

Background And Context

- Hematology-oncology response review requires integrating diverse clinical data with radiologic imaging, using disease-specific criteria (e.g., CLL, WM, Lugano) that prioritize different indicators.
- Reviewers need interpretable, derived data available before ADaM datasets are available, necessitating early specifications and generation of new analysis and reporting.
- Our approach spans end-to-end: requirements gathering, tool evaluation aligned with team programming skills and development of specifications/processes to operationalize early response assessments.
- Imaging vendors engaged by sponsors have varying report requirements, primarily driven by the response criteria in use.
- CLL-focused reports emphasize CBC measures (Hemoglobin, ANC, Absolute Lymphocyte count, WBC), derived baseline flags, change from baseline/nadir, plus bone marrow, lesions, procedures, symptoms, and adverse events.
- WM-focused reports prioritize Serum IgM, Serum Immunofixation, and Cryoglobulinemia, with less emphasis on CBC compared to CLL.

<https://nci-media.cancer.gov/pdq/media/images/755927.jpg>

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graph LR
    A[Extract Data] --> B[Specifications, Subject Tracker, Programs and other Metadata]
    B --> C[Report ready Data with collected and Analyzed values]
    C --> D[Reporting Tools/Programs]
    D --> E[Reports]
    E --> F[Blinded Independent Central Reviewer]
    F --> G[Sponsor]
    G --> H[Response Data]
    H --> I[CR, PR, SD, PD]
  
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Round 1:

Subject ID	curr. flag	extraction date
18001	Y	20230620
18002	Y	20230620
18003	Y	20230620
18004	Y	20230620

Round 2:

Subject ID	curr. flag	extraction date
18001		20230620
18002		20230620
18003		20230620
18004		20230620

Round 3:

Subject ID	curr. flag	extraction date
18001		20230620
18002		20230620
18003		20230620
18004		20230620
18001		20230824
18002		20230824
18005		20230824
18006		20230824
18001	Y	20230928
18002	Y	20230928
18003	Y	20230928
18006	Y	20230928

The diagram illustrates the iterative deduplication process across three rounds. Round 1 shows a table with 4 rows. Round 2 shows a comparison of Round 1's data with a new table, identifying duplicates. Round 3 shows a comparison of Round 2's data with a final table, identifying more duplicates. Arrows indicate the flow of data and comparison between rounds.

[illegible]

Category	SAS Score (approx.)	R Score (approx.)
Creating Data for the listings	65	65
Creating Polished reports with Modern Typography	10	85
Minimum setup to start creating pdfs	40	10
Easy control over column widths	55	10
Ease of creating graphs and placing it in grids for profile	10	90
Inserting free text paragraphs	10	85

Disclaimer:
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