Leveraging cfHPV-DNA to develop novel therapeutics for HPV-associated OPSCC.

As the rate of HPV-associated oropharyngeal squamous cell carcinoma (OPSCC) continues to surge, drug developers can leverage biomarkers such as cfHPV-DNA to guide novel therapeutic development. Learn how cfHPV-DNA testing can help.

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HPV-associated head and neck cancers present a growing problem in the United States:

Nearly **45,000** HPV-associated cancers are diagnosed annually in the US.[1]

Of these, **15,000** cases are head and neck cancers.[1]

Approximately **80%** of all OPSCC cases in US are associated with HPV.[2]

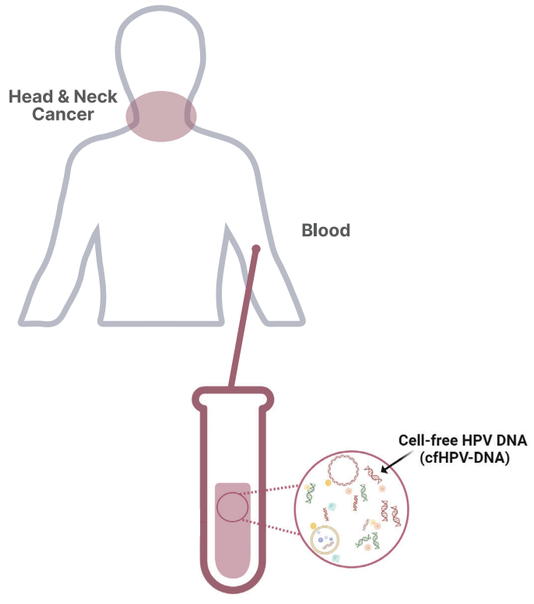
Incidence of HPV-associated OPSCC in **men** has surpassed that of cervical cancer in women, making OPSCC the most common cancer caused by HPV in the US.[3]

cfHPV-DNA has emerged as a biomarker of predicting benefit from novel therapeutics strategies.

How it works:

HPV-associated OPSCC tumor cells shed HPV-DNA into the bloodstream, allowing drug developers to detect and quantify cfHPV-DNA from a simple blood draw.

Using this method, HPV-SEQ — a commercially available plasma based NGS assay — provides quantitative detection of cfHPV 16 and 18 DNA.



HPV-SEQ is:

Ultrasensitive

Clinical sensitivity of detecting cfHPV-DNA in pretreatment baseline samples:

97.6%

(95% CI, 91.5% – 99.7%)[4]

Reliable and consistent

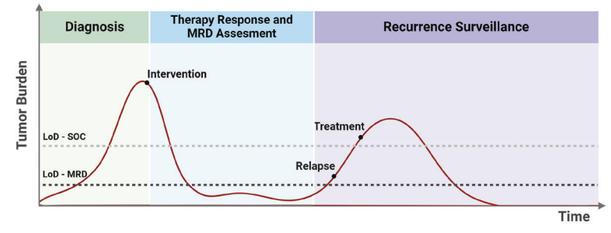
Can detect as low as 2 copies of HPV 16 and HPV 18 DNA

WITH LOW QUANTITATIVE VARIABILITY

(<30% CV above 5 copies)[4]

Using HPV-SEQ, drug developers can:

1. **Assess patients' trial eligibility,** by determining patients' HPV status and subtype with a simple blood draw.
2. **Gain real-time insights into treatment response,** by assessing dynamic changes in cfHPV-DNA quantitatively over the course of treatment.
3. **Detect recurrent disease — including distant recurrence — early,** with detection that predates the current standard of care. Up to 30% of patients with HPV+ OPSCC experience recurrence.[5]
4. **Enhance trial participants' experience,** by testing with a minimally invasive blood draw instead of biopsy or surgical procedures.



Leverage HPV-SEQ to enhance your next clinical trial

sysmex-inostics.com/cfhpv-dna-assay

References: 1. https://www.cdc.gov/cancer/hpv/statistics/cases.htm 2. Louredo, B. V. R., Prado-Ribeiro, A. C., Brandão, T. B., Epstein, J. B., Migliorati, C. A., Piña, A. R., et al.Santos-Silva, A. R. (2022, August). State-of-the-science concepts of HPV-related oropharyngeal squamous cell carcinoma: A comprehensive review. Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology, 134(2), 190–205. 3. Lechner M, Jones OS, Breeze CE, Gilson R. Gender-neutral HPV vaccination in the UK, rising male oropharyngeal cancer rates, and lack of HPV awareness. Lancet Infect. Dis. 2019;19:131–132 4. https://sysmex-inostics.com/cfhpv-dna-assay-astro/ 5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9272675/ Illustrations created with BioRender.com