

4.4 Sources

Purpose: The Sources Section is a feature of the Redouble AI system that ensures transparency and traceability in AI-generated answers. It displays all documents that contributed to the response, allowing you to verify information and access the original sources/ inputs. It is displayed at the end of an answer or in a dedicated panel on the right-hand side of the interface.

Functionality

Viewing sources

Steps:

1. Generate or open an answer to a question
2. Scroll to the bottom or to the side panel where the Sources are displayed
3. Review the list of referenced documents

Result: You can see all documents that contributed to the answer. Each document is shown with two names:

- **Display name** (shown in the list): AI-generated descriptive name for easy identification
- **Original filename** (shown on hover in blue): The actual name of the uploaded file

The screenshot displays the Redouble AI interface. On the left is a dark sidebar with the 'Redouble AI' logo and a list of document sections: 'Nivolumab CSR', 'Investigators and administrative structure', 'Method of assigning subjects', 'Sample size and power', 'Changes in the conduct of trial', 'Overall efficacy summary', 'Primary endpoint (pathological complete response)', 'Exploratory endpoint (clinical benefit)', 'Clinical downstaging prior to surgery', 'Definitive surgery outcome', 'Overall safety summary', 'Deaths', 'Other serious adverse events', 'Adverse events leading to discontinuation', and 'Adverse events leading to death'. The main content area is titled 'Nivolumab CSR' and shows the 'Investigators and administrative structure' section. The text describes the trial enrollment (773 patients), randomization (505 patients), and treatment (495 patients). It also details the geographic distribution of patients across four regions: Asia (43.6%), North America (31.1%), Europe (17.8%), and Rest of World (7.5%). On the right side of the main content area, there is a 'Sources' panel, which is highlighted with a red box. This panel lists two sources: 'CA209816_Supplemental_Tables_Demographics_Baseline' and 'CA209816_baseline_characteristics_treatment_data'. Below the 'Sources' panel, there is an 'Analysis' section and a 'Key Findings' section, both of which are partially visible.

Accessing source documents

Steps:

- 1. Locate the desired document in the Sources list
- 2. Click on the document name in the list
- 3. The document content will appear in a separate panel

Result: You can review the original document content. For more detailed information please view page [5.1 Edit/View Attached Documents](#)

Redouble AI

Nivolumab CSR

Investigators and administrative structure

Method of assigning subjects

Sample size and power

Changes in the conduct of trial

Overall efficacy summary

Primary endpoint (pathological complete response)

Exploratory endpoint (clinical benefit)

Clinical downstaging prior to surgery

Definitive surgery outcome

Overall safety summary

Deaths

Other serious adverse events

Adverse events leading to discontinuation

Adverse events leading to discontinuation

Nivolumab CSR

Investigators and administrative structure

DEMO - BMS Nivolumab Tables Part 1.pdf

CA209816_Supplemental_Tables_Demographics_Baseline

A total of 773 patients were enrolled in the CA209816 trial between March 2017 and December 2019. Of these enrolled patients, 505 (65.3%) were randomized and 495 (98.0% of randomized) were treated.

The randomized patients were distributed across three treatment arms: Arm A (Nivo + Ipi) with 113 patients, Arm C (Nivo + Chemo) with 179 patients, and Arm B (Chemo Concurrent) with 179 patients.

Patients were enrolled from multiple countries across four main geographic regions. The regional distribution was: Asia (43.6%), North America (31.1%), Europe (17.8%), and Rest of World (7.5%). The top enrolling countries were the United States with 186 patients (24.1% of enrolled), China with 166 patients (21.5% of enrolled), and Japan with 108 patients (14.0% of enrolled).

Regarding the key trial dates, the first patient first visit (FPFV) date is not explicitly stated in the provided documents. However,

Sources

CA209816_baseline_characteristics_treatment_data

Analysis

Key Findings

- 773 total patients enrolled in the study
- 505 patients (65.3%) were randomized
- 495 patients (98.0% of randomized) were treated
- Enrollment occurred between March 2017 and December 2019
- Three treatment arms: Arm A (N=113), Arm C (N=179), Arm B (N=179)
- Geographic distribution: Asia 43.6%, North America 31.1%, Europe 17.8%, Rest of World 7.5%
- Top enrolling countries: United States (186 patients), China (166 patients), Japan (108 patients)
- Database lock for pCR analysis occurred on 16-Sep-2020

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