SOPHiA GENETICS™

# MSK-IMPACT® Flex powered with SOPHiA DDM™

Elevate your comprehensive genomic profiling (CGP) research



Scale your CGP to new heights with a fully integrated, sample-to-report solution.
The flexible, modular design enables you to tailor analysis options – DNA capture, RNA capture, and/or HRD – at the sample level, supporting greater agility and cost-effectiveness in your research.

## CURATED

Target **533 DNA** and **140 RNA** genes selected from guidelines, key databases (incl. OncoKB™), and clinical trial data – with future-proof content derived from **MSK-IMPACT®**, curated by MSK experts.

## COMPREHENSIVE

Detect **key biomarkers** in **one harmonized workflow** – SNVs/Indels, CNVs (gene- and exon-level), fusions, gene expression, MSI, TMB, and HRD – with high concordance to MSK-IMPACT® used at MSK.

## AGILE

Tailor biomarker coverage at the **sample level** with flexible DNA capture, DNA WGS, and RNA capture combinations in a single run – maximizing cost efficiency and avoiding **unneccessary testing**.

## A modular approach for agile analysis

**EXPERTLY DESIGNED CONTENT**

**505 genes based on MSK-IMPACT®**
*DNA capture*

+

**28 genes based on guidelines and trials**
*DNA capture*

+

**SAMPLE-LEVEL MODULARITY**

**140 genes for RNA analysis[a]**
*RNA capture*

+

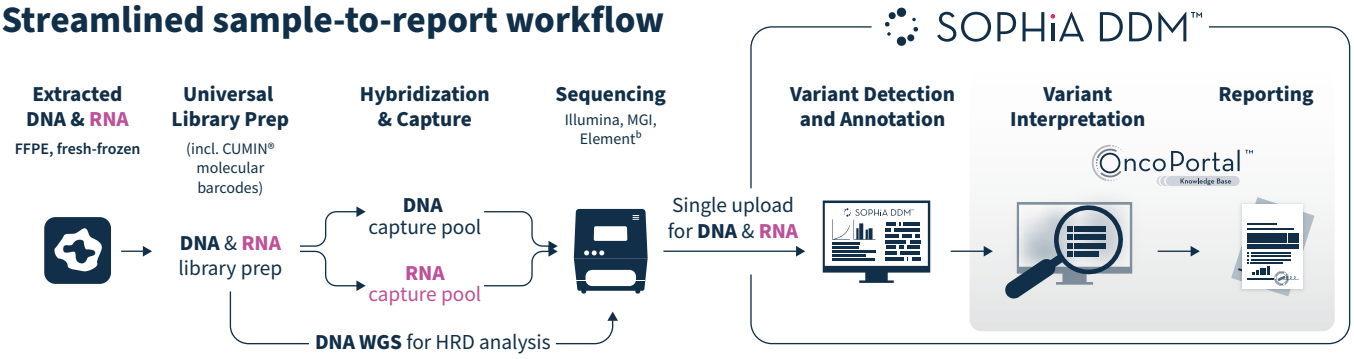
**HRD genomic integrity**
*DNA WGS*

=

**MSK-IMPACT® Flex** powered with **SOPHiA DDM™**

**Future-proof analysis with sample-level DNA, RNA, and HRD results**

## Streamlined sample-to-report workflow




Ready-to-sequence libraries in **1.5 (DNA)** or **2 (DNA + RNA)** days • **Automation** scripts available • **Flexible** sample **multiplexing** capability • **<5 day** turnaround[c]

[a]Powered by SOPHiA DDM™ RNAtarget PanCancer Solution. 140 genes in total, 135 for fusion detection. [b]Pipelines readily available for Illumina sequencers. Compatible with MGI and Element sequencers – additional assessment may be required. [c]For indicative purposes only; actual duration may be subject to change depending on the number of samples, server load, and other technical limitations.

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# High analytical concordance across biomarkers

The dedicated AI agents of SOPHiA DDM™ deliver consistently high concordance with established reference methods across all biomarker classes.

| Input type | Biomarkers | PPA [%] | OPA [%] |
|---|---|---|---|
| DNA capture[a] | SNV/Indel | 100 | - |
| | TMB | 95 | 97.9 |
| | MSI | 100 | 97.9 |
| | Gene-level CNVs | 91.8 | - |
| | Exon-level CNVs | - | 100 |
| | Gene fusion | 90.9 | - |
| DNA WGS[b] | HRD genomic integrity | - | 100 |
| RNA capture[c] | Gene fusion and exon-skipping | 100 | 100 |
| | Gene expression | 100 | - |

[a]Based on analysis of 48 FFPE DNA samples (pan-cancer), using centralized MSK-IMPACT® at MSK as reference method (analytical assessment of RUO products). [b]Based on analysis of 24 ovarian cancer FFPE DNA, using gold standard as reference method. [c]Based on analysis of 21 FFPE DNA samples (pan-cancer) using amplicon-based approach as reference method.

# Detect key variants and biomarkers

## From DNA (533 genes)

**SNVs/Indels in 533 genes (all genes of the panel):** *ABL1, ABRAXAS1, ACVR1, AGO1, AGO2, AKT1, AKT2, AKT3, ALB, ALK, ALOX12B, AMER1, ANKRD11, APC, APLNR, AR, ARAF, ARHGAP35, ARID1A, ARID1B, ARID2, ARID5B,* ***ASS1****, ASXL1, ASXL2, ATM, ATR, ATRX, ATXN7, AURKA, AURKB, AXIN1, AXIN2, AXL, B2M, BABAM1, BAP1, BARD1, BBC3, BCL10, BCL2, BCL2L1, BCL2L11, BCL6, BCOR,* ***BCORL1****, BIRC3, BLM, BMPR1A, BRAF, BRCA1, BRCA2, BRD4, BRIP1, BTK,* ***C11orf95****, CALR, CARD11, CARM1, CASP8, CBFB, CBL, CCND1, CCND2, CCND3, CCNE1, CCNQ, CD274, CD276,* ***CD58****, CD79A, CD79B, CDC42, CDC73, CDH1, CDK12, CDK4, CDK6, CDK8, CDKN1A, CDKN1B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CENPA, CHEK1, CHEK2, CIC, CMTR2, COP1, CREBBP, CRKL, CRLF2, CSDE1, CSF1R, CSF3R, CTCF, CTLA4, CTNNB1, CTR9, CUL3, CXCR4, CXorf67, CYLD, CYP19A1, CYSLTR2, DAXX, DCUN1D1,* ***DDR1****, DDR2, DICER1, DIS3, DNAJB1, DNMT1, DNMT3A, DNMT3B, DOT1L,* ***DPYD****, DROSHA, DUSP4, E2F3, EED, EGFL7, EGFR, EIF1AX, EIF4A2, EIF4E, ELF3, ELOC, EP300, EPAS1, EPCAM, EPHA3, EPHA5, EPHA7, EPHB1, ERBB2, ERBB3, ERBB4, ERCC2, ERCC3, ERCC4, ERCC5, ERF, ERG, ERRFI1, ESR1, ETAA1, ETV1, ETV6, EZH1, EZH2, FANCA,* ***FANCB****, FANCC,* ***FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, FAS****, FAT1, FBXW7, FGF19,* ***FGF23****, FGF3, FGF4, FGFR1, FGFR2, FGFR3, FGFR4, FH, FLCN, FLT1, FLT3, FLT4, FOXA1, FOXF1, FOXL2, FOXO1, FOXP1, FUBP1, FYN, GAB1, GAB2, GATA1, GATA2, GATA3,* ***GEN1****, GLI1, GNA11,* ***GNA13****, GNAQ, GNAS, GNB1, GPS2, GREM1, GRIN2A, GSK3B, H3F3A, H3F3B, H3F3C,* ***HDAC2****, HGF, HIST1H1C, HIST1H2BD, HIST1H3A, HIST1H3B, HIST1H3C, HIST1H3D, HIST1H3E, HIST1H3F, HIST1H3G, HIST1H3H, HIST1H3I, HIST1H3J, HIST2H3C, HIST2H3D, HIST3H3, HLA-A, HLA-B, HLA-C, HNF1A, HOXB13, HRAS, ICOSLG, ID3, IDH1, IDH2,* ***IDO2****, IFNGR1, IGF1, IGF1R, IGF2, IKBKE, IKZF1, IL10, IL7R, INHA, INHBA, INPP4A, INPP4B, INPPL1, INSR, IRF4, IRS1, IRS2, JAK1, JAK2, JAK3, JUN, KBTBD4, KDM5A, KDM5C, KDM6A, KDR, KEAP1, KIT, KLF4, KLF5, KMT2A, KMT2B, KMT2C, KMT2D, KMT5A, KNSTRN, KRAS, LATS1, LATS2,* ***LDB1****, LMO1, LYN, LZTR1, MAD2L2, MALT1, MAP2K1, MAP2K2, MAP2K4, MAP3K1, MAP3K13, MAP3K14, MAPK1, MAPK3, MAPKAP1, MAX, MCL1, MDC1, MDM2, MDM4, MED12, MEF2B, MEN1, MET, MGA, MITF, MLH1, MLLT1, MPL, MRE11, MSH2, MSH3, MSH6, MSI1, MSI2, MST1, MST1R, MTAP, MTOR, MUTYH, MYC, MYCL, MYCN, MYD88, MYOD1, NADK, NBN, NCOA3, NCOR1, NEGR1, NF1, NF2, NFE2L2, NFKBIA, NKX2-1, NKX3-1, NOTCH1, NOTCH2, NOTCH3, NOTCH4, NPM1, NRAS, NSD1, NSD2, NSD3, NTHL1, NTRK1, NTRK2, NTRK3, NUF2, NUP93, PAK1, PAK5, PALB2, PARP1, PAX5, PBRM1, PDCD1, PDCD1LG2, PDGFRA, PDGFRB, PDPK1, PGBD5, PGR, PHF6, PHOX2B, PIK3C2G, PIK3C3, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PIK3R2, PIK3R3, PIM1, PLCG2, PLK2, PMAIP1,* ***PML****, PMS1, PMS2, PNRC1, POLD1, POLE, POT1, PPARG, PPM1D, PPP2R1A,* ***PPP2R2A****, PPP4R2, PPP6C, PRDM1, PRDM14, PREX2, PRKAR1A, PRKCI, PRKD1, PRKN,* ***PRPF8****, PTCH1, PTEN, PTP4A1, PTPN11, PTPRD, PTPRS, PTPRT, RAB35, RAC1, RAC2, RAD21, RAD50, RAD51, RAD51B, RAD51C, RAD51D, RAD52, RAD54L, RAF1, RARA, RASA1, RB1, RBM10, RECQL, RECQL4, REL, REST, RET, RHEB, RHOA, RICTOR, RIT1, RNF43, ROS1, RPS6KA4, RPS6KB2, RPTOR, RRAGC, RRAS, RRAS2, RTEL1, RUNX1, RXRA, RYBP, SCG5, SDHA, SDHAF2, SDHB, SDHC, SDHD, SERPINB3, SERPINB4, SESN1, SESN2, SESN3, SETD2, SETDB1, SF3B1, SH2B3, SH2D1A, SHOC2, SHQ1, SLFN11, SLX4, SMAD2, SMAD3, SMAD4, SMARCA2, SMARCA4, SMARCB1, SMARCD1, SMARCE1, SMO, SMYD3, SOCS1, SOS1, SOX17, SOX2, SOX9, SPEN, SPOP, SPRED1, SPRTN, SRC, SRSF2, STAG2, STAT3, STAT5A, STAT5B,* ***STAT6****, STK11, STK19, STK40, SUFU, SUZ12, SYK, TAP1, TAP2, TBX3, TCF3, TCF7L2, TEK, TENT5C, TERT, TET1, TET2,* ***TFE3****, TGFBR1, TGFBR2, TMEM127, TMPRSS2, TNFAIP3, TNFRSF14, TOP1, TP53, TP53BP1, TP63, TRAF2, TRAF7, TRIP13, TSC1, TSC2, TSHR, U2AF1,* ***UGT1A1****, UPF1,* ***USH2A****, USP8, VEGFA, VHL, VTCN1, WT1, WWTR1, XIAP, XPO1, XRCC2, YAP1, YES1, ZFHX3, ZNRF3, ZRSR2*

***Note: DNA genes in bold are additional genes compared to the MSK-IMPACT® powered with SOPHiA DDM™ panel.***

**Whole gene amplifications and deletions in 520 genes:** *All genes of the panel EXCEPT for HIST2H3D, HIST2H3C, HIST1H3A, HIST1H3D, HIST1H3E, HIST1H3F, HIST1H3G, HIST1H3H, HIST1H3I, HIST1H3J, HLA-A, HLA-C, H3F3B*

**Gene-level and exon-level CNVs in 49 genes:** *APC, ARID1A, ATM, BAP1, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CDK12, CHEK1, CHEK2, DICER1, EGFR, EPCAM, FANCA, FANCD2, FANCL, FH, FLCN, MET, MLH1, MRE11, MSH2, MSH6, NBN, NF1, NF2, PALB2, PMS2, PPP2R2A, PTCH1, PTEN, RAD51B, RAD51C, RAD51D, RAD54L, RB1, SDHA, SDHB, SDHC, SMARCA4, SMARCB1, STK11, SUFU, TP53, TSC1, TSC2, WT1*

**Other biomarkers:** *MSI, TMB, HRD, TERT promoter, DNA fusions (22 genes), MET exon 14 skipping, tumor purity-ploidy estimates, absolute copy number, loss of heterozygosity status.*

## From RNA (140 genes)

**Fusions (partner-agnostic) in 135 genes:** *ACVR2A, AKT1, AKT2, AKT3, ALK, ARHGA-P26, ARHGA-P6, AR, AXL, BCOR, BRAF, BRD3, BRD4, CAMTA1, CCNB3, CCND1, CHMP2A, CIC, CRTC1, CSF1, CSF1R, CTNNB1, DNAJB1, EGF, EGFR, EPC1, ERBB2, ERBB4, ERG, ESR1, ESRRA, ETV1, ETV4, ETV5, ETV6, EWSR1, FGF1, FGFR1, FGFR2, FGFR3, FGR, FOSB, FOS, FOXO1, FOXO4, FUS, GLI1, GRB7, GREB1, HMGA2, IGF1R, INSR, JAK2, JAK3, JAZF1, KANSL1, KIT, KRAS, MAML2, MAP2K1, MAP3K8, MAST1, MAST2, MBTD1, MDM2, MEAF6, MET, MGEA5, MKL2, MN1, MSMB, MUSK, MYBL1, MYB, MYC, MYOD1, NCOA1, NCOA2, NCOA3, NFATC2, NFE2L2, NFIB, NOTCH1, NOTCH2, NR4A3, NRG1, NTRK1, NTRK2, NTRK3, NUMBL, NUTM1, PAX3, PAX8, PDGFB, PDGFD, PDGFRA, PDGFRB, PHF1, PHKB, PIK3CA, PKN1, PLAG1, PPARG, PRDM10, PRKACA, PRKACB, PRKCA, PRKCB, PRKCD, PRKD1, PRKD2, PRKD3, RAD51B, RAF1, RELA, RET, ROS1, RSPO2, RSPO3, SS18L1, SS18, STAT6, TAF15, TCF12, TERT, TFE3, TFEB, TFG, THADA, TMPRSS2, USP6, VGLL2, WWTR1, YAP1, YWHAE*

**Exon skipping in 9 genes:** *ALK (ex1–ex18; ex1–ex4 ), AR (ex3-ex4; ARV7, cryptic exon inclusion), BRAF (ex1–ex11; ex1–ex9; ex2–ex9; ex3–ex11; ex3–ex9), EGFR (ex1–ex8), ERBB2 (ex15–ex17 ), MET (ex13–ex15; ex14–ex16 ), NFE2L2 (ex1–ex3; ex1–ex4 ), NOTCH1 (ex1–ex28; ex20–ex28; ex2–ex28; ex2–ex29), PDGFRA (ex7–ex10). Kinase domain duplications in BRAF (ex18–ex10), EGFR (ex25–ex18), FGFR1 (ex18–ex10)*

**Gene expression in 56 genes:** *AKT1, AKT3, ALK, ALPK1, ARHGA-P26, BCOR, BRAF, CSF1, CTNNB1, DICER1, EGFR, ERBB2, ERG, ESR1, ETV1, ETV4, FGFR1, FGFR2, FGFR3, FUS, HMGA2, HRAS, JAK2, JAK3, KRAS, MAP2K1, MDM2, MET, MYBL1, MYOD1, NCOA1, NFE2L2, NFIB, NOTCH1, NRAS, NRG1, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, PKN1, PRKACA, PRKACB, PRKCD, RAD51B, RAF1, RET, ROS1, SS18L1, SS18, STAT6, TCF12, TFE3, THADA, YAP1*

# Specifications

| | | |
|---|---|---|
| **Sample type** | FFPE, fresh-frozen | |
| **Starting material** | 50 ng DNA | 50 ng RNA |
| **Sequencers** | • Illumina NextSeq® 550, NextSeq® 1000/2000, NovaSeq™ 6000, NovaSeq™ X<br>• Compatible with MGI/Complete Genomics and Element sequencers. | |
| **Recommended paired-end reads** | • DNA capture – 51 million<br>• RNA capture – 11 million<br>• DNA low-pass WGS (for genomic instability) – 20 million | |
| **Wet lab time** | 1.5 days for DNA | 2 days for DNA + RNA |
| **Limit of detection at 95% (LOD95)** | <5% VAF (3.6% VAF) for SNVs/Indels | |
| **Product codes** | BS0132ILLRSMY13 (DNA) - kit size 16, 32, 48, 96<br>CS2517ILLRSRY16 (RNA) - kit size: 16, 32, 48 | CS2517ILBRSRY16 (RNA) – kit size 96<br>DL0121ILLRSM (GIInger™) – dry lab only |

CNV, copy number variants; FFPE, formalin-fixed paraffin-embedded; HRD, homologous recombination deficiency; MSI, microsatellite instability; OPA, overall percent agreement; PPA, positive percent agreement; TMB, tumor mutational burden; VAF, variant allele frequency; WGS, whole genome sequencing.


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