



DS03 - Mapping Minimal Residual Disease (MRD) Biomarker Data in Hematologic Malignancies:

Clinical Significance and Data Standards in SDTM and ADaM

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What is a Biomarker?



 A biomarker must be measurable, biologically relevant, and clinically meaningful.

 MRD (Minimal Residual Disease) meets these criteria and can be used as a biomarker.

 MRD can be quantified as Positive or Negative.

 Biologically, MRD reflects both the depth of a patient's response to therapy and the remaining disease burden, which is directly associated with risk of relapse.

 Clinically, MRD serves as a prognostic biomarker: MRD negativity is linked to improved Event-Free Survival (EFS) and Overall Survival (OS).

 MRD also functions as a predictive biomarker, since MRD status can guide treatment decisions, including whether to intensify or de-escalate therapy.

What is MRD?



- MRD is increasingly used as a surrogate endpoint in clinical trials for accelerated approvals.
- MRD refers to a small number of malignant cells that remain in a patient after treatment, even when patients appear to be in complete remission or complete response by standard tests.
- Traditional morphologic evaluation of hematologic malignancies can identify malignant cells only when they constitute roughly 1 in 100 cells.
- In contrast, newer analytical platforms can identify very low levels of persisting disease, well below this threshold.
- This strategy is gaining increasing popularity and is being used across:
 - Acute Lymphoblastic Leukemia (ALL)
 - Acute Myeloid Leukemia (AML)
 - Chronic Myeloid Leukemia (CML)
 - Multiple Myeloma (MM)

MRD can serve as several types of biomarkers:

- Diagnostic biomarker: Helps detect a disease or confirm a specific disease subtype.
- Prognostic biomarker: Shows the likelihood of relapses, progression, or other clinical events based on the patient's disease at baseline (before new treatment).
- Predictive biomarker: Indicates whether a patient is more or less likely to benefit from a specific therapy.
- Efficacy response biomarker: Shows whether a biological response has occurred after treatment (for example, a drop in MRD levels).
- Monitoring biomarker: Measured repeatedly over time to track changes in disease burden or detect early relapses.

- MRD results can vary across labs and technologies, causing potential discrepancies.
- Variability drivers: lab-developed protocols, assay performance characteristics, and sample collection procedures; platforms differ in sensitivity, specificity, and workflows.
- Standardization is essential for consistent, comparable MRD results across sites/methodologies.
- Standardization elements: harmonized posttreatment time points, uniform sample processing, predefined MRD thresholds, and transparent assay performance reporting.
- Four MRD platforms: MPFC, NGS, RT-qPCR (recurrent gene fusions), ASOPCR.
- FDA does not favor a specific platform; sponsors should prespecify the platform and perform analytical validation for intended context of use.
- Single MRD technology preferred within a trial; if multiple platforms are used and results will be integrated, define the combining approach upfront and discuss with the agency.

- MRD is an increasingly accepted endpoint in oncology trials (especially hematologic malignancies) because it provides an early, sensitive, and biologically meaningful measure of treatment efficacy.
- Traditional endpoints (OS, PFS) often require large sample sizes and long follow-up, particularly when modern therapies produce high response rates and prolonged survival.

1. Acute Lymphoblastic Leukemia (ALL):

- MRD is a key prognostic indicator in ALL regardless of age, immunophenotype, or genetic subtype.
- Bone marrow is the preferred sample; use of blood requires justification.
- MRD should ideally be assessed at CR with full blood count recovery.
- When used as an efficacy endpoint, confirm absence of extramedullary disease at the same time as marrow and blood count assessments.

2. Chronic Myeloid Leukemia (CML):

- MRD detection/monitoring is standard due to advances from targeting BCR-ABL1.
- MRD should be reported on the International Scale (IS) (baseline 100%; molecular response as log reduction).
- RT-qPCR (IS) is preferred for monitoring treatment responses.
- MMR: BCR-ABL1 IS < 0.1%, or if IS not available, >3-log reduction from standardized baseline.
- Achieving MMR is associated with superior long-term outcomes and is a key therapeutic goal/indicator of benefit.

3. Multiple Myeloma (MM):

- Interest in MRD as a surrogate endpoint has grown; studies link MRD status with PFS and OS.
- Evidence is strongest in newly diagnosed post-transplant; fewer data in relapsed/refractory, non-transplant-eligible newly diagnosed, or smoldering myeloma—clinical benefit must be shown separately in each setting.
- MRD evaluation should generally be limited to patients in CR; assessing lesser responses requires justification.

Mapping MRD Data Into SDTM Domains



- Standardize MRD data from diverse sources (central/local labs, assay vendor files, eCRF) into CDISC SDTM v3.2 or later to support consistent analysis, cross-study comparability, and regulatory-ready submissions.
- In SDTM v3.2 or later MRD records maps to LB, BE, PF, or RS depending on specimen type (bone marrow aspirate vs peripheral blood) and collection/assessment method.
- BE — Biospecimen Events
Captures whether the MRD specimen was collected, specimen type, collection method/location/category, collection date/time, and condition for traceability.
- LB — Laboratory Test Results
Used when labs report MRD results (qualitative and/or quantitative) with test identification, method (e.g., NGS), specimen matrix, and timing.
- RS — Disease Response
Used when MRD is a protocol-defined endpoint/response classification (e.g., “MRD-negative at 10^{-4} ” at a timepoint; MRD remission; MRD negativity rate supporting a primary endpoint).

PF — Pharmacogenomics/Genetics Findings

(BCR:ABL1 by RT-qPCR in ALL/CML)

- BCR:ABL1 MRD by RT-qPCR maps best to PF because the measurand is a molecular gene-expression/fusion transcript endpoint rather than a routine lab analyte.
- PF supports essential context (target/transcript, specimen, RT-qPCR method, performing lab).
- Model MRD as atomic findings: raw copy number, normalized BCR::ABL1/ABL1 ratio (often unitless), %IS (when available), and log reduction as separate PF tests/records per subject/timepoint/specimen to preserve units, interpretation, traceability, and analysis.
- Handles qualifiers (not detected, below LOD/LOQ) by storing character results when numeric is not valid, while retaining method/specimen details; although results are produced by a lab, domain choice is driven by what is measured, hence PF over LB for transcript-based RT-qPCR BCR:ABL1 MRD.

STUDYID	DOMAIN	USUBJID	PFSEQ	PFREFID	PFSPID	PFTESTCD	PFTEST	PFTSTDTL	PFGENRI	PFGENTYP	PFCAT	PFSCAT
AB-1001	PF	PT-1001	1	30001087	e1a2	DETECT	Detection	e13/14a2	ABL	GENE	GENETIC EXPRESSION	RAW
AB-1001	PF	PT-1001	2	30001087	e1a2	DETECT	Detection	e1a2	ABL	GENE	GENETIC EXPRESSION	RAW
AB-1001	PF	PT-1001	3	90001087	e1a2	DETECT	Detection	e1a2	ABL	GENE	GENETIC EXPRESSION	RAW
AB-1001	PF	PT-1001	4	30001087	e1a2	DETECT	Detection	e13/14a2	BCR-ABL	GENE	GENETIC EXPRESSION	RAW
AB-1001	PF	PT-1001	5	30001087	e1a2	DETECT	Detection	e1a2	BCR-ABL	GENE	GENETIC EXPRESSION	RAW
AB-1001	PF	PT-1001	6	90001087	e1a2	DETECT	Detection	e1a2	BCR-ABL	GENE	GENETIC EXPRESSION	RAW
AB-1001	PF	PT-1001	7	30001087	e1a2	DETECT	Detection	e13/14a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	PERCENT
AB-1001	PF	PT-1001	8	30001087	e1a2	DETECT	Detection	e1a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	PERCENT
AB-1001	PF	PT-1001	9	90001087	e1a2	DETECT	Detection	e1a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	PERCENT
AB-1001	PF	PT-1001	10	30001087	e1a2	DETECT	Detection	e13/14a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	PERCENT
AB-1001	PF	PT-1001	11	30001087	e1a2	MR3	Molecular Response 3	e13/14a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	STATUS
AB-1001	PF	PT-1001	12	30001087	e1a2	MR3	Molecular Response 3	e1a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	STATUS
AB-1001	PF	PT-1001	13	90001087	e1a2	MR3	Molecular Response 3	e1a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	STATUS
AB-1001	PF	PT-1001	14	30001087	e1a2	MRD	Minimal Residual Disease	e13/14a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	STATUS
AB-1001	PF	PT-1001	15	30001087	e1a2	MRD	Minimal Residual Disease	e1a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	STATUS
AB-1001	PF	PT-1001	16	90001087	e1a2	MRD	Minimal Residual Disease	e1a2	BCR-ABL/ABL	GENE	GENETIC EXPRESSION	STATUS

PFORRES	PFORRESU	PFSTRES	PFSTRESN	PFSTRESU	PFSTAT	PFNAM	PFSPEC	PFMETHOD	VISITNUM	VISIT	EPOCH	PFTC	PFDY
27564		27564	27564			MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
37185		37185	37185			MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
343783		343783	343783			MolecularMD, OR	BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
1		1	1			MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
127		127	127			MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
208131		208128	208128			MolecularMD, OR	BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
0.003624		0.00365444	0.003654			MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
0.337164		0.337164	0.337164			MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
60.5205		60.5205	60.5205			MolecularMD, OR	BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
0.00412	International Scale	0.00412		International Scale		MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
Y		Y				MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
N		N				MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
N		N				MolecularMD, OR	BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
Y		Y				MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
N		N				MolecularMD, OR	PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8
N		N				MolecularMD, OR	BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYMERASE CHAIN REACTION	-1	SCREENING	SCREENING	27-Feb-2020	-8

Table 1- MRD data mapping into PF domain in SDTM3.2v

GF- Genomics Findings

- In SDTMIG v3.4, the earlier provisional PF domain is no longer recommended for genomics results; genomics and gene-expression results are represented in Genomics Findings (GF).
- Therefore, RT-qPCR MRD for BCR:ABL1 transcripts in ALL and CML (e.g., e1a2/e13a2/e14a2) should be mapped to GF.
- Create separate GF records for each reported MRD endpoint per timepoint and specimen (e.g., raw copies, BCR::ABL1/ABL1 ratio, log reduction; and separate records for peripheral blood vs bone marrow aspirate).
- Populate:
 - GFTESTCD/GFTEST (test)
 - GFORRES/GFSTRESC (original/standardized results) and GFSTRESN when numeric, with appropriate units
 - Context: GFSPEC (specimen), GFMETHOD (e.g., quantitative RT-PCR)
 - Timing/IDs: GFDTC and identifiers
 - Variable mapping is largely direct PF → GF renaming, except:
PFGENRI/PFGENTYP → GFSYM/GFSYMTYP.

GF- Genomics Findings

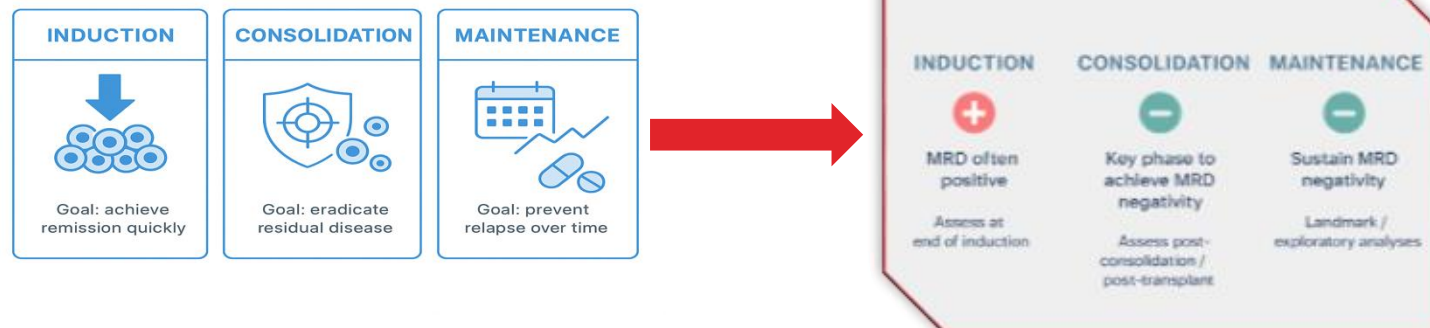
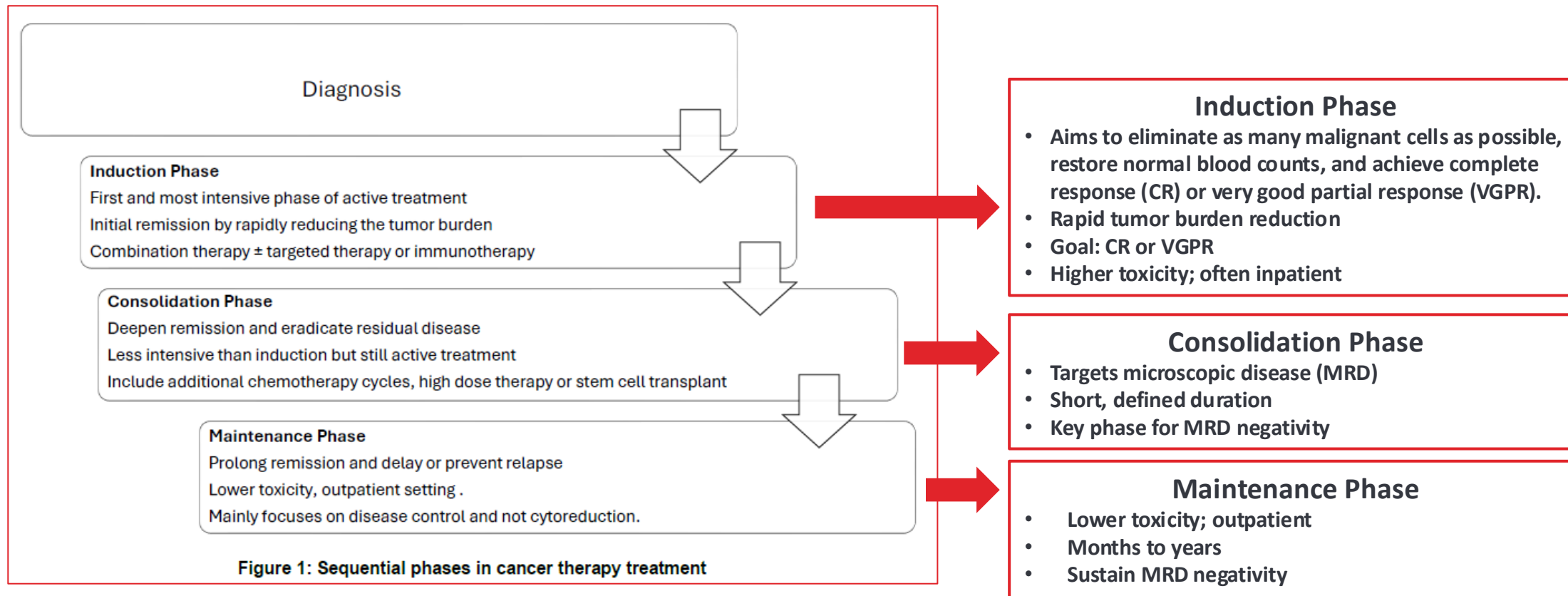


STUDYID	DOMAIN	USUBJID	GFSEQ	GFREFID	GFSPID	GFCAT	GFSCAT	GFTESTCD	GFTEST	GFTSTDTL	GFORRES	GFORRESU
AB-1001	GF	PT-1001	1	30001087	e1a2	GENETIC EXPRESSION	RAW	DETECT	Detection	e13/14a2	27564	
AB-1001	GF	PT-1001	2	30001087	e1a2	GENETIC EXPRESSION	RAW	DETECT	Detection	e1a2	37185	
AB-1001	GF	PT-1001	3	90001087	e1a2	GENETIC EXPRESSION	RAW	DETECT	Detection	e1a2	343783	
AB-1001	GF	PT-1001	4	30001087	e1a2	GENETIC EXPRESSION	RAW	DETECT	Detection	e13/14a2	1	
AB-1001	GF	PT-1001	5	30001087	e1a2	GENETIC EXPRESSION	RAW	DETECT	Detection	e1a2	127	
AB-1001	GF	PT-1001	6	90001087	e1a2	GENETIC EXPRESSION	RAW	DETECT	Detection	e1a2	208131	
AB-1001	GF	PT-1001	7	30001087	e1a2	GENETIC EXPRESSION	PERCENT	DETECT	Detection	e13/14a2	0.003624	
AB-1001	GF	PT-1001	8	30001087	e1a2	GENETIC EXPRESSION	PERCENT	DETECT	Detection	e1a2	0.337164	
AB-1001	GF	PT-1001	9	90001087	e1a2	GENETIC EXPRESSION	PERCENT	DETECT	Detection	e1a2	60.5205	
AB-1001	GF	PT-1001	10	30001087	e1a2	GENETIC EXPRESSION	PERCENT	DETECT	Detection	e13/14a2	0.00412	International Scale
AB-1001	GF	PT-1001	11	30001087	e1a2	GENETIC EXPRESSION	STATUS	MR3	Molecular	e13/14a2	Y	
AB-1001	GF	PT-1001	12	30001087	e1a2	GENETIC EXPRESSION	STATUS	MR3	Molecular	e1a2	N	
AB-1001	GF	PT-1001	13	90001087	e1a2	GENETIC EXPRESSION	STATUS	MR3	Molecular	e1a2	N	
AB-1001	GF	PT-1001	14	30001087	e1a2	GENETIC EXPRESSION	STATUS	MRD	Minimal R	e13/14a2	Y	
AB-1001	GF	PT-1001	15	30001087	e1a2	GENETIC EXPRESSION	STATUS	MRD	Minimal R	e1a2	N	
AB-1001	GF	PT-1001	16	90001087	e1a2	GENETIC EXPRESSION	STATUS	MRD	Minimal R	e1a2	N	

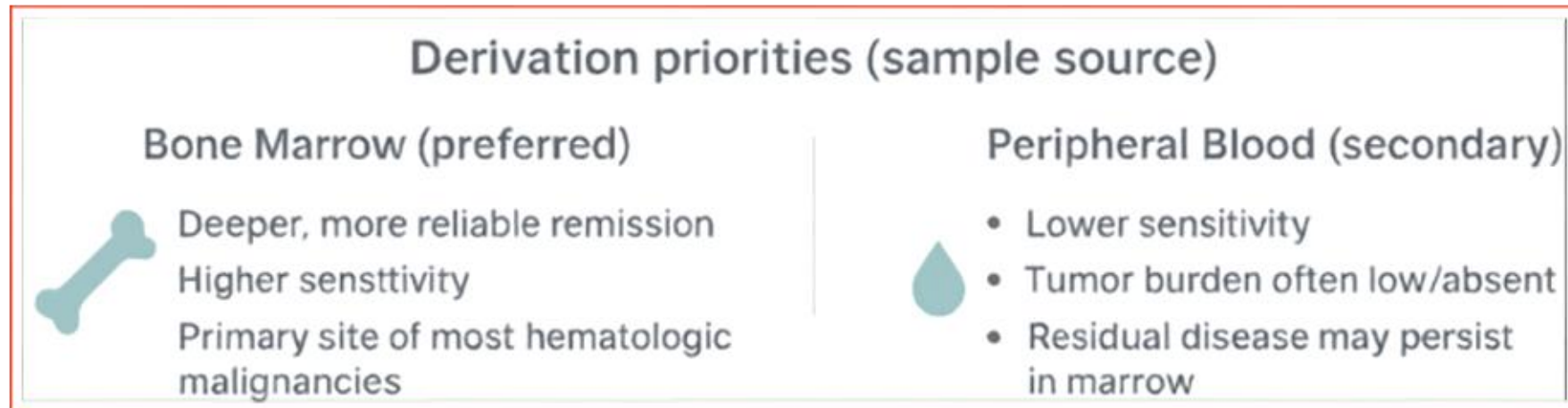
GFSTRESC	GFSTRESN	GFSTRESU	GFSTAT	GFSPEC	GFMETHOD	GFNAM	VISITNUM	VISIT	EPOCH	GFDTCT	GFDTY
27564	27564			PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
37185	37185			PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
343783	343783			BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
1	1			PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
127	127			PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
208128	208128			BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
0.0036544	0.003654			PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
0.337164	0.337164			PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
60.5205	60.5205			BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
0.00412	0.00402	International Scale		PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
Y				PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
N				PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
N				BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
Y				PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
N				PERIPHERAL BLOOD	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8
N				BONE MARROW	QUANTITATIVE REVERSE TRANSCRIPTASE POLYME	MolecularMD, OR	-1	SCREENIN	SCREENIN	2020-02-2	-8

Table 2- MRD data into GF Domain in SDTM 3.4v

INDUCTION - CONSOLIDATION - MAINTENANCE PHASES FOR ANALYSIS



- The source data and analysis of ADaM mapping for MRD data largely depends on the identification and SDTM mapping domains used.
- If the biomarker is used for efficacy endpoints as in case of ALL (Acute Lymphoblastic Leukemia), then a specialized domain following BDS structure might be handy.
- While, if the biomarker is used for surrogate endpoints as in case of Multiple myeloma, then it can be mapped to ADLB.



ADMR: Analysis Molecular Response Dataset



- **Objective**
 - Use MRD as an efficacy/response parameter implemented in ADMR (Analysis Molecular Response) for ALL (Acute Lymphoblastic Leukemia)
- **ADMR overview (analysis-ready MRD)**
 - Standardizes MRD across specimen types (bone marrow, peripheral blood)
 - Harmonizes assays (NGF, NGS, PCR, flow, ctDNA)
 - Supports binary negativity, quantitative MRD, and assay sensitivity thresholds
 - Enables timepoint-based analyses (e.g., post-induction, post-transplant)
- **Key analysis variables**
 - AVALC (categorical MRD result): Negative | Positive | Not Evaluable | Missing
 - ADT (analysis date): MRD sample collection date derived from relevant SDTM date
 - AVISIT (analysis timepoint): assigned using protocol-aligned visit windows
 - DTYPE = “DERIVED”: indicates algorithmic classification

Obs	USUBJID	ITTFL	TRT01P	PARAM	PARAMCD	AVALC	AVISIT	ADT	PFSPEC	APHASE
1	PT-101	Y	TRT A	Minimal Residual Disease	MRD	Y	Screening	27JAN2020	PERIPHERAL BLOOD	Induction Period
2	PT-101	Y	TRT A	Minimal Residual Disease	MRD	N	Screening	27JAN2020	PERIPHERAL BLOOD	Induction Period
3	PT-101	Y	TRT A	Minimal Residual Disease	MRD	N	Screening	27JAN2020	BONE MARROW	Induction Period
4	PT-101	Y	TRT A	Minimal Residual Disease	MRD	N	End of Cycle 1	02MAR2020	BONE MARROW	Induction Period
5	PT-101	Y	TRT A	Minimal Residual Disease	MRD	N	End of Cycle 2	01APR2020	PERIPHERAL BLOOD	Induction Period
6	PT-101	Y	TRT A	Minimal Residual Disease	MRD	N	End of Cycle 3	11JUN2020	PERIPHERAL BLOOD	Induction Period
7	PT-101	Y	TRT A	Minimal Residual Disease	MRD	Y	End of Cycle 3	11JUN2020	BONE MARROW	Induction Period
8	PT-101	Y	TRT A	Minimal Residual Disease	MRD	N	End of Cycle 5	03AUG2020	PERIPHERAL BLOOD	Induction Period
9	PT-101	Y	TRT A	Molecular Response at End of Induction	MOLRSREN	MR4	End of Cycle 3	11JUN2020		Induction Period

Table 3: Mapping MRD data in Analysis dataset (ADMR)

Handling Missing MRD Data

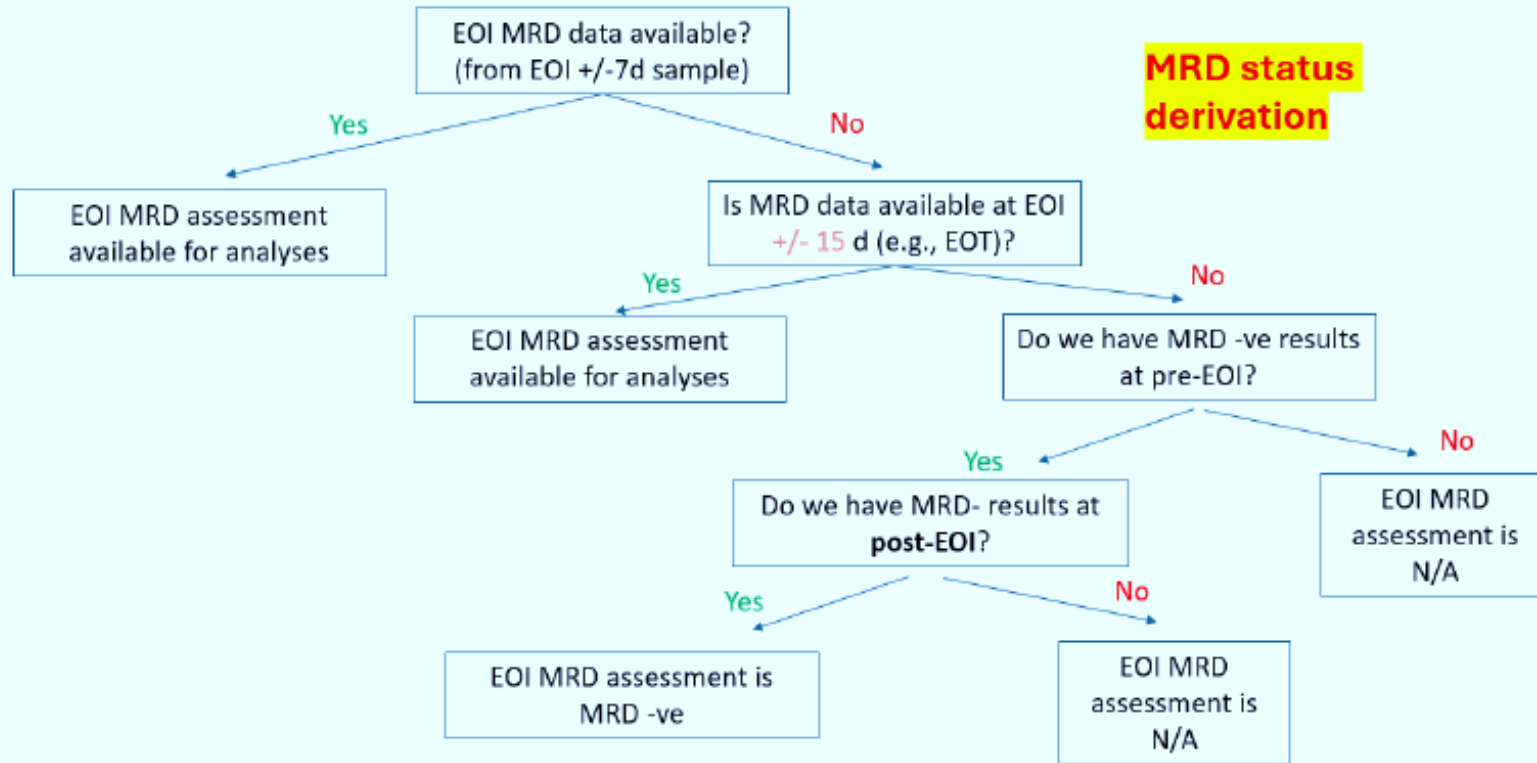


Figure 2: Flowchart logic for handling missing MRD status at End of Induction timepoint

- Missing EOI MRD is common in practice; the SAP defines pre-specified handling for these cases
- If EOI MRD is missing, the algorithm first searches for an MRD assessment within a 15-day window around EOI for response classification.
- If still unavailable, it uses pre-EOI and post-EOI MRD results; if both are MRD negative, the EOI response is derived as MRD Negative.

- If Bone marrow assessment was unavailable, then the protocol of the study allowed Peripheral Blood for the timepoint.
- If both the results were missing, then the timepoint was classified as missing. If multiple assessments are done on the same day, then the latest timestamp was used with priority of central data over local data.

Key Takeaways and Conclusion



- Measurable Residual Disease (MRD) has emerged as a regulatory-grade endpoint, particularly in hematologic malignancies, with strong correlation to long-term clinical outcomes.
- Its high sensitivity and ability to deliver earlier efficacy signals support accelerated drug development and more informed benefit–risk assessment.
- Advances in assay standardization and validation have enabled regulatory acceptance and integration of MRD as an intermediate endpoint in clinical trials.
- Continued technological innovation and real-world evidence are expected to expand MRD’s applicability, reshaping oncology trial design and expediting patient access to effective therapies.

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Conflict of Interest



The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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THANK YOU!

Q & A