Pieces are designed to the millimeter before PAAB review, leaving no flexibility to add balance text, RWE boxes, clarifying footnotes, or additional references.

Why it delays you

Even minor wording changes force major design rework and reproofing, adding days or weeks between rounds.

How to avoid it

- Build design “breathing room” into layouts, especially around core claims and data visuals.
- Anticipate common additions so the layout can absorb them without starting over: RWE boxes, fair balance expansions, clarification notes.

In Closing...

These pitfalls are not about catching teams out; they’re where process and strategy most often break down. Running through a short internal checklist that covers these 10 areas before each submission can significantly reduce the number of review rounds and keep your launch and campaign timelines intact.

Need fewer PAAB rounds and more predictable approvals?
CSI helps pharma and agencies create PAAB-ready materials that are clinically credible and efficient to review. Contact us today at info@craftscience.ca