EVALUATING POTENTIAL APPLICATIONS OF ILLUMINA TruSight™ Oncology 500 (NGS) ASSAYS

Request for Proposals, February 2022 (RFPONC2022)

Background

Illumina has launched globally the **TruSight™ Oncology 500 (TSO 500) tissue and circulating tumor DNA (ctDNA) assays**, which are for Research Use Only (RUO) and not for use in diagnostic procedures. These next-generation sequencing (NGS) assay kits are available for oncology research:

- The TSO 500 NGS assays enable in-house, pan-cancer comprehensive genomic profiling of tumor samples from FFPE tissues and plasma. TSO 500 contains DNA + RNA assay targeting 523 genes for assessment of all DNA and RNA variant types (TSO 500 ctDNA assay is a DNA only test). It supports identification of all relevant DNA and RNA variants implicated in various solid tumor types. In addition, it accurately measures key current immuno-oncology biomarkers: microsatellite instability (MSI) and tumor mutational burden (TMB).

This request for proposal (RFP) solicits investigator sponsored clinical research projects to evaluate potential applications of the TSO 500 tissue and ctDNA assays in North America and Asia Pacific Japan regions. Proposals should be focused on solid tumors, including lung, breast, colorectal, prostate, bladder, head-neck, gastric-esophageal, and cancers of unknown primary (CUP). Both retrospective and prospective studies will be considered.

This call for proposals seeks studies to assess:

1. The potential clinical utilities of decentralized comprehensive genomic profiling (CGP) of tumor tissue and liquid biopsy samples in localized and advanced stage cancers.
2. The potential improvement in diagnostic yield by testing tumor tissue and ctDNA simultaneously or sequentially (concordance between tumor tissue and plasma can be part of the study).
3. The detection of splice variant, gene fusion and signature biomarker, such as TMB, MSI, in tumor tissue and plasma.

We seek proposals that:

- Demonstrate the advantage of in-house (decentralized) CGP testing vs test-send-out for tumor tissue or ctDNA analysis or both.
- Exhibit the utility of liquid biopsy (e.g. faster turn-around time and time to therapy) in certain patient populations and disease indications, such as tumor accessibility or patient unfit for biopsy, limited tumor biopsy sample, and bone only metastasis (Studies that indicate the concordance or the reflex nature of tissue/liquid CGP assays in major cancer type).
- Establish the incremental benefit of tumor tissue testing in conjunction with liquid biopsy.
- Illustrate the benefit of splice variant and fusion gene detection with DNA + RNA workflow and gene signature biomarker identification with the large and comprehensive NGS panel.

We will not consider funding for:

- Studies that focus on cancer screening or disease monitoring using circulating DNA
- Studies that are in the hematological malignancy space

Timeline:

- Proposals are due by April 15th and/or September 15th.
- Proposals can be submitted immediately and will be evaluated on a rolling basis.
- Proposals will be reviewed by Illumina internal experts and be evaluated based on the scientific merits of the proposals, and a decision will be made by May 15th or October 15th, 2022.
- Study protocol is required at the time of contracting for accepted proposal

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Funding Requests:

In Scope	***Out of Scope***
TSO 500 kits and sequencing reagents	Overhead cost
Study cohorts are properly powered for the objectives	Resources to support activities related to the study such as sample collection, data collection, and data analysis.
Have the expertise of running NGS assays (with equipment such as Covaris E220evolution, LE220, or ME220)	Core funding for research, lab and clinical personnel participating in the study.
Proposals will be evaluated relative to similar activities in other regions and geographies. TSO 500 kits and sequencing reagent will be provided in kind relative to value.	

To Apply: Please submit the attached Study Proposal Template and email to iResearch@illumina.com:

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TruSight™ Oncology 500 tissue and ctDNA assay description

TruSight™ Oncology 500 (TSO 500) is a next-generation sequencing (NGS) assay that enables in-house comprehensive genomic profiling of tumor samples. It supports identification of all relevant DNA and RNA variants implicated in various solid tumor types. In addition, it accurately measures key current immuno-oncology biomarkers: microsatellite instability (MSI) and tumor mutational burden (TMB).

TSO 500 has pan-cancer biomarker content aligned with key guidelines and clinical trials, and the DNA + RNA assay targeting 523 genes for assessment of all DNA and RNA variant types, plus MSI and TMB.

TruSight™ Oncology ctDNA is a pan-cancer next-generation sequencing (NGS) assay that enables in-house comprehensive genomic profiling (CGP) from blood plasma.

The broad panel is designed with similar DNA content as its tissue counterparts (TruSight™ Oncology 500 and TruSight™ Oncology 500 High-Throughput), it detects SNVs, Indels, CNVs, fusion, and key immuno-oncology (IO) biomarkers.

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TruSight™ Oncology 500 tissue and ctDNA assay Gene List

Small Variants

- ABL1
- ABL2
- ACVR1
- ACVR1B
- ALOX12B
- ANKRD11
- ANKRD26
- ARAF
- ARFRP1
- ARID1B
- ARID2
- ARID5B
- ASXL1
- ASXL2
- ATRX
- AURKA
- AURKB
- AXIN1
- AXIN2
- AXL
- B2M
- BBC3
- BCL10
- BCL2L1
- BCL2L11
- BCL2L2
- BCOR
- BCORL1
- BCR
- BIRC3
- BLM
- BMPR1A
- BRD4
- BTG1
- C11orf30
- CALR
- CASP8
- CBFB
- CBL
- CD274
- CD276
- CD74
- CDC73
- CDK8
- CDKN1A
- CDKN1B
- CDKN2B
- CDKN2C
- CENPA
- CHD2
- CHD4
- CIC
- CRKL
- CRLF2
- CSF3R
- CSNK1A1
- CTCF
- CTLA4
- CTNNA1
- CUL3
- CUX1
- CXCR4
- CYLD
- DAXX
- DCUN1D1
- DDX41
- DHX15
- DICER1
- DIS3
- DNAJB1
- DNMT1
- DNMT3B
- DOT1L
- E2F3
- EED
- EGFL7
- EIF1AX
- EIF4A2
- EIF4E
- EML4
- EPCAM
- EPHA3
- EPHA5
- EPHA7
- EPHB1
- ERCC3
- ERCC4
- ERCC5
- ERRFI1
- ETS1
- ETV1
- ETV4
- ETV5
- ETV6
- EWSR1
- FAM123B
- FAM46C
- FANCA
- FANCC
- FANCD2
- FANCE
- FANCF
- FANCG
- FAS
- FAT1
- FGF19
- FH
- FLCN
- FLI1
- FLT4
- FOXA1
- FOXO1
- FOXP1
- FRS2
- FUBP1
- FYN
- GABRA6
- GATA1
- GATA2
- GATA3
- GATA4
- GATA6
- GID4
- GLI1
- GNA13
- EPHB1
- ERCC3
- ERCC4
- ERCC5
- ERRFI1
- ETS1
- ETV1
- ETV4
- ETV5
- ETV6
- EWSR1
- FAM123B
- FAM46C
- FANCA
- FANCC
- FANCD2
- FANCE
- FANCF
- FANCG
- FAS
- FAT1
- FGF19
- FH
- FLCN
- FLI1
- FLT4
- FOXA1
- FOXO1
- FOXP1
- FRS2
- FUBP1
- FYN
- GABRA6
- GATA1
- GATA2
- GATA3
- GATA4
- GATA6
- GID4
- GLI1
- GNA13
- GPR124
- GPS2
- GREM1
- GRIN2A
- GRM3
- GSK3B
- H3F3A
- H3F3B
- H3F3C
- HGF
- HIST1H1C
- HIST1H2BD
- HIST1H3A
- HIST1H3B
- HIST1H3C
- HIST1H3D
- HIST1H3E
- HIST1H3F
- HIST1H3G
- HIST1H3H
- HIST1H3I
- HIST1H3J
- HIST2H3A
- HIST2H3C
- HIST2H3D
- HIST3H3
- HLA-A
- HLA-B
- HLA-C
- HNRNPK
- HOXB13
- HSD3B1
- HSP90AA1
- ICOSLG
- ID3
- IFNGR1
- IGF1
- IGF1R
- IGF2
- IKBKE
- IKZF1
- IL10
- IL7R
- INHA
- INHBA
- INPP4A
- INSR
- IRF2
- IRF4
- IRS1
- IRS2
- JAK1
- JUN
- KAT6A
- KDM5A
- KDM5C
- KDM6A
- KEAP1
- KEL
- KIF5B
- KLF4
- KLHL6
- KMT2B
- KMT2C
- KMT2D
- LAMP1
- LATS1
- LATS2
- LMO1
- LRP1B
- LYN
- LZTR1
- MAGI2
- MALT1
- MAP2K4
- MAP3K1
- MAP3K13
- MAP3K14
- MAP3K4
- MAPK1
- MAPK3
- MAX
- MDC1
- MED12
- MEF2B
- MEN1
- MGA
- MITF
- MST1
- MST1R
- MYB
- MYOD1
- NAB2
- NCOA3
- NCOR1
- NEGR1
- NF2
- NFE2L2
- NFKBIA
- NKX2-1
- NKX3-1
- NOTCH4
- NSD1
- NTRK1
- NTRK2
- NTRK3
- NUP93
- NUTM1
- PAK1
- PAK3
- PAK7
- PARK2
- PARP1
- PAX3
- PAX5
- PAX7
- PAX8
- PBRM1
- PDCD1
- PDCD1LG2
- PDK1
- PDPK1
- PGR
- PHF6
- PHOX2B
- PIK3C2B
- PIK3C2G
- PIK3C3
- PIK3R2
- PIK3R3
- PIM1
- PLCG2
- PLK2
- PMAIP1
- PMS1
- PNRC1
- POLD1
- POLE
- PPARG
- PPM1D
- PPP2R1A
- PPP6C
- PRDM1
- PREX2
- PRKAR1A
- PRKCI
- PRKDC
- PRSS8
- PTPRD
- PTPRS
- PTPRT
- QKI
- RAB35
- RAC1
- RAD21
- RAD50
- RAD52
- RAF1
- RANBP2
- RARA
- RASA1
- RBM10
- RECQL4
- REL
- RFWD2
- RHEB
- RHOA
- RIT1
- RNF43
- RPS6KA4
- RPS6KB2
- RPTOR
- RUNX1
- RUNX1T1
- RYBP
- SDHA
- SDHAF2
- SDHB
- SDHC
- SDHD
- SETBP1
- SETD2
- SF3B1
- SH2B3
- SH2D1A
- SHQ1
- SLIT2
- SMAD2
- SMAD3
- SMARCA4
- SMARCD1
- SMC1A
- SMC3
- SNCAIP
- SOCS1
- SOX10
- SOX17
- SOX2
- SOX9
- SPEN
- SPOP
- SPTA1
- SRSF2
- STAG1
- STAG2
- STAT3
- STAT4
- STAT5A
- STAT5B
- STK40
- SUFU
- SUZ12
- SYK
- TAF1
- TBX3
- TCEB1
- TCF3
- TCF7L2
- TERC
- TET1
- TFE3
- TFRC
- TGFBR1
- TGFBR2
- TMEM127
- TMPRSS2
- TNFAIP3
- TNFRSF14
- TOP1
- TOP2A
- TP53
- TRAF2
- TRAF7
- TSHR
- U2AF1
- VEGFA
- VTCN1
- WISP3
- WT1
- XIAP
- XPO1
- YAP1
- YES1
- ZBTB2
- ZBTB7A
- ZFHX3
- ZNF217
- ZNF703
- ZRSR2

Fusions + Splice Variants

- ABL1
- AKT3
- ALK
- AR
- AXL
- BCL2
- BRAF
- BRCA1
- BRCA2
- CDK4
- CSF1R
- EGFR
- EML4
- ERBB2
- ERG
- ESR1
- ETS1
- ETV1
- ETV4
- ETV5
- EWSR1
- FGFR1
- FGFR2
- FGFR3
- FGFR4
- FLI1
- FLT1
- FLT3
- JAK2
- KDR
- KIF5B
- KIT
- KMT2A (MLL)
- MET
- MLLT3
- MSH2
- MYC
- NOTCH1
- NOTCH2
- NOTCH3
- NRG1
- NTRK1
- NTRK2
- NTRK3
- PAX3
- PAX7
- PDGFRA
- PDGFRB
- PIK3CA
- PPARG
- RAF1
- RET
- ROS1
- RPS6KB1
- TMPRSS2

Small Variants

- AKT1
- AKT3
- APC
- ARID1A
- ATR
- BAP1
- BARD1
- BCL2
- BCL6
- BRIP1
- BTK
- CARD11
- CCND2
- CD79A
- CD79B
- CDH1
- CDK12
- CDKN2A
- CEBPA
- CREBBP
- CSF1R
- CTNNB1
- DDR2
- DNMT3A
- EP300
- ERBB4
- ERG
- ESR1
- EZH2
- FAM175A
- FANCI
- FANCL
- FBXW7
- FLT1
- FLT3
- FOXL2
- GEN1
- GNA11
- GNAQ
- GNAS
- HNF1A
- HRAS
- IDH1
- IDH2
- INPP4B
- JAK3
- KDR
- MAP2K1
- MAP2K2
- MCL1
- MLH1
- MLL
- MLLT3
- MPL
- MRE11A
- MSH2
- MSH3
- MSH6
- MTOR
- MUTYH
- MYD88
- NBN
- NF1
- NOTCH1
- NOTCH2
- NOTCH3
- NPM1
- PALB2
- PIK3CD
- PIK3CG
- PIK3R1
- PMS2
- PP2R2A
- PTCH1
- PTPN11
- RAD51
- RAD51B
- RAD51C
- RAD51D
- RAD54L
- RB1
- ROS1
- SLX4
- SMAD4
- SMARCB1
- SMO
- SRC
- STK11
- TERT
- TET2
- TP53
- TSC1
- TSC2
- VHL
- XRCC2

Amplifications

- AKT2
- ALK
- AR
- ATM
- BRAF
- BRCA1
- BRCA2
- CCND1
- CCND3
- CCNE1
- CDK4
- CDK6
- CHEK1
- CHEK2
- EGFR
- ERBB2
- ERBB3
- ERCC1
- ERCC2
- ESR1
- FGF1
- FGF2
- FGF3
- FGF4
- FGF5
- FGF6
- FGF7
- FGF8
- FGF9
- FGF10
- FGF10
- FGF14
- FGF19
- FGF23
- FGFR1
- FGFR2
- FGFR3
- FGFR4
- JAK2
- KIT
- KRAS
- LAMP1
- MDM2
- MDM4
- MET
- MYC
- MYCL1
- MYCN
- NRAS
- NRG1
- PDGFRA
- PDGFRB
- PIK3CA
- PIK3CB
- PTEN
- RAF1
- RET
- RICTOR
- RPS6KB1
- TFRC

NTRK1, NTRK2, NTRK3 (pan-cancer) | MSI (pan-cancer)

Lung	Melanoma	Colon	Ovarian	Breast	Gastric	Bladder	Myeloid	Sarcoma
AKT1	*BRAF*	*AKT1*	*BRAF*	*AKT1*	*BRAF*	*MSH6*	*ABL1*	ALK
ALK	*CTNNB1*	*BRAF*	*BRCA1*	*AR*	*KIT*	*PMS2*	*ASXL1*	APC
BRAF	*GNA11*	*HRAS*	*BRCA2*	*BRCA1*	*KRAS*	*TSC1*	*CALR*	BRAF
DDR2	*GNAQ*	*KRAS*	*KRAS*	*BRCA2*	*MET*		*CEBPA*	CDK4
EGFR	*KIT*	*MET*	*PDGFRA*	*ERBB2*	*MLH1*		*ETV6*	CTNNB1
ERBB2	*MAP2K1*	*MLH1*	*FOXL2*	*FGFR1*	*PDGFRA*		*EZH2*	ETV6
FGFR1	*NF1*	*MSH2*	*TP53*	*FGFR2*	*TP53*		*FLT3*	EWSR1
FGFR3	*NRAS*	*MSH6*		*PIK3CA*			*GATA2*	FOXO1
KRAS	*PDGFRA*	*NRAS*		*PTEN*			*IDH1*	GLI1
MAP2K1	*PIK3CA*	*PIK3CA*					*IDH2*	KIT
MET	*PTEN*	*PMS2*					*JAK2*	MDM2
NRAS	*TP53*	*PTEN*					*KIT*	MYOD1
PIK3CA		*SMAD4*					*MPL*	NAB2
PTEN		*TP53*					*NPM1*	NF1
RET							*RUNX1*	PAX3
TP53							*SF3B1*	PAX7
TMB							*SRSF2*	PDGFRA
							TP53	PDGFRB
								SDHB
								SDHC
								SMARCB1
								TFE3
								WT1

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