

P2.361: Effectiveness of Lorlatinib as Real-World First-Line Treatment in ALK-Positive Advanced or Metastatic NSCLC in Germany (LORALK)

Frank Griesinger¹, Karsten Schulmann², Lothar Müller³, Martin Mänz⁴, Gina Rüter⁵, Mischo Kursar⁴

¹Pius-Hospital, Oldenburg, ²DGD Lungenklinik Hemer, Hemer, ³Praxis Onkologie UnterEms, Leer, ⁴AIO-Studien-gGmbH, Berlin, ⁵Pfizer, Berlin

Correspondence: frank.griesinger@uni-oldenburg.de

AIO-Studien-gGmbH



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BACKGROUND & OBJECTIVES

The CROWN trial¹⁻³ demonstrated that the third-generation anaplastic lymphoma kinase (ALK) tyrosine kinase inhibitor lorlatinib significantly improved progression-free survival (PFS) compared with crizotinib in patients with previously untreated ALK+ advanced or metastatic non-small cell lung cancer (aNSCLC), with a notable durable disease control, including a protective effect against brain metastases and a manageable safety profile. Based on these results and current German guideline recommendations, lorlatinib is a preferred first-line treatment option for patients with ALK+ aNSCLC^{4,5}. However, prospective real-world data on treatment outcomes, tolerability, and quality of life associated with first-line lorlatinib remain limited. LORALK is a German observational, non-interventional, prospective, multicenter study designed to generate prospective real-world evidence on first-line lorlatinib treatment in routine clinical care.

STUDY SITES

- EU Post Authorization Study register number: EUPAS1000000583
- Target enrollment: ~70 patients from ~25 German oncology centers (22 sites identified; Fig. 1)

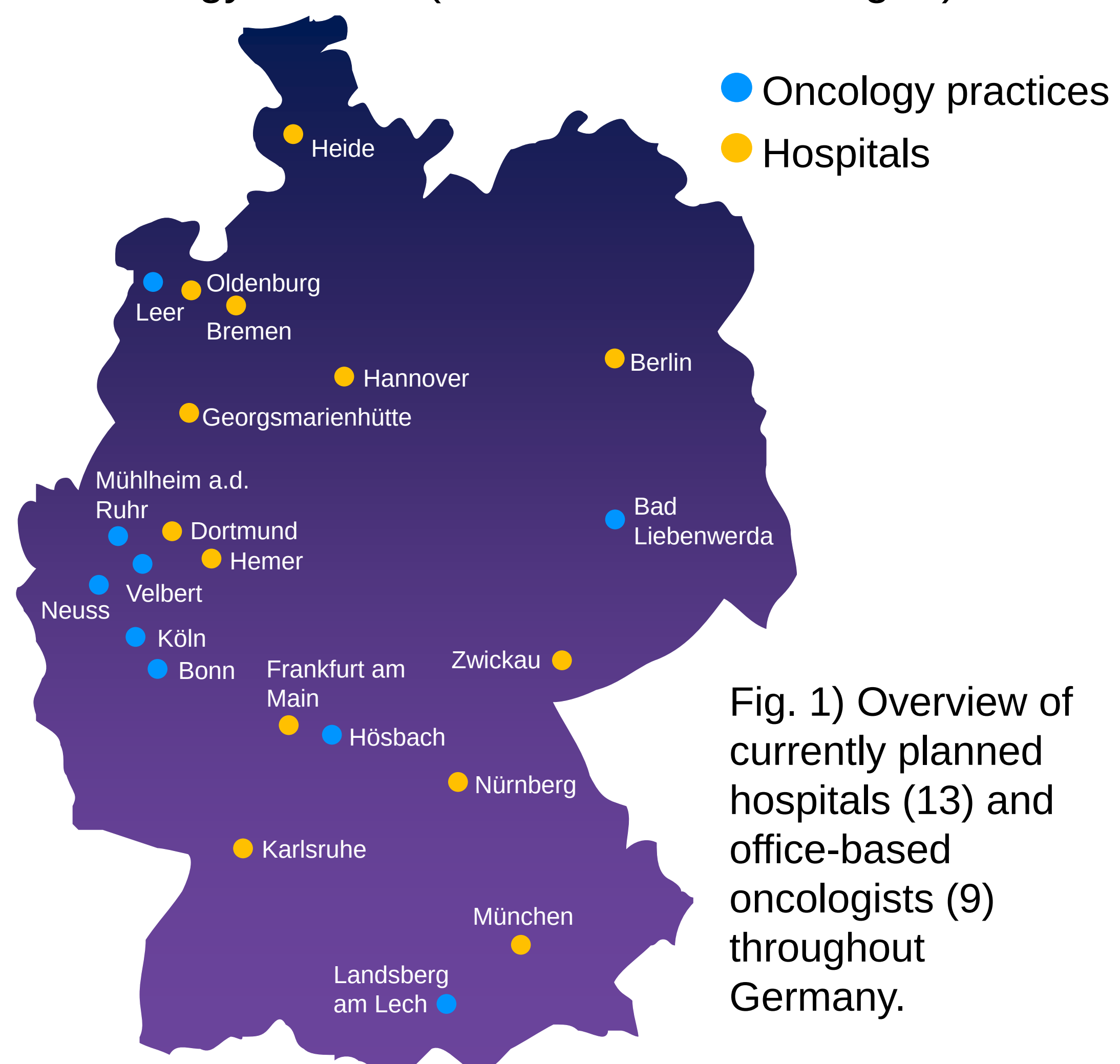


Fig. 1) Overview of currently planned hospitals (13) and office-based oncologists (9) throughout Germany.

REAL-WORLD ENDPOINTS*



Real-World (rw) Effectiveness

Primary endpoint

- Progression-free survival at 18 months (rw-PFS)
- Time to next treatment (TTNT)

Tumor control

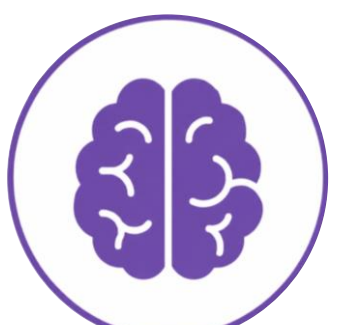
- Objective response rate (rw-ORR)
- Disease control rate (rw-DCR)
- Duration of response (rw-DOR)

CNS Outcomes

- Intracranial response rate (IC-RR)
- Intracranial time to progression (IC-TTP)
- Cumulative incidence of brain metastases

Treatment outcomes

- Duration of treatment (rw-DOT)
- Overall survival (rw-OS)



Safety

- Treatment-related AEs, including metabolic events, peripheral neuropathy and CNS effects based on CTCAE v6
- Dose modifications & interruptions



Quality of life (QoL)

Online collection of:

- EORTC QLQ-C30 → to assess quality of life in cancer patients
- EORTC QLQ-LC13 → complementary used to assess quality of life in lung cancer patients
- WPAI:GH → to assess impairments in paid and unpaid work

*list is not exhaustive

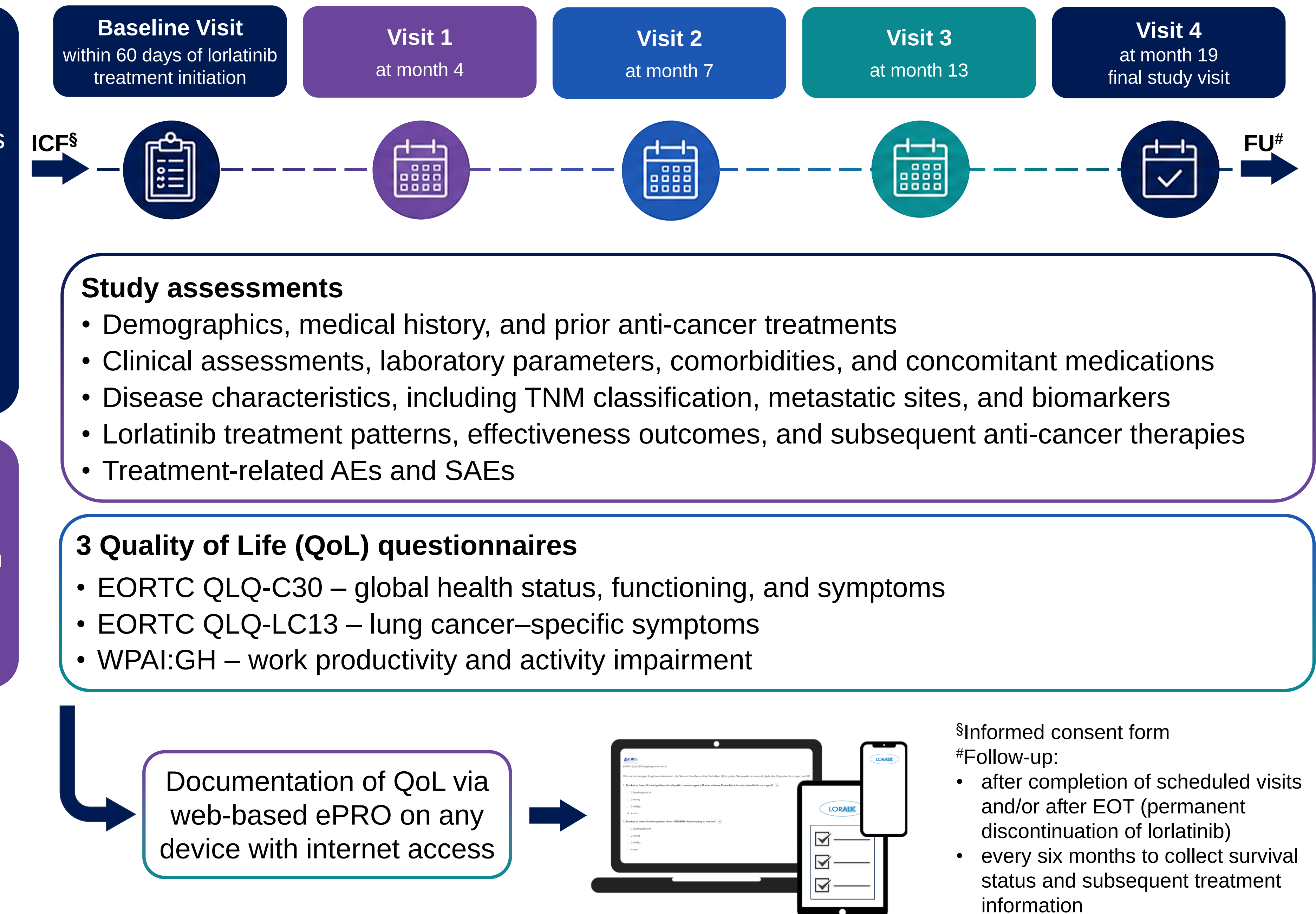
STATUS

- Study activation ongoing; additional sites may be added.
- Patient recruitment and data collection are planned to start in August 2026.
- Period of data collection: ~41 months
- Interim analysis: planned after 18 months

STUDY DESIGN

~70 patients with ALK+ aNSCLC enrolled across oncology centers in Germany

First-line lorlatinib in routine clinical practice



STATISTICAL CONSIDERATIONS

- Descriptive, non-interventional study without formal hypothesis testing
- Sample size is based on the expected feasibility of recruiting patients with ALK+ aNSCLC in routine clinical practice in Germany
- Time-to-event endpoints analyzed using Kaplan–Meier methods with 95% confidence intervals
- Binary endpoints summarized as proportions with exact 95% confidence intervals

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