NHS Cancer Vaccine Launch Pad (CVLP) Synopsis

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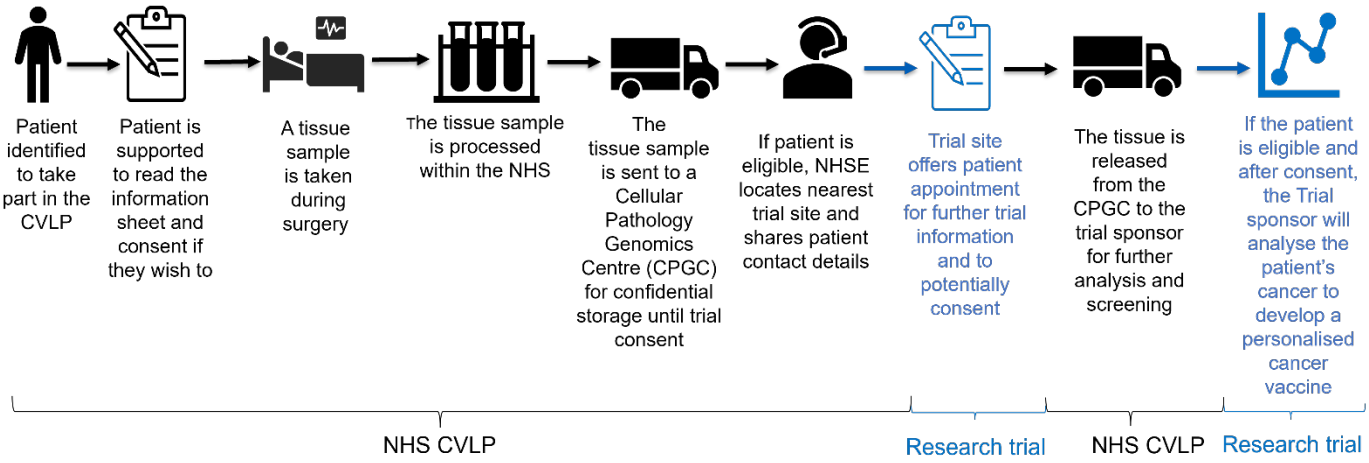
Study details

Background: The NHS Cancer Vaccine Launch Pad (CVLP) is a platform facilitating access to clinical trials of cancer vaccine treatment.

Patients will be asked to consent to be put forward for research trials of cancer vaccines. Following consent, surplus tissue samples, obtained through standard of care pathways, will be used to assess their eligibility for current or future cancer vaccine trials run by trial sponsors. The details of any available trials will be shared with the participant and their local treating clinical team, to see if they would consider taking part in the trial(s) for which they are eligible and to facilitate this if so.

The CVLP opened to recruitment in September 2023 and continues to support the first trial sponsor to partner with the CVLP, BioNTech SE, with identification of patients suitable for their BNT113-01 cancer vaccine trial in colorectal cancer patients.

Overarching CVLP pathway:



The CVLP is expanding to support a second cancer vaccine trial in Recurrent / Metastatic Head and Neck Squamous Cell Carcinoma (HNSCC).

Trial Sponsor: BioNTech SE

Trial Name: BNT113-01 (AHEAD-MERIT)

Trial background: The BNT113-01 study is a randomised phase II trial of BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first line therapy in patients with unresectable recurrent or metastatic HNSCC which is positive for HPV16 and expresses PD-L1. The study includes a pre-screening stage where investigators can pre-screen patients who might be candidates for the trial in the near future. This pre-screening phase is available for all patients and allows tumour samples to be submitted for central HPV16 DNA and PD-L1 expression testing prior to screening into the main trial.

Referring sites: We are looking for referring sites to

1. Identify patients eligible for the CVLP who are also suitable for BNT113-01 pre-screening based on the eligibility criteria below and consent them into the CVLP.
2. Refer participants suitable for BNT113-01 pre-screening to the nearest trial site using the CVLP database.
3. Organise for local pathology to release an FFPE block to the Cellular Pathology Genomics Centre (CPGC).
4. Keep trial sites informed on follow-up schedules or procedures taking place locally to investigate suspected recurrence or metastatic disease.
5. Complete and return data to the Southampton Clinical Trials Unit (SCTU) on the patients screened and recruited into the CVLP.

Eligibility Criteria

CVLP:
• Aged 16+ • Have a tumour which has been, or will be resected or biopsied • Have the capacity to consent to involvement in the CVLP *There will be additional eligibility criteria to be considered that will be specific for each vaccine trial that patients are considered and referred to.*
Additional eligibility criteria to consider specific for BNT113-01 (AHEAD-MERIT) Pre-Screening:

• Aged 18+
• Patients with previously histologically confirmed HNSCC with no prior systemic anticancer therapy administered in the recurrent or metastatic setting.
• Patients with a clinical situation at a relatively high risk of developing recurrent or metastatic disease. Examples include the below but this list is not exhaustive and is at the discretion of the investigator:
  ○ Completed treatment for T4 or N3 HNSCC (including rT4/rN3 relapses) up to 5 years prior to pre-screening entry and prior standard of care surveillance has not revealed tumour relapse.
  ○ Have been treated for oligometastatic disease with ablative therapies.

- Have clinical findings suggestive of recurrent or metastatic HNSCC pending confirmatory studies that is not expected to be curative with surgery or radiotherapy.
- Are under follow-up for local equivocal findings/residual lesions after radical treatment that may represent persistent malignant disease.

- Archival tumour tissue <5 years old to submit for central HPV16 and PD-L1 testing.