NASH CASE STUDY

# Tackling the specificities of NASH/MASH clinical trials

Kayentis

Global eCOA & DCT provider

**Only 5%** of all NASH clinical trial registered protocols **report PROs as outcomes of interest**

## NASH-CHECK is the only NASH-specific PRO

as of today, and is reported in only **0.6%** of all NASH protocols

## Integrating PROs into studies on NASH is crucial

NASH is a debilitating chronic illness that significantly impairs patients' quality of life, affecting their daily routines, work, and mobility

- ✓ Patient-centric appraisals are needed in the quest for treatments
- ✓ Integrating PROs in NASH studies expands insights beyond NASH metrics, and helps understand NASH patients' concerns

Source: https://clinicaltrials.gov/

# KAYENTIS KEY SUCCESS FACTORS

## for NASH/MASH clinical trials

## Kayentis has extensive experience in NASH/NAFLD and hepatic disorders research

- ✓ **Numerous studies in NASH, liver fibrosis, acute and chronic liver failure (ACLF), and autoimmune hepatitis**
- ✓ **From early phase to Phase 4 studies involving dozens to thousands of study participants worldwide**
- ✓ **Implementation of a huge volume of relevant questionnaires, including the NASH-CHECK PRO, a 31-item questionnaire with:**
  - 10 items assessing symptoms, using 11-point numerical rating scales (NRSs) ranging from 0 to 10
  - 21 items assessing HRQoL, grouped into activity limitations (8 items) and emotions and lifestyle (13 items)

## Kayentis' enhanced patient-centric eCOA data entry

- **Highly flexible data entry, tailored to meet patients' individual needs:** Provisioned Devices, WebCOA, BYOD, and remote interview mode

- **A user-friendly solution featuring additional features for the comfort of the patient:**
  - A **televisit** option directly embedded in our eCOA app: very helpful when the patient cannot go to the site (eg, if patients are very sick or physically debilitated)
  - An **embedded media player** giving patients direct access to clear and simple information
  - **eDiary customizable alerts**: increased flexibility according to the patient's own schedule
  - The "**Participant Feedback Questionnaire**", giving a voice to the patient regarding their study experience

## Kayentis, a key partner to biotech and big pharma companies

- **eCOA expert since 2005**

- **A customer-centric approach,** with a dedicated governance team to ensure alignment with client standards and expectations

- **End-to-end project management excellence**, with:
  - Early cross-functional **review of every protocol**
  - Highly qualified (PhD, PharmD, MSc) and clinically focused Project Managers
  - **Operational scalability**, with strong processes to streamline set-up, maintenance, and close-out activities
  - **Strong data management expertise**, with data managers involved from the very start
  - **Worldwide logistics and 24/7 helpdesk**

# Kayentis, global eCOA & DCT provider

## Broad experience...

Since **2005**
eCOA expert

**300+**
clinical trials phase I-IV

**20**
different therapeutic areas

## ...in a wide range of study types

From **15** patients in an early phase trial to **+10,000** in a late-phase study

From local to global studies **100%** of countries covered

Studies lasting **up to 10** years

## ...with strong scientific and operational support

**Clinical & Scientific**
dedicated team to support your study

**Operational capabilities**
USA - Europe - Asia

**24/7**
HELPDESK

Kayentis

To learn more, please contact us at sales@kayentis.com