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BiomeOne®: multi-centric validation of a novel microbiome-based biomarker to predict response to cancer immunotherapy

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INTRODUCTION

- The intestinal microbiome has a substantial influence on the cancer-related response to immune checkpoint inhibitor (ICI) therapy.
- BiomeOne® is a tumor-agnostic CE-IVD marked medical device that uses baseline stool samples to analyse the intestinal microbiome and predict patient response to ICI.
- The aim of our study was to evaluate the prognostic potential of BiomeOne® in a cohort of non-small cell lung cancer (NSCLC), melanoma and renal cell carcinoma (RCC) patients.

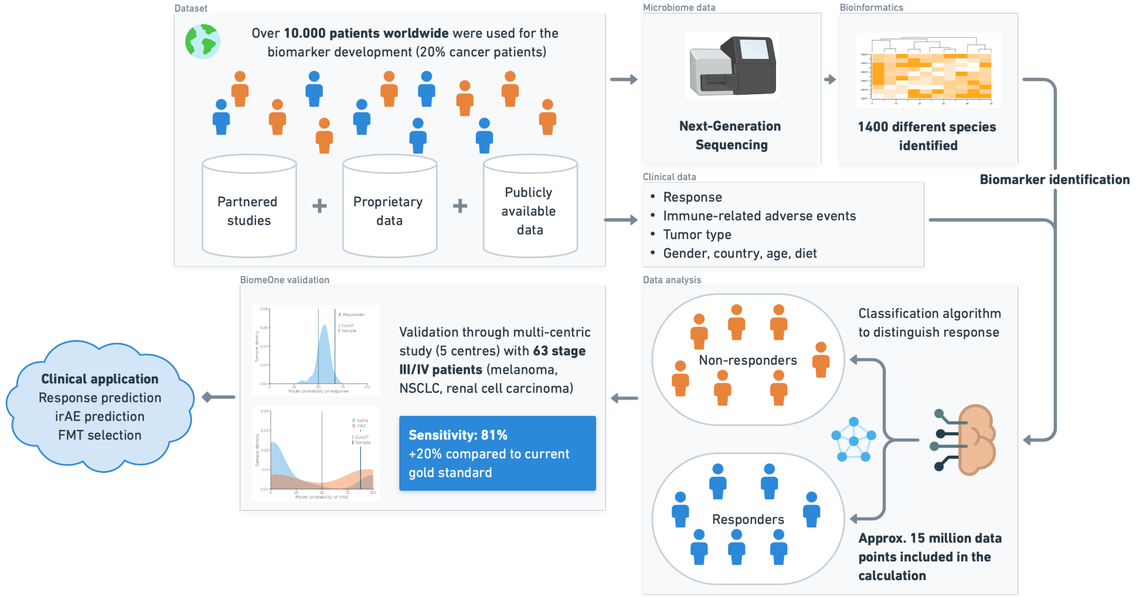

Figure 1. Schematic representation of biomarker development (=training dataset).

METHODS

- 65 patients: NSCLC (42), RCC (16) and melanoma (7) treated with ICI. No systemic antibiotic treatment 30 days prior to ICI therapy initiation;
- Stool samples collected with at-home kit (Norgen Biotek), prior to ICI treatment initiation and at week 12;
- 16S rRNA sequencing at both time-points;
- Statistical evaluation using Wilcoxon test, Mann-Whitney U test (alpha-diversity), PERMANOVA (beta-diversity) and ALDEx2, ANCOM-BC and MaAsLin2 (differential abundance);
- Clinical response was assessed at the end of first line therapy. Responders (R) were classified as complete and partial responders (CR, PR) and non-responders (NR) as stable and progressive disease (SD, PD). Best response was compared with the outcome of BiomeOne® analysis.

RESULTS

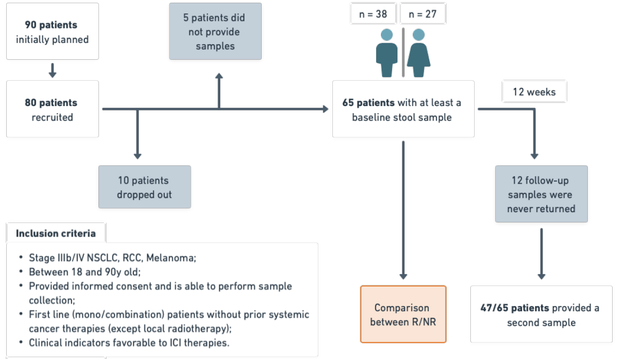

Figure 2. Experimental planning and inclusion criteria.

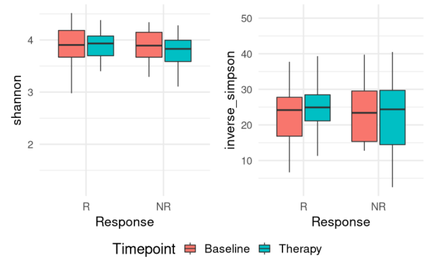

Figure 3. Alpha-diversity indices Shannon (P = 0.30) and inverse Simpson (P = 0.37) did not differ between R and NR nor between baseline and week 12 (P > 0.77).

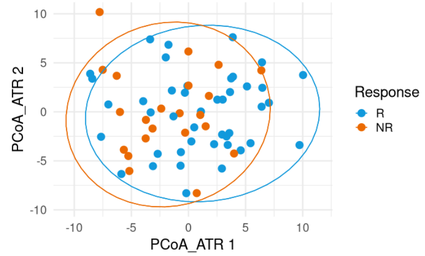

Figure 4. Beta-diversity did not differ between R and NR (P > 0.05).

- *Suterella* sp., *Faecalibacterium* sp. and *Haemophilus* sp. were found to be differentially abundant between R and NR (P < 0.05).
- No significant differences between the 3 tumour types, suggesting that the biomarker is tumour agnostic.

Table 1. Comparison between BiomeOne® results and clinical response.

	Responder CR + PR	Non-responder SD + PD	Total
BiomeOne: High	34 (pass)	10 (fail)	**44**
BiomeOne: Low	8 (fail)	11 (pass)	**19**
Total	**42**	**21**	**63**

- BiomeOne® was able to identify responders to ICI treatment with a sensitivity of 81% and a positive predictive value of 77%.

CONCLUSIONS

The presented research demonstrates the potential of BiomeOne® as a novel, non-invasive test to predict the outcome of ICI therapy. Further research will be necessary to expand the scope of BiomeOne® to other tumour entities.

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