

Document Audit — Nicola’s Case Factual Accuracy

Date: May 31, 2026 **Trigger:** Discovery that “Stage IV” framing was incorrect; verified pathology report shows Stage IIA (pT2 pN0) high-grade triple-negative invasive ductal carcinoma with metaplastic features.

Executive summary

Three documents contain the false “Stage IV” framing of Nicola’s case (6 instances total). These are unambiguous errors that misrepresent the empirical anchor of the framework and must be corrected.

Beyond the staging error, the audit identified two further accuracy issues across the document set: (1) **inconsistent year framing** across documents (some say diagnosis 2009, some 2010, some 2011) and (2) **omission of the metaplastic histology feature** in all documents — even though this feature actually *strengthens* the empirical anchor by making the long survival more notable than ordinary stage II TNBC would.

Outreach letters and the CCE tool are clean. Most framework papers handle the case carefully — they avoid stating a specific stage and properly caveat what the case demonstrates. The errors are concentrated in three documents.

1. THE STAGE IV ERROR (must fix — false statement about Nicola)

Document 1 — patient-guide.md (3 errors)

Line 17 (Before-you-begin section, opening framing): > Current: *“one patient whose 15-year survival after **stage IV BRCA1+ triple-negative breast cancer** was treated within the framework’s principles.”* > Should read: *“one patient whose 15-year recurrence-free outcome after **Stage IIA (pT2 pN0) high-grade BRCA1+ triple-negative invasive ductal carcinoma with metaplastic features** was treated within the framework’s principles.”*

Line 99 (Section 4, the empirical-anchor paragraph): > Current: *“the framework’s author’s wife was diagnosed with **stage IV BRCA1+ triple-negative breast cancer in 2011... Fifteen years later**, she is alive.”* > Should read: *“the framework’s author’s wife was diagnosed with **Stage IIA (pT2 pN0) high-grade BRCA1+ triple-negative invasive ductal carcinoma with metaplastic features**, treated surgically in 2011 (with neoadjuvant Coley protocol beginning approximately one month before surgery)... **Fifteen years recurrence-free**, she remains well.”*

Line 246 (Section 9, hope-and-realism close): > Current: *“one patient, **fifteen years after stage IV BRCA1+ triple-negative breast cancer diagnosis**”* > Should read: *“one patient, **fifteen years recurrence-free after Stage IIA high-grade BRCA1+ triple-negative breast cancer with metaplastic features**”*

Document 2 — compassionate-use-clinical-protocol.md (2 errors)

Line 467 (Section 7 — TNBC indication opening): > Current: “the 2011 case that motivated the framework was a **stage IV BRCA1-positive triple-negative breast cancer**” > Should read: “the 2011 case that motivated the framework was a **Stage IIA (pT2 pN0) high-grade BRCA1-positive triple-negative invasive ductal carcinoma with metaplastic features**”

Line 1373 (Section 13.4 — empirical anchor narrative): > Current: “A patient with **stage IV BRCA1-positive triple-negative breast cancer** received, at CHIPSA Hospital in Tijuana, a combination protocol...” > Should read: “A patient with **Stage IIA (pT2 pN0) high-grade BRCA1-positive triple-negative invasive ductal carcinoma with metaplastic features** received, at CHIPSA Hospital in Tijuana, a combination protocol...”

Note: Other “stage IV” references in this document (lines 137, 475, 482, 951) refer to patient eligibility populations or general indication discussion, not Nicola’s case. These are correct as written and require no change.

Document 3 — plain-language-illustrated-summary.html (1 error)

Line 571 (illustrated narrative): > Current: “In 2011, a woman with **stage IV BRCA1 triple-negative breast cancer — the most aggressive kind** — was given a combination approach...” > Should read: “In 2011, a woman with **Stage IIA high-grade BRCA1 triple-negative breast cancer with metaplastic features — a difficult-to-treat subtype generally resistant to standard chemotherapy** — was given a combination approach...”

Note: “The most aggressive kind” is also imprecise — the metaplastic subtype is genuinely difficult to treat, but stage IV would be more aggressive. The corrected framing is more accurate.

2. YEAR/DURATION INCONSISTENCY (should fix — internal contradiction)

The documents are split into two groups, using different framings for the same case:

Framing	Documents using it
“2009” / “sixteen years”	neo-coley-v2-framework.md · neo-coley-v2-revised-v6.md · neo-coley-v2-revise-fr-v6.md · cover-letter-CII.md
“2010” (mixed)	paper-3-FINAL.md (some refs) · paper-4-FINAL.md (some refs) · neo-coley-v2-framework.md (one ref “2009-2010”)

Framing	Documents using it
“2011” / “fifteen years”	patient-guide.md · compassionate-use-clinical-protocol.md · paper-3-FINAL.md (some refs) · paper-4-FINAL.md (some refs) · plain-language-illustrated-summary.html

What this likely means: - Diagnostic biopsy: 2009 or 2010 (date needs your confirmation) - Surgery: 4/5/2011 (verified by pathology report) - “2011” framing = anchored on surgery date - “2009” or “2010” framing = anchored on initial diagnosis date

The cancer-survival convention is to measure from date of diagnosis, not date of surgery. So if diagnosis was in 2009 or 2010, the correct framing is “sixteen years” not “fifteen years.” If diagnosis was in 2011, “fifteen years” is correct.

Question for you: What is the verified date of initial diagnostic biopsy? This determines: - Whether the framework documents should say “2009 diagnosis” or “2010 diagnosis” - Whether to use “16 years” or “15 years” recurrence-free framing - Which set of documents needs adjustment to match the other

3. MISSING METAPLASTIC FEATURE (should add — strengthens the case)

Zero documents currently mention metaplastic histology. Adding this feature is not just for accuracy — it actually *strengthens* the empirical anchor:

- Conventional Stage IIA TNBC: 5-year OS \approx 75-85%; 15-year recurrence-free survival is favorable but expected for patients who clear the 5-year mark
- **Metaplastic Stage IIA TNBC: 5-year OS \approx 50-70% across published series;** generally chemoresistant; recurrence patterns more aggressive
- 15-year recurrence-free survival in Stage IIA *metaplastic* BRCA1+ TNBC is genuinely above expectation

This also retrospectively justifies the choice of cisplatin + gemcitabine over conventional AC-T. Standard anthracycline/taxane regimens have limited activity in metaplastic carcinoma; platinum + gemcitabine has documented activity. The Wiesenthal assay-guided selection was clinically sound — and prescient.

Recommendation: Add “with metaplastic features” or “with foci of metaplastic transformation” to every description of Nicola’s case across all documents. This requires no change to the framework’s structural arguments; it just makes the empirical anchor more precise and clinically meaningful.

4. DOCUMENTS CONFIRMED CLEAN (no changes needed)

These documents do not contain factual errors about Nicola's case:

Framework papers (carefully written): - neo-coley-v2-framework.md — Lines 340-342 describe the index case as “one patient in 2009-2010” with “sixteen-year follow-up,” explicitly avoiding stage claims and properly caveating what the case demonstrates. Lines 334-336 describe the *separate* stage IV melanoma case (the friend's daughter) with appropriate caveats. All correct. - neo-coley-v2-revised-v6.md and neo-coley-v2-revise-fr-v6.md — Use “sixteen years” and “2009” framing; no stage claim; AI disclosure handled properly. May want to align with whatever year/duration framing you choose, but no factual error. - paper-3-FINAL.md and paper-4-FINAL.md — Use “2011” and “15-year” framing; no stage claim. May want to align framing; no factual error.

Outreach letters (all clean): - letter-chamie.docx/pdf, letter-gravekamp.docx/pdf, letter-hobohm.docx/pdf, letter-jaeger-karbach.docx/pdf, letter-repasky.docx/pdf, letter-upadhaya.docx/pdf — None reference Nicola's case directly. Framed around the scientific argument.

Tool: - combinatorial-completeness-engine.html — No references to Nicola's case in narrative. The “TNBC · BRCA+” preset uses general biomarker values; doesn't make staging claims.

Other: - cover-letter-CII.md/docx/pdf — Says “sixteen years of personal study” (Eric's study duration, not Nicola's survival). Internally consistent with the “2009” framing. - coley-question-layman.md and coley-question-layman-fr.md — Reference “fifteen years” only in the context of “the past fifteen years of medical progress” (checkpoint inhibitor era), not Nicola's case. - neo-coley-v2-summary.md — No case references. - All neo-coley-derivative-v*.md files (v1-v6) — These are working drafts of a separate paper; case is not the focus. - All other working documents and per-mode audits.

5. RECOMMENDED CORRECTIONS PLAN

Tier 1 — Must fix (false statements):

1. patient-guide.md — Fix 3 stage IV errors. Regenerate PDF + DOCX.
2. compassionate-use-clinical-protocol.md — Fix 2 stage IV errors. Regenerate PDF + DOCX.
3. plain-language-illustrated-summary.html — Fix 1 stage IV error. Regenerate PDF.

Tier 2 — Should fix (consistency + completeness):

4. Decide on canonical framing: 2009 (16 years) OR 2010 (16 years) OR 2011 (15 years).
5. Align all framework papers (paper-3, paper-4, neo-coley-v2-framework, neo-coley-v2-revised-v6 EN/FR) to the canonical framing.

6. Add metaplastic feature mention to all empirical anchor descriptions across documents.

Tier 3 — Optional refinements:

7. Adjust description of the 2011 chemo regimen (cisplatin + gemcitabine) to note its appropriateness for metaplastic TNBC — adds clinical sophistication to the narrative.
 8. Review CCE tool “TNBC · BRCA+” preset to ensure biomarker defaults are reasonable for the actual case (currently uses generic values).
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6. QUESTIONS FOR YOU BEFORE I PROCEED

1. **Diagnostic biopsy date.** What is the verified date of the initial diagnostic biopsy? The surgical pathology references “a previous biopsy” but doesn’t give its date. This determines the canonical year/duration framing.
2. **Canonical framing.** Once we have the diagnosis date, do you want me to standardize all documents to one framing? (My recommendation: yes — internal inconsistency weakens credibility when documents are cross-referenced.)
3. **Metaplastic mention.** Should I add “with metaplastic features” or “with foci of metaplastic transformation” to every empirical-anchor description across documents?
4. **Order of operations.** Should I:
 - (a) Fix all three Tier 1 documents first (most urgent), then come back to Tier 2 with your decisions, or
 - (b) Wait for your direction on year/metaplastic before any edits, then do everything in one consistent pass?

I recommend (b) — slightly slower but ensures consistency across all documents and avoids redo work.

Awaiting your direction.