

The K.Vita Service Evaluation

K.Vita is a new product for the dietary management of drug-resistant epilepsy (DRE). Will you help us gather more real-world evidence to support its use?

The K.Vita service evaluation is co-ordinated by Dr Natasha Schoeler, Research Dietitian n.schoeler@ucl.ac.uk at University College London Great Ormond Street Institute of Child Health, London, UK in collaboration with Vitaflo (International) Ltd.

Why collect real-world evidence for K.Vita?

- To add to the knowledge and practical experience gained during the clinical trial regarding product tolerance, acceptance, and adherence
- To identify specific epilepsy-associated conditions and syndromes that may be the most responsive to dietary management using K.Vita, to inform the choice of patient populations for further clinical trials
- To help evaluate what clinical care is required during initiation and follow-up
- To evaluate the content of the current HCP and patient practical guides

What data will be collected?

Data is collected anonymously and confidentially for each patient who starts K.Vita, and includes:

- Clinical diagnosis
- Reason(s) for the use of K.Vita
- Details of introduction
- Daily K.Vita intake
- Frequency of seizures and/or paroxysmal events

How will data be collected?

- Ethical approval and informed consent is not required, but the service evaluation must be registered with your local Audit (or similar) department (Natasha can provide support with this)
- You notify Natasha when a patient starts, or is about to start K.Vita. She will assign a patient identifier and email you a link to a MSForms questionnaire
- Further questionnaire links will be sent 3, 6 and 12 months after your patient starts (or subsequently discontinues) K.Vita
- Questionnaires take around 15 minutes to complete (with the information at hand)
- Data can be filled in and submitted at each time point or retrospectively

Once analysed the results will be:

- Used to update guidance provided by Vitaflo on the use of K.Vita
- Used to plan further product evaluation and research
- Disseminated via relevant conferences and peer-reviewed papers (to include acknowledgement of all HCPs involved in data collection)

Your contribution toward the collection of data will be very much appreciated, and help to shape the future use of K.Vita by patients with DRE, who often have limited treatment options.

To thank you for your participation and time, Vitaflo offer payment on a completed questionnaire basis.

Interested in taking part, or want more information?

Please email n.schoeler@ucl.ac.uk



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