PATIENT INCLUSION – FIRST STEPS
APDS Registry - a level 3 ESID Registry project

All essential documents for download: https://www.uniklinik-freiburg.de/cci/studien/apds-registry.html
For username and password please contact: annette.uhlmann@uniklinik-freiburg.de

Inclusion criteria

1. male and female patients with a PIK3CD or PK3R1 mutation, all ages
2. patients (or their legal representatives) able to communicate with the investigator, to understand and comply with the requirements of the registry project and to provide (or having provided) informed consent including the confirmation that the data may be used for industry-sponsored study

How to include a patient

1. Patient Consent: http://esid.org/Working-Parties/Registry/Informed-patient-consent
   - **Patients must sign the ESID Registry patient consent Version 3 or newer (France: CEREDIH consent)** – if the patient has signed this Version previously, no new consent required
   - let the consent be dated and signed by patient and investigator
   - give a copy of the signed document to patient, keep original in the patient record

2. Patient registration fax
   - Complete fax, date and sign; send to Clinical Research Unit (CRU) CCI by
     fax: +49 (0)761 270-74250 or by E-mail: annette.uhlmann@uniklinik-freiburg.de
   - shortly after you will receive the confirmation form with
     i. validation of patient eligibility
     ii. the APDS project-specific patient identification number. **Please use this number for documentation in ESID level 3 APDS registry and for marking each single page of APDS paper CRF.**

3. Patient identification log

   Note the APDS patient ID number in the patient identification log (template for download available) together with the patients ESID ID and the patients name, so that you can identify the patient during the whole documentation period. Please keep the log at your centre at a safe place! **The APDS patient ID number will be used in all future correspondence on this patient.**

How to document patient data

- log in in ESID registry online registry: https://cci-esid-reg.uniklinik-freiburg.de/EERS/login/auth
- in tab 'Studies' select 'APDS' and enter APDS patient ID
- complete all data fields until no 'flag' will be indicated any longer

You need further support? Please contact us

Study Physician:	For technical support:	For administrative support:
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