Towards Preanalytical Best Practices for Liquid Biopsy Studies: A BLOODPAC Landscape Analysis

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BLOODPAC is a public-private consortium that develops best practices, coordinates clinical and translational research, and manages the BLOODPAC Data Commons to broadly support the liquid biopsy community and accelerate regulatory review to aid patient accessibility. BLOODPAC previously recommended 11 preanalytical minimal technical data elements (MTDEs) for BLOODPAC-sponsored studies and data submitted to BLOODPAC Data Commons. The current landscape analysis evaluates the overlap of the BLOODPAC MTDEs with current best practices, guidelines, and standards documents related to clinical and research liquid biopsy applications. Our findings indicate an existing high degree of concordance among these documents. Where differences exist, the BLOODPAC preanalytical MTDEs can be considered a minimal practicable set for organizations to utilize. These MTDEs were developed following extensive examination of best practices and iterative conversations with the U.S. FDA. BLOODPAC recommends the use of these MTDEs in submissions to data commons and to support liquid biopsy clinical trials and research globally.

BLOODPAC is a public-private consortium that develops best practices, coordinates clinical, and translational research, and manages the BLOODPAC Data Commons to support the liquid biopsy research community. BLOODPAC previously recommended 11 preanalytical Minimal Technical Data Elements (MTDEs) for BLOODPAC-sponsored studies and data submitted to BLOODPAC Data Commons (**Figure 1**). The current landscape analysis evaluates the overlap of the MTDEs with 10 current best practices and standards documents related to clinical and research liquid biopsy applications.

BACKGROUND

Liquid biopsy refers to a broad group of minimally invasive tests performed on blood or other body fluids that provide molecular or cellular information. Diverse potential clinical applications of liquid biopsy assays can inform medical decisions and improve the care of patients with cancer; however, further studies are required to evaluate the analytical and clinical validity and utility of many of these applications.[1]

BLOODPAC is a public-private consortium of industry, academic, non-profit, and federal agency stakeholders with a common goal to accelerate regulatory approval and clinical implementation of novel blood-based tests for cancer within the framework of precision medicine. Central to this effort has been the development of coordinated approaches and common infrastructure for pre-competitive and post-publication data sharing. Over 60 current BLOODPAC collaborators contribute to mutually agreed-upon definitions, common approaches to data submission, collaborative efforts to fill knowledge and data gaps, and deposition of data into the BLOODPAC Data Commons. The BLOODPAC Data Commons[2] is a cloud-based data platform with rules-based access that makes data findable, attributable, interoperable, and reusable (FAIR).[3]

The BLOODPAC Preanalytical Working Group coordinated the development of 11 minimum technical (preanalytical) data elements (MTDEs) for any data submitted to the Data Commons.[4] This development process was guided by initial analysis of data submitted to the BLOODPAC Data Commons and leveraged

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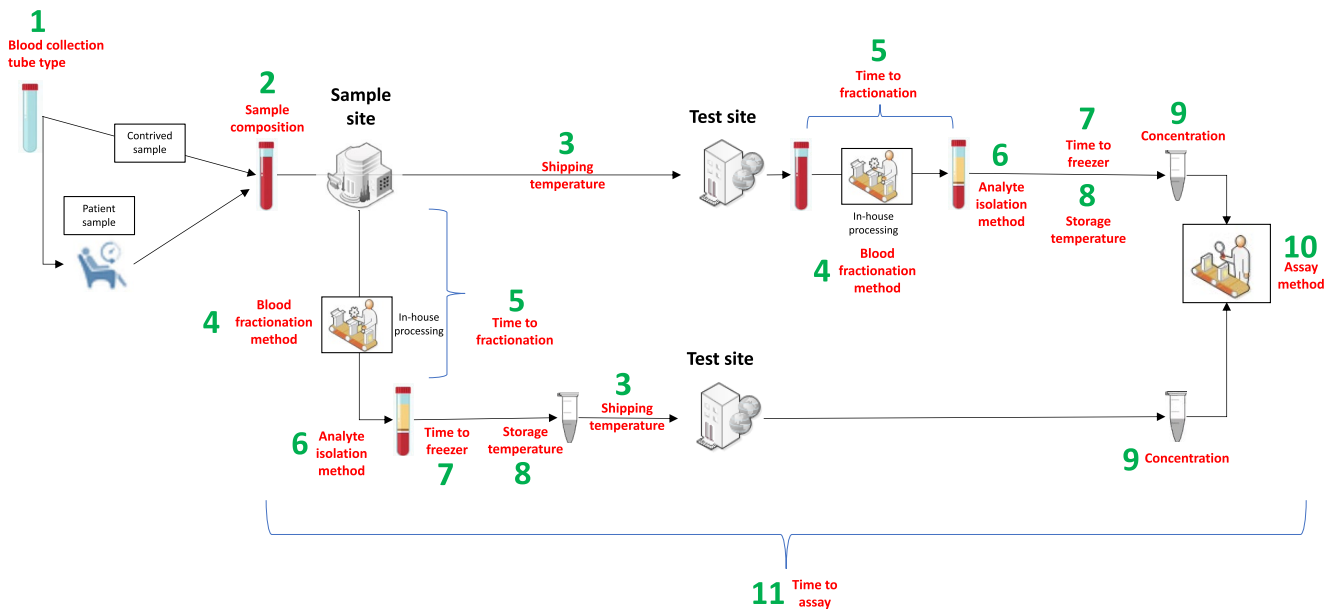

Figure 1 BLOODPAC preanalytical minimal technical data elements (MTDEs). Figure is adapted from Febbo *et al*.[4]

input from the diverse BLOODPAC membership in collaboration with the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) and the College of American Pathologists (CAP) Preanalytics for Precision Medicine Project team. This work was based on the first principle that preanalytical variables can significantly influence liquid biopsy assay performance and results. The 11 preanalytical MTDEs allow the diverse BLOODPAC membership—including test developers, translational researchers, pharmaceutical partners, and clinicians—to collect and report critical standardized preanalytical data for BLOODPAC-sponsored studies and other liquid biopsy data submitted to the BLOODPAC Data Commons. Importantly, these MTDEs are freely accessible and available to the broader community, and we recommend broad adoption of the MTDEs by the community engaged in liquid biopsy assay development.

In an ongoing effort to apply this work, the BLOODPAC Recommended Data Elements (RDE) Working Group performed a landscape analysis to evaluate the extent to which the preanalytical MTDEs previously recommended by BLOODPAC overlap with published best practices and standards documents related to clinical and research liquid biopsy applications. A point-by-point comparison was performed to identify similarities and differences across the recommendations and requirements in these documents. The current landscape compares the BLOODPAC MTDEs with 10 documents with varying degrees of specificity, often written with different goals. This analysis demonstrates that most data elements discussed are universally recognized as important; however, this manuscript illustrates an unmet need for global preanalytical data elements that are consensus-based, publicly available, and readily accessible for liquid biopsy assay development.

BLOODPAC'S PROCESS FOR LANDSCAPE ANALYSIS

In 2020, following the publication of the 11 preanalytical MTDEs, the BLOODPAC RDE Working Group initiated this landscape review project. This process included solicitation of representatives from groups that had published evidence-based best practice recommendations and standards that included discussion of preanalytical variables in liquid biopsy assays. Through BLOODPAC meeting presentations and Consortium-wide communications, the RDE Working Group queried the BLOODPAC Consortium to identify other potential source documents. These documents included standards from regulatory agencies that certify or accredit laboratories performing clinical testing.

Documents evaluated were divided into four categories: standards, guidelines, evidence-based best practice recommendations, and expert experience-based opinions (**Table 1**).[5–7] We excluded expert experience-based opinions in this analysis due to the emerging nature of these documents. The 10 evaluated documents were classified as either standards or evidence-based best practice recommendations; no guidelines within this topic area were identified.

Each document was independently evaluated by two subject-matter experts to determine whether each of the 11 preanalytical MTDEs was recommended or required by the document. Some documents focused on circulating, cell-free DNA (cfDNA) applications, including the ASCO/CAP Joint Review,[8] ESMO Recommendations,[1] ISO 20186-3:2019,[9] NCI Biospecimen Evidence-Based Practices,[10] and AMP Recommendations.[11] Other documents were focused on general clinical or biobanking practices and did not necessarily include any specific cfDNA or liquid biopsy recommendations. Especially in the latter documents, the subject-matter expert determined if the preanalytical MTDEs might be reasonably inferred to apply to liquid biopsy applications. Once primary data extraction was complete, the MTDEs were discussed and finalized by full committee and consortium consensus agreement.

LANDSCAPE ANALYSIS

The review for inclusion of the 11 MTDEs in the 10 standards and evidence-based best practice recommendations documents

Table 1 Overview of MTDEs and definitions used in the article

	Definition	Documents selected for review
Standards	Enforceable licensure, accreditation, or certification requirements from regulatory agencies and bodies. These are rules and regulations that must be followed	CAP clinical requirements CAP biorepository requirements ISO 20186-3:2019 Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Guidelines	High-quality, evidence-based documents adhering to rigorous methodological quality standards that have been established by inter-society and government agency consensus. The Institute of Medicine defines clinical practice guidelines as "statements that include recommendations, intended to optimize patient care, that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options"	None were identified during the review process
Benchmarks, recommendations, best practices	Evidence-based and consensus expert opinions from specialty professional societies, policy makers, regulatory agencies, and other stakeholders/organizations. These recommendations are strong suggestions and may be based on a systematic review that does not necessarily adhere to guideline standards. These typically precede development of guidelines when the scientific evidence base is still being established.	BLOODPAC MTDEs AMP Recommendations ASCO/CAP Joint Review CLSI MM13 ESMO Recommendations ISBER Recommendations NCI Biospecimen Evidence-based practices
Expert experience-based opinions, task force	Expert opinions and/or opinions from professional societies and organizations, group meetings, and/or conferences. These may serve as a state of the science, gap analysis, and/or be intended to prompt hypothesis-testable research. These are developing criteria, often experience-based, and may include conference proceedings. These documents are less fully developed/mature documents than those created from systematic evidence review of the literature	Excluded from the review process as the strength of recommendations is not as robust

is summarized in **Figure 2**. The MTDEs were developed as recommendations for BLOODPAC-sponsored studies and for liquid biopsy data to be submitted to the BLOODPAC Data Commons and other public databases.[4] The 10 documents reviewed for this landscape analysis were generally written for different intended audiences and purposes than the MTDEs, and therefore placed different emphasis on preanalytical discussions. The ASCO/CAP Joint Review,[8] ESMO Recommendations,[1] and AMP Recommendations[11] focused on clinical applications of cfDNA assays in patients with cancer. The AMP Recommendations, CAP Molecular Pathology and All Common Checklists, CLIA Standards, CLSI MM13, and ISO 20186-3:2019 are focused on recommendations and requirements for clinical laboratories. The CAP Biorepository Checklist, ISBER Recommendations,[12] and NCI Biospecimen Evidence-Based Practices[10] are focused on biospecimen processing for research and some clinical settings.

Despite the different intended audiences and purposes of the evaluated comparator documents, our review revealed that the MTDEs were very consistent across the 10 documents. Of the 11 preanalytical MTDEs, each document was determined to be consistent with 9–11 MTDEs. In most instances, a data element that was not covered in a document was related to a topic that was clearly outside of the scope primarily addressed by the document. For example, the ISO 20186-3:2019 document is focused on isolation of cfDNA from plasma; hence data elements related to Assay Method and Time to Assay were not directly addressed in this document. We cannot exclude that these data elements are covered in other ISO documents. Importantly, no document made recommendations or proposed requirements that were inconsistent with any of the MTDEs.

Each of the MTDEs was supported by most of the examined documents. Nine of the 11 MTDEs were supported by all examined documents. As discussed above, the Assay Method data element was supported by nine of the 10 examined documents. Given the variability in available liquid biopsy assays and associated performance, the Working Group reiterates that this is a critical data element to interpret liquid biopsy data. Finally, the Time to Assay data element was supported by six of the 10 examined documents. This data element is likewise critical for the interpretation of clinical trials and related studies where specimens may not undergo immediate testing. As discussed above, the discrepancy with including the Assay Method and Time to Assay data elements by the examined documents appears to be due, at least in part, to document scope. All data elements will be monitored prospectively in data submitted to the BLOODPAC Data Commons to assess whether any data element modification is warranted.

In summary, the current landscape analysis indicates that the 11 preanalytical MTDEs established by BLOODPAC are typically included in current standards and evidence-based best practice recommendations that would be used for liquid biopsy assays. This analysis therefore provides further support for the validity of these data elements, and moreover, highlights areas for consideration when updating existing documents and the BLOODPAC preanalytical MTDEs.

TOWARDS STANDARDIZATION

On behalf of the BLOODPAC community, this landscape analysis demonstrates a high degree of concordance among current standards and best practice documents related to clinical and

Data Element	BLOODPAC Data Model Element	Description	BLOODPAC	ASCO/CAP Joint Review (2018)	CAP Molecular Pathology and All Common Checklists (2022)	CAP Biorepository Checklist (2022)	ISO 20186-3:2019	CLIA Standards	ISBER Best Practices (2018)	ESMO Recommendations (2022)	NCI Biospecimen Evidence-Based Practices (2020)	CLSI MM13 (2020)	AMP Recommendations (2023)	How many of the documents were in agreement.
Blood Collecton Tube	blood_tube_type	The kind of tube used to collect the sample(s) taken from a biological entity for testing, diagnostic, propagation, treatment, or research purposes.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Sample Composition	Composition	Sample type describing the cellular composition of the sample, as specified from a controlled vocabulary, containing clinical, contrived, and other terms.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Shipping Temperature	shipping_temperature	The temperature, in centigrade, at which the biospecimen was kept while it was being transported from the procurement site to its processing destination.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Blood Fractionalization Method	blood_fractionation_method	The name or description of the method used to obtain the blood fraction sample. (e.g., Ficoll Method, Novartis Protocol #001, 2,000 g centrifuge at 4°C with gentle deceleration). Alternatively, if you have provided a detailed protocol, enter its file_name here.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Time to Fractionation	hours_to_fractionation_upper, hours_to_fractionation_lower	The upper/lower limit on the amount of time, in hours, between the blood draw and the fractionation into its components. If the exact time is known, make this value equal to that of the lower limit. If the time is completely unknown, enter Unknown. If no fractionation was performed on this sample, enter Not Applicable.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Analyte Isolation Method	analyte_isolation_method	The name or general description of the method used to isolate the analyte. Alternatively, if you have provided a protocol, put the file_name here	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Time to Freezer	hours_to_freezer_upper, hours_to_freezer_lower	The upper/lower limit on the amount of time, in hours, that it took between the sample being fractionated and the aliquot being frozen or otherwise preserved. If the exact time is known, make this value equal to that of the lower limit. If the time is completely unknown, enter Unknown. If no fractionation was performed on this sample, enter Not Applicable.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Storage Temperature	storage_temperature	The temperature, in centigrade, at which the aliquot was preserved and/or stored.	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Concentration: Cellular Concentration or Molecular Concentration	molecular_concentration or cellular_concentration	If the analyte is a molecule (e.g., DNA or RNA), report the observed concentration in nanograms per microliter (for molecular concentration). If the measurement is a cell count, then this is reported as cells per microliter (cellular_concentration)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	10
Assay Method	assay_method	General name or description of the method used to characterize the analyte.	✓	✓	✓	✓	--	✓	✓	✓	✓	✓	✓	9
Time to Assay	days_to_assay	The amount of time, in days, between the date used for index and the assay used to address this analyte.	✓	--	✓	--	--	✓	✓	--	✓	✓	✓	6
How many of the MTDEs were in document.			11	10	11	10	9	11	11	10	11	11	11	

KEY

✓ Directly mentioned or inferred

-- Not mentioned, not applicable or not covered

Figure 2 Visual cross-comparison of BLOODPAC MTDEs with 10 current best practices and standards documents related to clinical and research liquid biopsy applications.

research liquid biopsy applications. This indicates it is feasible to comply with recommendations and requirements from multiple organizations simultaneously. Where differences exist, especially within the research community involved in liquid biopsy assay development, BLOODPAC urges synchronization and universal employment of the BLOODPAC preanalytical MTDEs. These data elements have been distilled to a minimum practicable set following extensive examination of best practices and iterative conversations with the U.S. FDA. The benefits of standardization include improved quality, efficiency, process transparency, and clarity for regulators about liquid biopsy assay performance and safety, without interference from procedural artifact.

Several documents reviewed herein are proprietary and therefore not readily available, particularly within the research community involved in liquid biopsy assay development. The ultimate benefit of standardized preanalytical practices for liquid biopsies will not be realized until a universal standard set is accepted globally and enforced throughout the biomedical research community. The current landscape analysis also suggests that most of the BLOODPAC preanalytical MTDEs are supported by clinical laboratory standards. This indicates that widespread implementation of MTDEs as benchmarks across both research and clinical domains is possible. As a consortium working towards standardization, BLOODPAC will quantify compliance with the inclusion of the 11 preanalytical MTDEs for all BLOODPAC Data Commons submissions. Given the diverse BLOODPAC membership, which includes both public and private institutions, this effort provides a model for expanded synchronization and standards.

These standardization efforts offer the immediate ability of all stakeholders to share data of uniform type, quality, and completeness, collected under a set of preanalytical specifications that represents a consensus and use-specific refinement of existing requirements and recommendations. Through the BLOODPAC Data Commons, the searchable data repository maintained and quality-controlled by the organization, data can be shared and analyzed across the liquid biopsy community. The Data Commons allows BLOODPAC to support the integration and interpretation of liquid biopsy data, thereby accelerating the application of liquid biopsies to patient care.

NEXT STEPS

The initial development of the preanalytical MTDEs by the BLOODPAC Consortium brought together pharmaceutical and diagnostic companies, regulatory and accreditation agencies, academic groups, and other organizations. This diverse group, which at times had heterogeneous practices within a single

organization, agreed upon 11 preanalytical standards for liquid biopsy biospecimens. The current landscape analysis reinforces that these elements already have broad adoption across current standards or evidence-based best practice recommendations from independent groups. Continued harmonization efforts can build upon this existing work to provide standardized datasets to facilitate regulatory review, reduce the time to bring meritorious products to market, and ultimately improve the care of patients with cancer.

From the outset, BLOODPAC recognized the overarching and central importance of standardization to maximize partner coordination, process efficiency, and the highest output quality. BLOODPAC itself, however, is not a standards-setting organization nor one with supervisory authority. Instead, it seeks to promote routine and universal use of best-in-class, evidence-based, expert-endorsed recommendations and best practices developed by authoritative bodies and supplemented specifically for liquid biopsy use by the BLOODPAC Consortium of multi-disciplinary thought leaders. Its goal is to harmonize the efforts of liquid biopsy developers, investigators, and users worldwide. To achieve this goal, we continue to work with regulatory and other standard-setting organizations to further promote the BLOODPAC MTDEs in formal standards, guidelines, and best practice documents.

BLOODPAC also recognizes that standardization of preanalytical data elements is only the necessary first step in streamlining and accelerating regulatory approval and clinical implementation of novel blood-based tests for cancer with evidence supporting analytical and clinical validity. Ongoing projects at BLOODPAC also focus on defining analytical variables and patient context variables, both of which are necessary to support clinical validation studies. Likewise, we recognize that this is a rapidly evolving field, requiring ongoing evaluation of BLOODPAC's projects. Our large, public-private consortium with diverse stakeholders is well-positioned to accomplish these tasks. BLOODPAC looks forward to working with the larger liquid biopsy community to support the clinical implementation of novel blood-based tests for cancer that are already improving the care and survival of patients with cancer.

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CONFLICT OF INTEREST

The authors declared no competing interests for this work.

DISCLOSURES

The work described here was done through the BLOODPAC Consortium, which is a not-for-profit consortium consisting of members from industry, academia, not-for-profits, and the U.S. government agencies, including companies that sell liquid biopsy assays, companies that use liquid biopsy assays as companion diagnostics, organizations that do research related to liquid biopsies, organizations that conduct clinical trials involving liquid biopsies, and agencies that develop policies and procedures related to liquid biopsies. In addition, some of the authors are employed by companies in the liquid biopsy field, employed by companies that have projects and partnerships with liquid biopsy companies, have stock in companies in the liquid biopsy field, or consult with companies in the liquid biopsy field. The authors worked together collaboratively to develop this analysis of data elements for the liquid biopsy field as a whole and the authors do not have any particular or specific conflict with the work described in this paper, beyond those just enumerated. In addition, the reference standards CLSI MM13 and ISO 20186-3:2019 were purchased by BLOODPAC for review in this analysis.

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