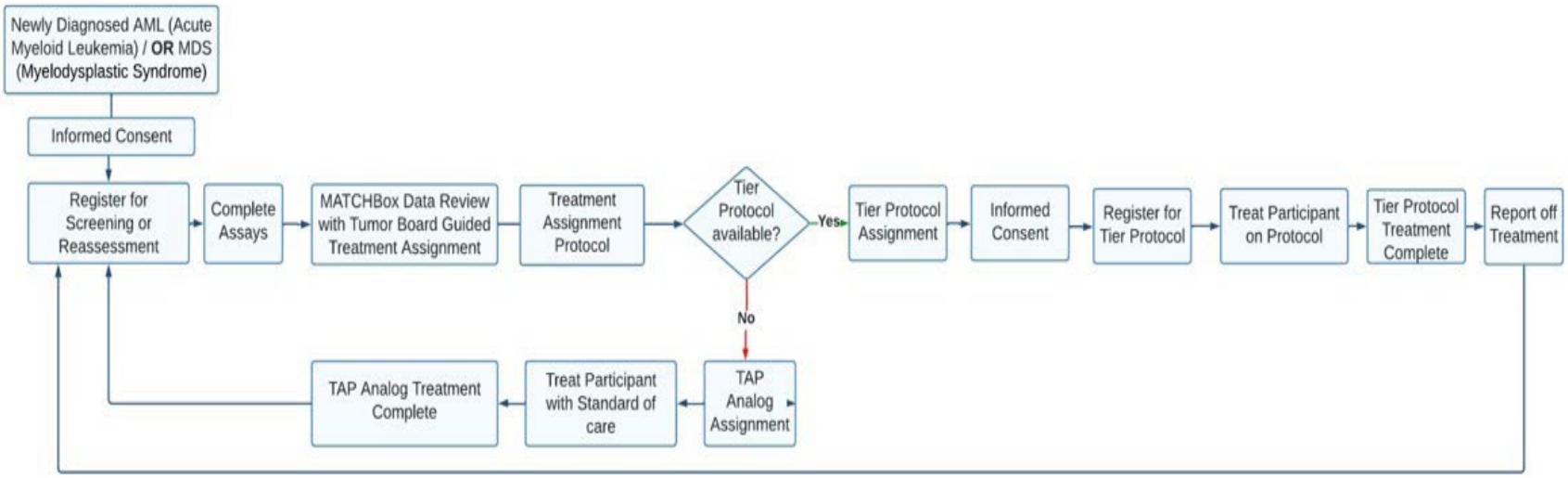
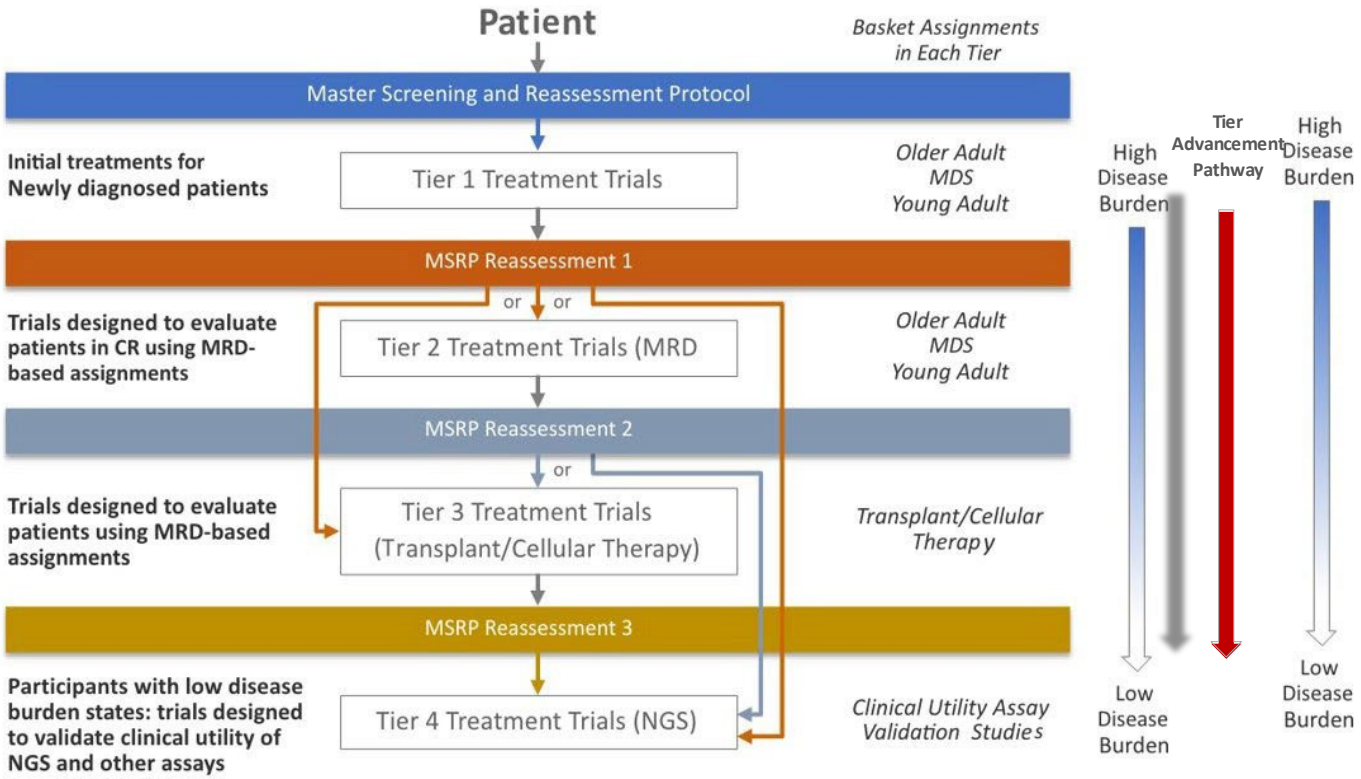
**SCHEMA**

**MyeloMATCH Treatment Options**



# myeloMATCH Screening and Treatment Substudy Schema




Legend: There are five clinical baskets within myeloMATCH, as follows: younger AML basket (18-59 years of age), older AML basket (60 years of age and older) (and unfit AML of any age), MDS basket, transplant/consolidation basket, and Duplex Sequencing (DS) basket.
The baskets are contained in tiers as shown.

Each myeloMATCH treatment substudy contains specific eligibility criteria. If a participant is found to be ineligible for the assigned myeloMATCH treatment substudy, or if the site has not opened the study that the participant was assigned to, indication of ineligibility (via the assigned study's OPEN checklist) will trigger re-evaluation and assignment to another treatment substudy or TAP.

5.1 Disease Related Criteria

a. Participants must be suspected to have previously *untreated* acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). Participants with AML cannot have a history of previously treated myeloproliferative neoplasms (MPN) or MDS.

b. Participants must be ≥ 18 years of age.

c. Participants must not have known acute promyelocytic leukemia (APL).

5.2 Prior/Concurrent Therapy Criteria

a. Participants must not have received prior anti-cancer therapy for AML or MDS.

Note: Hydroxyurea to control the white blood cell count (WBC) is allowed.

Note: Prior erythroid stimulating agent (ESA) is not considered prior therapy for the purposes of eligibility. Participants must not be currently receiving any cytarabine-containing therapy other than up to 1 g/m$^2$ of cytarabine, which is allowed for urgent cytoreduction.

b. Participants are allowed prior use of hydroxyurea, all-trans retinoic acid (ATRA), BCR-ABL directed tyrosine kinase inhibitor, erythropoiesis-stimulating agent, thrombopoietin receptor agonist and lenalidomide, with a maximum limit of 1 month of exposure.

Note: Participants receiving hydroxyurea prior to treatment substudy or TAP assignment must agree to discontinue hydroxyurea before beginning substudy or TAP treatment.

5.3 Clinical/Laboratory Criteria

a. Participants must not have a prior or concurrent malignancy that requires concurrent anti-cancer therapy.

Note: active hormonal therapy is allowed.

b. Participants must have a Zubrod Performance Status evaluation within 28 days prior to registration (See Section 10.5).

5.4 Specimen Submission Criteria

a. Participants must agree to have translational medicine specimens submitted per Section 15.2.

b. Participants must be offered the opportunity to participate in specimen banking as outlined in Section 15.3.

**Note:** Specimens must be collected and submitted following the initial paper-based process and subsequently via the Precision Medicine Specimen Tracking Forms in Medidata Rave instance for the MyeloMATCH MSRP as outlined in Section 15.4.

5.5 Regulatory Criteria

NOTE: As a part of the OPEN registration process (see Section 13.5 for OPEN access instructions) the treating institution's identity is provided in order to ensure that the current (within 365 days) date of institutional review board approval for this study has been entered in the system.

a. Participants ***must*** be informed of the investigational nature of this study and must sign and give informed consent in accordance with institutional and federal guidelines.

For participants with impaired decision-making capabilities, legally authorized representatives may sign and give informed consent on behalf of study participants in accordance with applicable federal, local, and CIRB regulations.

5.6 Site Requirement

a. The MYELOMATCH screening study must be opened at the enrolling site before participants can enroll on the treatment substudies.

b. The MYELOMATCH screening study should only be used in sites where the relevant AML treatment substudies are open or if the site is willing to follow the MSRP Tier Advancement Pathway (TAP) for patients in the event that the site does not have the relevant study open and transfer to another site that does have the study open. For example, if a site does not have a myeloMATCH Tier 1 study for older AML open for enrollment, such older AML patients should only be consented for the MSRP if the site is willing to treat the patient with standard of care on TAP or is willing to transfer the patient to a center with a study open that the patient would otherwise match to.