Devices, Software Applications and Living Aids - Requests for Parkinson’s UK Support

Type of document | Charity Policy
---|---
Date | Final November 2017
Authors | Parkinson’s UK devices/apps/living aids team
Review date | November 2018

Contents:
Introduction .................................................................................................................. 2
Our policy for support .................................................................................................. 2
How does it work? ......................................................................................................... 2
   Medical Devices ...................................................................................................... 3
   Non-medical devices/software applications/living aids ............................................. 3
Consumer ready products ......................................................................................... 4
   Technology for use by people living with Parkinson’s .............................................. 4
   Technology for use by health and social care professionals .................................... 4
   Sale in our online shop ........................................................................................... 4
Working with commercial and non-commercial organisations .................................. 5
Contacting local groups ............................................................................................. 5
Parkinson’s UK staff involvement ............................................................................. 6
Governance issues ....................................................................................................... 6
Market research .......................................................................................................... 6
Where can I find more information? .......................................................................... 6
When the project is completed .................................................................................. 7
   Feedback & Acknowledgement .............................................................................. 7
   Payments ................................................................................................................. 7
Appendix A – Flowcharts ........................................................................................... 8
   Consumer Ready Product ....................................................................................... 8
   Product in development ......................................................................................... 9

In this policy:

Devices and software applications (apps) are defined as: Any mechanical or electronic product made or adapted for the benefit of people affected by Parkinson’s.

Living aids are defined as: Self-help devices or equipment that assist people affected by Parkinson’s in daily living activities.
Introduction

Parkinson's UK is a charity that drives better care, treatments and quality of life for everyone affected by Parkinson’s. We provide information and support to those affected by the condition and fund high quality research.

Devices, apps and living aids are becoming increasingly important for people living with Parkinson’s in the day to day management of their condition, and also for health and social care professionals involved in their care.

Parkinson’s UK specialist teams together with people who are living with Parkinson’s, collaborate with organisations to develop good quality devices, mobile technology and living aids which will benefit those affected by the condition.

We also have an on-line shop selling a range of specialist living aids which are designed to help people with Parkinson’s take back control.

Our policy for support

Parkinson’s UK can offer in-house guidance and input from people affected by Parkinson’s throughout the cycle of development of devices, apps and living aids. This may include concept, design and development, testing and validation, clinical investigation, regulatory issues, review and dissemination of information. We have a process for assessment and evaluation of products for inclusion on our ‘Safe to Suggest’ list or where appropriate for inclusion on a resource list for health and social care professionals.

We cannot help with market research on products already available in the market, and we do not assist with promotion for sale of products – unless they have gone through our approval process for sale through our own online shop.

Please see the flowchart in Appendix A of this policy for more details.

How does it work?

We welcome requests for support in development of devices, apps and living aids. Also, we welcome requests for addition of marketed products for to our ‘Safe to Suggest’ list or ‘health and social care professional resource’ list.

We are happy to discuss your request – please use our dedicated inbox to contact us: devicesandapps@parkinsons.org.uk.

We request that all initial contacts are made through this channel and that our local groups are not contacted directly until the request has been assessed by Parkinson’s UK team.

We will ask you to complete a Support Request Form to give us information about your product/development programme and to outline the support you would like from Parkinson’s UK. We recommend applications for support are made as early as
possible and at least 6 weeks in advance of the required start date.

Each request for support is reviewed by the Parkinson’s UK devices, apps and living aids team. We will ascertain whether the technology has potential benefit for people affected by Parkinson’s. We will consider whether you have outlined a clear, useful purpose that fits our strategy and apply a quality assurance checklist. Depending on the stage of the project this may include: compliance with regulatory requirements, usability, ongoing sustainability, technical robustness and secure and transparent use of personal data. For requests regarding Parkinson’s UK support for use of a marketed product we may recommend referral to our external quality assessment partner to ensure it meets our required standards before offering in-house support for evaluation by people living with Parkinson’s.

We also need to fully understand how support from Parkinson’s UK can add value.

More details of the criteria we may apply are included on the flowchart in Appendix A. It will be at the discretion Parkinson’s UK whether the project is eligible for support and how this is provided.

Approved requests will be allocated to the appropriate team in the charity. A single point of contact within the charity will be provided so that you have continuity in communication with us regarding your project/s.

How we provide support varies depending on a number of factors and is at the discretion of Parkinson’s UK. We will have a written record, agreed by both parties, outlining the support to be provided (the format of this will be proportional to the level of support agreed).

Medical Devices

- Please refer to: [MHRA Decide if your product is a medicine or medical advice](#)

If your device/app/living aid is on (or should be on) the pathway to registration as a medical device it is likely to be allocated to the Parkinson’s UK Research Support Team. Please refer to the [Research Support Policy](#).

Non-medical devices/software applications/living aids

This may include concept, design and development, testing and validation, product review and dissemination of information. Support will be tailored to meet your objectives. This may include:

- **Feedback on concept/design**
  - User testing
  - Involvement of health and social care professionals
• Development
  Advice on feasibility of technical development programme and future product roadmap
  User input into usability/utility/practicality

• Testing and validation
  User testing in ‘real world’
  Potential for integration into clinical practice

We recommend that these activities are planned with input from people affected by Parkinson’s.

Consumer ready products

Technology for use by people living with Parkinson’s

• Adding to our ‘Safe to suggest list’

  Assessment for inclusion in our new public website area and resources about devices, apps and living aids.

Technology for use by health and social care professionals

• Adding to our Excellence Network Resource list

  Assessment for inclusion in the UK Parkinson’s Excellence Network resource directory. This does not include medical devices used in clinical decision making/clinical treatment which should be assessed through appropriate regulatory pathways.

  The first step is put forward the product for assessment by our external partner - this will incur a cost payable to the partner organisation for their assessment service. Products which meet the appropriate standards will be then be evaluated by our Parkinson’s UK panel of volunteer assessors. In the case of technology aimed at health and social care professionals, we will involve those professionals in review of the device/app/living aid.

Sale in our online shop

  For any queries regarding sale of a consumer ready product in our on-line shop or demonstration of a product at a Parkinson’s UK local group please contact our Product Manager
Working with commercial and non-commercial organisations

We welcome applications for support of development of devices, apps and living aids from both non-commercial and commercial organisations subject to the following criteria:

**Non-commercial Organisation Request**

Development teams should generally be affiliated with an appropriately accredited institution or enterprise which is supporting the development of this technology. We will not support projects which are not part of a development programme intended to deliver a final product to benefit people affected by Parkinson’s (for example student projects).

- Parkinson’s UK strongly recommends that support requests include the intention to refund reasonable out of pocket expenses incurred by volunteer contributors.

**Commercial organisation request**

This covers development undertaken by pharmaceutical, biotechnology, medical diagnostic and device industries.

Parkinson’s UK will need to know the name of the institution/company responsible for the product development and intended purpose of the technology for delivering benefit for people affected by Parkinson’s.

- Parkinson’s UK will only support commercial requests which cover all reasonable out of pocket expenses incurred by volunteers who contribute to the project.
- We will not undertake any support which may suggest that Parkinson’s UK is recommending a product to the community of people affected by Parkinson’s, although we will consider assessing the product for inclusion in our ‘safe to suggest’ list.

Development projects based outside the UK will be considered on an individual basis if associated with an accredited institution or an eligible commercial partner.

**Contacting local groups**

We request that all initial contacts regarding development, testing, demonstrating and sales of devices apps and living aids are made via our dedicated inbox and that our local groups are not contacted directly at this stage. Local groups should refer any such direct contacts to the dedicated inbox or to an individual member of the Parkinson’s UK team. If the request for support is not taken further by the team the option remains for individual members of local groups to decide to be involved in e.g. in usability testing. It is the responsibility of the organisation undertaking any activity with local group members to ensure that required ethical and governance standards are complied with. It is a requirement of Parkinson’s UK that there is no direct marketing of products through local groups without consulting our Product Manager.
Parkinson’s UK staff involvement

Any request for Parkinson’s UK staff to play a formal role in supporting your project, for example, as a co-applicant for funding or as member of a steering committee or advisory board, please contact the relevant Departmental Director at an early stage in the planning process. If you do not know who to contact please ask via our inbox: devicesandapps@parkinsons.org.uk

Governance issues

The developers and host institution or company are responsible for ensuring adherence to all relevant governance requirements including regulatory requirements where applicable.

If the support requested requires input from people affected by Parkinson’s, we will not pass on contact details of members, volunteers or research supporters to a third party until documented consent to contact has been obtained.

The use of the Parkinson’s UK name or logo must have prior written agreement. We will also seek permission before using any organisation name or logo.

Parkinson’s UK is not responsible for, and therefore is not liable for, any claims concerning negligence, harm or oversight that might arise during the course of your project. The host institution or company is responsible for maintaining appropriate policies of insurance covering personal indemnity, public liability and employer’s liability insurance.

The developers and host institution/company are responsible for ensuring that the people affected by Parkinson’s involved in the project are notified and aware of any information of a confidential nature that cannot be shared.

Market research

We will not consider support for market research (for example post market evaluations etc.) conducted solely for commercial purposes which would normally fall under the remit of a market research professional.

We are consulting our stakeholders as to whether it is appropriate for Parkinson’s UK to provide a platform to list market research opportunities.

Where can I find more information?

Contact us through our dedicated inbox devicesandapps@parkinsons.org.uk and we will contact you to discuss your project and how we can help.

If you are specifically looking for people affected by Parkinson’s to help shape your research you can find out more from our website:
If you are looking for Patient and Public Involvement contributors, find out more from:

Web: www.parkinsons.org.uk/researchinvolvement

If you are looking for people affected by Parkinson’s to Participate in your research, find out more from:

Web: www.parkinsons.org.uk/participation

For information about selling your product through our Online Shop please contact: please contact our product manager: Product Manager

Parkinson’s UK supports the UK Parkinson’s Excellence Network of health and social care professionals and we will work with its members where professionals’ involvement is needed. Find out more about the Excellence Network from:

Web: www.parkinsons.org.uk/excellencenetwork

When the project is completed

Feedback & Acknowledgement

If we agree to support your project, we require you to:

- If people affected by Parkinson’s have provided input as part of the support we ask that you send a plain English summary (Parkinson’s UK can help you to draft this) of the outcomes resulting from this support to your contributors/participants and Parkinson’s UK. We recommend that you provide this summary to Parkinson’s UK as soon as possible following the conclusion of the project.
- Acknowledge Parkinson’s UK support in any relevant publications and provide a copy of the publication to us.
- Give advance notice of any related media releases which happen within a year of the support provided.
- Complete a short ‘Impact Assessment and Feedback Survey’ so that Parkinson’s UK can assess and improve our Support Service.

Payments

Parkinson’s UK does not request any payment for the use of our resources in supporting your project.

Any additional payments made to people affected by Parkinson’s beyond out of pocket expenses are outside of the remit of Parkinson’s UK.

This policy has been developed in collaboration with people affected by Parkinson’s and will be reviewed on an ongoing basis.
Appendix A – Flowcharts

Consumer Ready Product

Adding to our ‘Safe to Suggest’ or ‘Healthcare Professional Resource’ lists
Product in development

Support for development of devices and apps

**Devices and apps defined as ‘work in progress’**

- **MAY REQUIRE REGISTRATION AS A MEDICAL DEVICE**
  - **RESEARCH**
    - See Research Policy

- **DOES NOT REQUIRE REGISTRATION AS A MEDICAL DEVICE**
  - **SELF-ASSESSMENT**
    - You'll need to fill out our questionnaire with details of your business and app/device to kick-start the assessment.
  - **NEEDS REVIEW**
    - We'll work out the level and types of support you might require from Parkinson's UK and whether we can offer it.

**Ways we might be able to support you**

- **FEEDBACK ON CONCEPT/DESIGN**
  - USER TESTING
  - INVOLVEMENT OF HEALTH & SOCIAL CARE PROFESSIONALS

- **VALIDATION**
  - TESTING IN ‘REAL WORLD’
  - POTENTIAL FOR INTEGRATION INTO CLINICAL PRACTICE

- **DEVELOPMENT**
  - FEASIBILITY ADVICE
  - PRODUCT ROADMAP ADVICE
  - USABILITY TESTING