umotif®

GIRAF case study

uMotif eCOA / ePRO platform, combined with home blood sampling, powers decentralized Rheumatic Fatigue study

uMotif platform and dried blood spot sampling (DBSS) power innovative remote research initiative – driving high levels of participant engagement, timely data capture, and new insight possibilities in the quest for understanding rheumatic disease (RMD) fatigue.

Needed: Insight into association between RMD-fatigue and inflammation

Approximately 75% of patients with RMDs, such as rheumatoid arthritis, fibromyalgia, and osteoarthritis, experience fatigue, which can be unpredictable and impact daily activities.

While the causes of RMD-fatigue remain unclear, inflammation – either directly or indirectly related to other co-morbidities, such as pain and mood – has long been suspected as playing a role.

Researchers at the University of Manchester launched the Gaining Insight into RheumAtic Fatigue (GIRAF) study 2019 to better understand connections between RMD-fatigue and inflammation. This first-of-its-kind study featured fully remote data collection using uMotif's eCOA / ePRO platform and DBSS.

Challenge: Timely, accurate, and convenient data and blood sample collection

Understanding the relationship between inflammation, RMD symptoms, and fatigue requires frequent blood sampling as well as detailed and prompt symptom assessments. Lab-conducted blood draws, however, significantly increase the time and engagement burden on study participants who must travel to collection sites. This limits the frequency of sample collection and prevents the opportunity for daily sampling. The need to record and report symptoms throughout the day using traditional logs also elevates participant requirements significantly.

To ease these burdens, the research team wanted to use a fully remote data and blood collection model. To do this, it needed:

- a user-friendly platform to collect serial assessments of symptoms at various times of day over an extended period; and
- a more convenient and effective way to collect blood samples

The team found a highly effective solution, combining DBSS technology with uMotif's eCOA / ePRO platform, which puts patients at the center of clinical research to improve the participant experience and reliability of patient-reported data.

> **We wanted to look at daily changes, so we needed to capture daily symptom assessments, along with data from blood collection. The uMotif app, with its robust functionality, enabled us to efficiently capture and record daily symptom data, while supporting engagement that elevated DBSS compliance.**

Katie Druce
Research Fellow and Patient and Public Engagement Lead at the Centre for Epidemiology Versus Arthritis

Why uMotif?

uMotif provided an easy-to-use and patient-centric tool to boost engagement and data accuracy; was secure and compliant with GDPR and other requirements; and could support a rapid launch with flexible and highly configurable modules. In addition, members of the research team had used the uMotif eCOA / ePRO platform in previous studies and had achieved high engagement – between 89%-91% – across a period of up to six months.

How it worked

Over 30 days, participants completed daily symptom monitoring using uMotif's smartphone/tablet app, designed in collaboration with patients to ensure an optimal user experience. They received prompts twice daily to complete 10 symptom ratings, including fatigue severity, mood, and coping, on a 1-5 scale. The study also included real-time data monitoring and targeted completion reminders if a participant had not reported for three or more days.

Patients completed DBSS on days 1-7, 14, and 30 and mailed the completed tests back to the research team. C-reactive Protein (CRP) values – an inflammation marker – were extracted from the tests. To boost DBSS participation, patients received reminders via the uMotif smartphone app.

Impact: High engagement, accurate data, research innovation

Together, uMotif's eCOA / ePRO platform and DBSS provided a valuable model for capturing the symptom assessments and biological samples necessary to gain insight into previously unanswerable questions about RMD-related fatigue.

Symptom reporting

Completion rates for reporting fatigue, pain, and mood were high across the study, as was symptom reporting continuity:

- 97.5% completed data on average weekly
- 85% provided data on five or more days per week

DBSS participation

DBSS proved to be a feasible tool for sample collection in RMD studies:

- 84% completion of dry blood spot samples, far higher than expected
- Full viability of samples returned to the study team
- High completion rates were seen across all disease groups (rheumatoid arthritis, osteoarthritis and fibromyalgia)

Rapid launch, efficient data collection

- Launched in eight weeks – from concept to data capture
- Recruited participants in two weeks, including onboarding to uMotif
- Benefitted from highly efficient data collection model

Find out more about how uMotif can help drive unparalleled patient engagement and data capture in your next study.

Contact us