

example, the analyzing comprises the determination of at least one clinical decision. Such clinical decision, in one example, includes determining disease prognosis, predicting recurrence of disease, predicting targets of therapy of disease, inclusion of subjects of clinical trials, or therapeutic treatment strategy for at least one subject.

In one aspect, the present disclosure provides a method of determining a prognosis of a cancer in a subject, comprising assessing representative data from a subject, wherein the representative data comprises an identification of one or more low-prevalence subclones at 20% prevalence or less, wherein the representative data are generated in a method comprising analyzing a homogenate composition derived from one or more fixed surgical resection tissue samples and/or one or more fixed residual surgical tissue samples by means of shearing, wherein the one or more fixed surgical resection tissue samples and/or one or more fixed residual surgical tissue samples are from a tumor of the subject and are not formalin-fixed and paraffin embedded (FFPE), wherein any heterogeneity of cells within the obtained one or more fixed surgical resection tissue samples and/or the one or more fixed residual surgical tissue samples is substantially uniformly distributed within the homogenate composition, and wherein any aliquot removed from the homogenate composition comprises one or more populations of cellular structures at a proportion at which they existed within the one or more fixed surgical resection tissue samples and/or the one or more fixed residual surgical tissue samples, wherein the analyzing comprises generating quantitative and/or qualitative data for one or more markers in one or more aliquots of the homogenate composition, wherein the quantitative data and/or the qualitative data is generated from (i) immunocytochemically staining the cellular structures within at least a first aliquot of the homogenate composition; (ii) flow cytometry analysis within at least a first aliquot of the homogenate composition; or sequencing genomic material derived from cellular structures within at least a first aliquot of the homogenate composition.

WHAT IS CLAIMED IS:

1. A method of determining a prognosis of a cancer in a subject, comprising assessing representative data from a subject, wherein the representative data comprises an identification of one or more low-prevalence subclones at 20% prevalence or less,
5 wherein the representative data are generated in a method comprising analyzing a homogenate composition derived from one or more fixed surgical resection tissue samples and/or one or more fixed residual surgical tissue samples by means of shearing, wherein the one or more fixed surgical resection tissue samples and/or one or more fixed residual surgical tissue samples are from a tumor of the subject and are not formalin-fixed and paraffin embedded (FFPE), wherein any heterogeneity of cells
10 within the obtained one or more fixed surgical resection tissue samples and/or the one or more fixed residual surgical tissue samples is substantially uniformly distributed within the homogenate composition, and wherein any aliquot removed from the homogenate composition comprises one or more populations of cellular structures at a proportion at which they existed within the one or more fixed surgical resection tissue
15 samples and/or the one or more fixed residual surgical tissue samples, wherein the analyzing comprises generating quantitative and/or qualitative data for one or more markers in one or more aliquots of the homogenate composition, wherein the quantitative data and/or the qualitative data is generated from (i)
20 immunocytochemically staining the cellular structures within at least a first aliquot of the homogenate composition; (ii) flow cytometry analysis within at least a first aliquot of the homogenate composition; or sequencing genomic material derived from cellular structures within at least a first aliquot of the homogenate composition.
- 25 2. The method of claim 1, wherein the one or more markers comprise a DNA, a protein, an RNA, a lipid, a cell organelle, a metabolite, or a cell.
3. The method of claim 1, further comprising comparing the representative data to a predetermined value for the data.

4. The method of claim 3, wherein the predetermined value is selected from clinical trial data, a data for a subject, a data from scientific literature, a data for a biologic or small molecule under clinical development.

5. The method of claim 1, wherein the representative data comprises a representative oncology data, wherein the representative oncology data comprises quantitative and/or qualitative data of at least one tumor marker from a first biological sample, said tumor marker is associated with the presence of a tumor, the method further comprising:

- a. measuring the tumor marker in the first biological sample, wherein the measured values of the tumor marker is normalized;
- b. obtaining a composite score based on the normalized measured value; and
- c. comparing the composite score to a predetermined score to determine a cancer risk value of the subject.

6. The method of claim 1, wherein the cellular structures comprise a cell cluster, an individual cell, a fragment of a cell, an organelle, a peptide, a nucleic acid, a lipid, a metabolite, or a combination thereof.

7. The method of claim 6, wherein the homogenate composition comprises up to 25%, up to 50%, up to 75% or up to 100% of the cellular structures from the obtained one or more fixed surgical resection tissue samples and/or the one or more fixed residual surgical tissue samples.

8. The method of claim 6, wherein the homogenate composition comprises 100% of the cellular structures from the obtained one or more fixed surgical resection tissue samples and/or the one or more fixed residual surgical tissue samples.

9. The method of any one of claims 6 to 8, wherein the homogenate further comprises one or more of a non-human cell, a human cell, a non-native protein, a nucleic acids, or a small molecule, a dye, a virus, a bacterium, a parasite, protozoan, or a chemical.

10. The method of claim 9, wherein the small molecule comprises a hapten, a peptide tag, a protein tag, a fluorescent tag, a nucleic acid tag, and combination thereof.

5 11. The method of claim 1, further comprising calculating a quantitative score for the prognosis of the cancer, wherein the prognosis is classified based on the quantitative score.

12. The method of claim 1, wherein the representative data comprises information about
10 number, types, states, and/or percentage of the cellular structures in the homogenate.

13. The method of claim 12, wherein the cellular structures comprise stem cells, epithelial cells, blood cells, fat cells, skin cells, endothelial cells, cancer cells, or immune cells.

15 14. The method of claim 13, wherein the immune cells comprises neutrophils, monocytes, macrophages, dendritic cells, natural killer cells, T-cells, and/or B-cells,

15. The method of claim 14, wherein the T-cells comprise killer T cells, helper T cells, regulatory T cells, pan T cells, naïve T cells, activated T cells, and/or gamma delta T-
20 cells.

16. The method of claim 12, wherein the states of cellular structures comprise proliferation, apoptosis, necrosis, migration, epithelial-mesenchymal transition (“EMT”), mitosis, cell cycle arrest, S-phase, senescence, and/or differentiation.
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17. The method of claim 1, wherein the representative data comprises information about a marker in the homogenate composition.

18. The method of claim 17, wherein the marker is selected from the group of a DNA, a protein, an RNA, a lipid, a cell organelle, a metabolite, or a cell.
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19. The method of claim 17, wherein the marker comprises one or more of Alpha-fetoprotein, Alpha-methyl acyl-CoA racemase, Calcitonin, Carcinoembryonic antigen, Carcinoembryonic antigen peptide-1, Des-gamma carboxy prothrombin, Desmin, Early prostate cancer antigen-2, Estrogen receptor, Fibrin degradation product, Glucose-6-phosphate isomerase, Human chorionic gonadotropin, Keratin 19, Lactate dehydrogenase, Leucyl aminopeptidase, Lipotropin, Metanephrines, Neprilysin, Normetanephrine, Prostate-specific antigen, Prostatic acid phosphatase, Synaptophysin, Thyroglobulin, a transcription factor selected from Tumor associated glycoprotein 72, Vimentin, and the combination thereof.
20. The method of claim 17, wherein the marker is selected from the group of: a protein modification, said modification is selected from a group consisting of acetylation, ADP-ribosylation, acylation, ADP-ribosylation, amidation, covalent attachment of a flavin, covalent attachment of a heme, covalent attachment of phosphatidylinositol, cross-linking, cyclization, disulfide bond formation, demethylation, formation of covalent cross-links, formation of cystine, formation of pyroglutamate, formylation, gamma-carboxylation, glycosylation, GPI anchor formation, hydroxylation, iodination, methylation, myristoylation, oxidation, proteolytic processing, phosphorylation, prenylation, racemization, selenoylation, sulfation, arginylation, and ubiquitination.
21. The method of claim 17, wherein the marker is selected from the group of: a genomic polymorphism, a pharmacogenomics single nucleotide polymorphism (SNP), a genomic SNP, a somatic polymorphism, and differential expression of a protein, a lipid, and/or a cellular organelle, a single nucleotide position; an intragenic region or an intergenic region; an exon or an intron; a coding region or a non-coding region; a promoter, an enhancer, a 5' untranslated region (5' UTR), or a 3' untranslated region (3' UTR); a cDNA; an SNP; a somatic mutation, a germ line mutation or both; a point or a single mutation; a deletion mutation; an in-frame deletion, an intragenic deletion, a full gene deletion; an insertion mutation; an intragenic insertion; an inversion mutation; an intra-chromosomal inversion; a linking mutation; a linked insertion

mutation; an inverted duplication mutation; a tandem duplication; an intrachromosomal tandem duplication; a translocation; a chromosomal translocation, a non-reciprocal translocation; a rearrangement; a genomic rearrangement; a rearrangement of one or more introns; a rearranged intron; a 5'- or a 3'-UTR, an altered nucleotide sequence, encodes an altered amino acid sequence, a chromosomal translocation, an intra-chromosomal inversion, a change in copy number, a change in expression level, a change in protein level, a change in protein activity, or a change in methylation status, in a cancer tissue or cancer cell, as compared to a normal, healthy tissue or cell.

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- 10 22. The method of claim 1, wherein the sequencing comprises next generation sequencing, single cell sequencing, or single nucleus sequencing.