STRATIFY YOUR mCRC PATIENTS FOR OPDIVO® (NIVOLUMAB) ± YERVOY® (IPILIMUMAB) WITH THE IDYLLA™ CDx MSI TEST

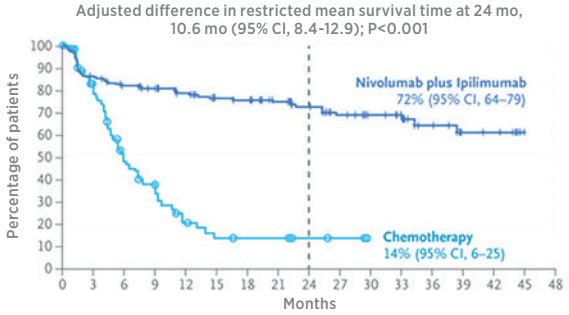
CheckMate-8HW trial

CheckMate-8HW[1,2] showed that central confirmation of MSI-H/dMMR test results with a clinically validated assay **improved outcomes for mCRC patients eligible for OPDIVO® (nivolumab) ± YERVOY® (ipilimumab)**.

PFS at 24 months for dMMR/MSI-H mCRC patients was **72%** with 1L OPDIVO® and YERVOY® and **14%** with chemotherapy, following central confirmation of dMMR/MSI-H results (Checkmate-8HW) - see Figure[2].

13% of enrolled patients classified as MSI-H/dMMR by local testing were classified as MSS/pMMR on central confirmation. The improved survival and higher response rates in the centrally confirmed population indicate that the local results were false positives, underscoring the **importance of standardized testing** to accurately identify MSI-H/dMMR status[2].

Progression-free Survival (Kaplan-Meier Curve)



Idylla™ CDx MSI Test

The **Idylla™ CDx MSI Test** was used as one of the **central confirmation testing methods** in CheckMate-8HW, where the PFS benefit of OPDIVO® plus YERVOY® over chemotherapy was consistently observed (HR 0.20), supporting the **Test's ability to accurately identify eligible MSI-H mCRC patients**.

The Idylla™ CDx MSI Test is the **first-ever, fully automated, sample-to-result companion diagnostic** approved by the FDA for CRC patients[3].
The Test delivers fast and standardized MSI results, **supporting optimal therapy decisions, reducing patient anxiety**[4], **and overcoming outcome disparities**[5].

YOUR PATIENTS, OUR PRIORITY.

> **The results obtained with the CheckMate-8HW trial establish OPDIVO® + YERVOY® as the potential to be a standard-of-care treatment for MSI-H/dMMR mCRC**

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REFERENCES

(1) CheckMate 8HW, a Phase 3 clinical trial, evaluated the efficacy of nivolumab plus ipilimumab combination therapy or investigator's choice chemotherapy for the treatment of subjects with deficient mismatch repair/microsatellite instability - high (dMMR/MSI-H) metastatic colorectal cancer (NCT04008030).

(2) Andre, T. et al. (2024). Nivolumab plus Ipilimumab in Microsatellite-Instability-High Metastatic Colorectal Cancer. *The New England journal of medicine, 391*(21), 2014–2026. https://doi.org/10.1056/NEJMoa2402141

(3) Idylla™ CDx MSI Test (A0220/6) is approved in the US under P250005.

(4) Miles, A. (2017). The psychological implications of diagnostic delay in Colorectal Cancer patients. In L. Olsson (Ed.), *Timely diagnosis of symptomatic cancer: Colorectal cancer* (pp.103-119). Springer International Publishing. https://doi.org/10.1007/978-3-319-65286-3_7

(5) Froelich, W. (2020). Disparities in MSI/MMR Biomarker Testing for Colorectal Cancer. *Oncology Times, 42*(22), 35. https://doi.org/10.1097/01.COT.0000723664.21999.cc

ABBREVIATIONS

1L: first-line; CI: confidence interval, CRC: colorectal cancer; FDA: U.S. Food and Drug Administration; HR: hazard ratio; mCRC: metastatic or unresectable colorectal cancer; MSI-H: microsatellite-high; MSS: microsatellite stable; dMMR: deficient mismatch repair: pMMR: proficient mismatch repair; PFS: progression-free survival; CDx: companion diagnostic

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