

REQUIREMENTS TO APPLY FOR DIGA REGISTRATION

- SECURITY ● QUALITY
- PRODUCT PERFORMANCE
- DATA PRIVACY ● DATA SECURITY
- CARE DELIVERY IMPROVEMENTS
- MEDICAL/HTA/OTHER BENEFITS

HEALTHCARE MARKET
240 BLN €
 PUBLIC SPENDINGS (2018)
73 MLN PATIENTS
 (STATUTORY HEALTH INSURANCE)

FAST TRACK

OFFERS THE CHANCE TO HAVE A DIGA REIMBURSED IN THE FIRST **12 MONTHS** AND TO USE THAT TIME WINDOW TO COLLECT THE NECESSARY SCIENTIFIC EVIDENCE IN A REAL-WORLD SETTING



ADDED VALUE OF THE DVG

- + CLEAR SET OF CRITERIA FOR LISTING/ENTRY INTO PUBLIC HEALTH MARKET
- + 12-MONTH TRIAL IN STANDARD CARE UNDER REAL CONDITIONS
- + FINAL DECISION: 12-24 MONTHS



CRITERIA

- ✓ MEDICAL PRODUCT CLASS I OR II A UNDER MDR
- ✓ MAIN FUNCTION RELIES ON DIGITAL TECHNOLOGIES
- ✓ INTEND USE IS CENTERED AROUND THE PATIENT, POSSIBLE TO INCLUDE THE DOCTOR
- ✓ PRODUCT FUNCTIONS:
 - DETECTION (MONITORING) ● TREATMENT
 - PALLIATION / ABATEMENT OF PAIN
 - COMPENSATION OF DISEASES
 - INJURIES ● DISABILITIES

GERMANY'S NEW LAW FOR DIGITAL HEALTH APPS SUMMER 2020



ANY DOCTOR IN GERMANY WILL BE ALLOWED TO PRESCRIBE HEALTH APPS



MORE INFO
WWW.HIH-2025.DE

DVG "DIGITALE VERSORGUNG GESETZ" MEANS DIGITAL HEALTHCARE ACT



UNDER THE NEW LEGISLATION

PRESCRIBED APPS CAN BE REIMBURSED BY THE COUNTRY'S STATUTORY HEALTH INSURANCE

DIGA DIGITAL HEALTH APPLICATION (DIGITALE GESUNDHEITSANWENDUNGEN)