Real-world HRQL in patients with melanoma derived using a digital ‘bring your own device’ platform

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BACKGROUND
Melanoma
Melanoma is an aggressive form of skin cancer that originates from melanocytes in the basal layer of the epidermis. Although it is the most frequently occurring skin cancer, it can also arise in the mucous membranes of the mouth and genitalia, the respiratory, gastrointestinal and uveal tracts and affects men and women alike. It is the most common form of cancer in the UK, with 4,830 new cases registered across the UK in 2014.2

New treatments for melanoma are gradually transforming the disease into a chronic condition. For advanced disease stages, the median survival has significantly increased from 9 months in stage 4 patients with limited treatment options, to a 5-10 year survival rate of up to 50% with a proportion of them living for 15-20 years.3

In the early setting, adjunct therapy including a checkpoint inhibitor is the objective of treatment with many patients with normal life expectations being exposed to treatments with potential side effects (including long term, irreversible damage to the immune system).4

The value of real-world data
Real-world data offers the potential to impact a clinical decision situation such as melanoma, and its treatments, on patients’ lives, symptoms, functioning, and other forms of productivity and daily activities, such as eating, for example. The NICE guidelines5 guide researchers to collect real-world data as a condition of entry into a National Cancer Research Institute (NCRI)3 trial, to address uncertainty in technology appraisal.

In the real-world setting, data can be collected from a broader range of patients that is ensuring a broad spectrum of patients that includes those with comorbidities and across all age ranges.

In the UK, melanoma patients are registered at the population level by one of the National Cancer Registries and numerous regional melanoma registries; however, none of the existing UK registries collect health-related quality of life (HRQL) or patient reported outcome (PRO) data.

Furthermore, the COI requires collection over 24 months, which is often insufficient time to develop and extract from a de-identified dataset, particularly using paper-based data capture.

The value of patient reported outcomes
Patient reported outcomes (PROs) are measures that enable evaluation of the experience of individuals living with a specific disease from their perspective. PROs provide the most accurate and precise description of disease burden and the impact of treatment. They are typically measured using instruments that have been developed for this purpose. These include disease-specific instruments designed to be used to measure outcomes and a specific condition such as the EORTC QLQ-C30, a measure of quality of life in cancer patients. While PROs are increasingly evaluated in clinical trials and daily practice, they are rarely measured in the real-world setting. Collection of PROs in the real-world has significant additional value compared with PROs measured within clinical trials. The data

• include different colons of patients, with co-morbidities that are not included in RCTs
• provide increased opportunity for patients to report symptoms difficult to capture on real visits, such as daily burden of disease, diet and exercise
• demonstrates how a condition such as melanoma and its treatments affects patients in the long term.

The MyRealWorld™ melanoma registry
The MyRealWorld registry has been developed in collaboration with the Patient Advocacy Organisation (PAO) Melanoma UK and the Royal Marsden NHS Foundation Trust (RMLT). The registry records patient demographics, treatment patterns, AEs, ECOG performance status, and PRO data. The registry will be used for secondary analyses, and the data from this patient population will be compared to clinical trial data.6

Using the study app on their mobile device (“flying your own device” (BYOD) technology), patients are asked to fill in the EORTC QLQ-C30, a questionnaire that is widely used in oncology across different types of cancers, every month. The instrument is performed using EORTC across different types of cancers. The EORTC QLQ-C30 is a validated five functional scales and a melanoma-focused subset of the PRO-CTCAE (QD-MEL). The EORTC QLQ-C30 is developed in the real-world setting (not fully validated at the time of registry launch, but that was included in the study). The EORTC QLQ-C30 comprises:

• five functional scales (physical, role, cognitive, emotional, and social)
• a global health status / HRQL scale
• three symptom scales (fatigue, pain, and nausea and vomiting)

The response categories of the symptom scales in the EORTC QLQ-C30 are as follows:

Not at all; a little; ‘Quite a bit’; Very much

RESULTS
The data presented here are based on 73 registry participants who provided symptom burden and disease stage data and a total sample of 145 participants recruited at the time of data cut. 325 participants are currently registered.

Patient demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Race</th>
<th>HRQL Population</th>
<th>Disease Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>50–60</td>
<td>70%</td>
<td>30%</td>
<td>40%</td>
<td>50%</td>
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</tbody>
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Patient recruitment & inclusion criteria
Patients are recruited in collaboration with Melanoma UK. The inclusion criteria is based to ensure a wide selection of people is recruited:

• resident in UK, with NHS (or CHI) number
• currently on any treatment for melanoma
• age 50+ years
• will use their own smartphone or tablet.

Study objective
The PRO data collected in the real-world setting in patients with melanoma using the European Organisation for Research and Treatment of Cancer Quality of Life questionnaire (QLQ-C30) provides valuable insights on the use of a digital real-world evidence app, and to identify key determinants of HRQL.

METHODS
The app collects the following set of data:

• Patient demographics
• Background demographics completed at baseline
• collects demographic data, data relating to the diagnosis and treatment of the melanoma, and data relating to lifestyle (e.g. diet, exercise, alcohol intake, smoking)

The background questions are completed at baseline.

• patients are asked to update their information every 6 months

• patients are recruited to complete these profiles with their own smartphones

• Monthly PROs

• patients are asked to complete three PRO questionnaires in the EORTC QLQ-C30 and a melanoma-focused subset of the PRO-CTCAE (QD-MELB) in a development (not fully validated at the time of registry launch, but that was included in the study).

The EORTC QLQ-C30 comprises:

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• a global health status / HRQL scale
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• patients with more advanced disease (Stage 3/4) have slightly lower physical, role and social level of functioning. Among the functional scales, scores were lowest for the emotional scale.

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CONCLUSIONS

All scales and single-item measures range in score from 0 to 100.

A high score for a functional scale represents a high level of functioning.

A high score for the global health status / QoL represents a high QoL.

A high score for the symptom scale / item represents a high level of symptomatology / problems

The EORTC QLQ-C30 global health status scores were lower in patients with more advanced disease. Differences in symptom scales according to BRAF status were observed, with BRAF positive patients having lower Global health status QoL. The symptom scales mostly affected by melanomas were insomnia, fatigue and pain. Among the functional scales, scores were lower for the emotional scale.

The melanoma registry continues to grow, and data collected in this real-world setting is close to real-time that will offer important insight to drug developers, health technology assessment agencies, clinicians and patients.

REFERENCES