Poster # P092

VOYAGER: A Real-world Study of Faricimab in Patients With nAMD and DMO

Clare Bailey, MD, FRCP, FRCOphth[1]; Monica Bengus, MD[2]; Usha Chakravarthy, FRCOphth, PhD, CBE[3]; Gloria C. Chi, PhD, MPH[4]; Stefan Scheidl, MSc, PhD[2]; Richard Pohler, PhD[5]; Adam Wilson, MSc[6]; Melanie Dodds, BSc[7]; and Robyn Guymer, AM, MBBS, PhD[8]

On Behalf of the VOYAGER Study Steering Committee

[1] Bristol Eye Hospital, University Hospitals Bristol and Weston, NHS Foundation Trust, Bristol, UK; [2] F. Hoffmann-La Roche Ltd., Basel, Switzerland; [3] Queen's University of Belfast, Royal Victoria Hospital, Belfast, Northern Ireland; [4] Genentech, Inc., South San Francisco, CA, USA; [5] Roche Products Ltd., Welwyn Garden City, UK; [6] IQVIA, London, UK; [7] Medisoft, Leeds, UK; [8] Centre for Eye Research Australia, Royal Victorian Eye and Ear Hospital, University of Melbourne, Melbourne, Australia

Key Clinical Questions

- What is the long-term effectiveness and safety of faricimab and the Port Delivery System with ranibizumab (PDS) in real-world clinical practice, and how is effectiveness impacted by treatment regimen/philosophy and anatomical factors?
- Can E2e, an automated transfer from electronic medical records (EMR) to electronic data capture (EDC) solution, reduce study site data entry burden and improve data quality?

Conclusions

VOYAGER will close evidence gaps between clinical study and real-world outcomes by evaluating longer term outcomes with faricimab and the PDS and how treatment regimens/ philosophies and anatomical factors affect outcomes

The novel Investigator Interface will help clinicians monitor disease evolution at the individual patient level to better inform treatment decisions

The data collected in VOYAGER will be critical to providing optimal long-term benefits to patients with neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DMO)

The EMR to EDC solution could improve efficiency and data quality by reducing data entry burden and human transcription errors

If successful, EMR to EDC could be expanded to other VOYAGER study sites and could be used for further studies

Presented at The Royal College of Ophthalmologists Annual Congress Birmingham, UK | 22–25 May 2023

Results

1. VOYAGER Study Rationale and Key Outputs

Explore **long-term effectiveness and safety** in the real-world setting

Gain insights into **real-world treatment patterns** and factors driving **clinician treatment decisions**

Provide a novel **Investigator Interface** that will allow **HCPs** to gain a **complete picture of individual response** to **optimise individual treatment**

Gather imaging data to validate **key anatomical features** that influence **visual outcomes**

The VOYAGER study will provide a unique opportunity to see how faricimab and the PDS are being used in the real world and to provide meaningful long-term data and resources to optimise their use in the real world

HCP, healthcare provider; PDS, Port Delivery System with ranibizumab.

2. Patient Eligibility and Products in Scope

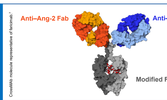
Inclusion Criteria:

☑ Adult patients being treated with faricimab or the PDS for nAMD or DMO
(Products and/or indications in scope for the VOYAGER study to be updated as new products and/or indications are approved.)

Exclusion Criteria:

☒ Participation in an interventional ophthalmology clinical trial within 28 days prior to enrolment

Faricimab
A bi-specific antibody which simultaneously inhibits VEGF and Ang-2[a]



Approved in **multiple countries worldwide** for **nAMD** and **DMO**[8,9]

PDS
A permanent refillable ocular implant delivering a continuous supply of ranibizumab (anti-VEGF)[10]

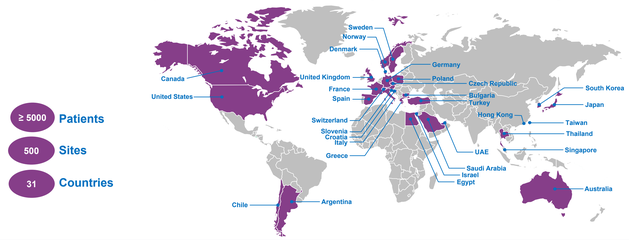


Approved in the **United States** for **nAMD** in adults who have previously responded to ≥ 2 anti-VEGF injections[11,a,b]

Please note currently PDS implantations are paused including in ongoing global clinical trials

[a] The FDA has issued a **boxed warning** for the PDS because it has been associated with a 3-fold higher rate of endophthalmitis compared with monthly intravitreal injections of ranibizumab. [b] Roche/Genentech has voluntarily recalled the PDS (Susvimo) Ocular Implant and Insertion Tool Assembly, including the ranibizumab drug vial and initial fill needle (lot numbers 3499188 and 3523071), which are sold together, and paused implantations including in ongoing global clinical trials.
Ang-2, angiopoietin-2; DMO, diabetic macular oedema; Fab, fragment antigen binding; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery System with ranibizumab; VEGF, vascular endothelial growth factor.

3. The VOYAGER Study Will Obtain Data From a Variety of Clinical Practice Settings



UAE, United Arab Emirates.

4. VOYAGER Study Objectives and Endpoints

Primary Effectiveness Objective

To evaluate the **effectiveness** of faricimab and the PDS in their approved retinal indications on **VA at 12 months** in the real-world setting

Primary Endpoint

Change in VA (approximate ETDRS letter score) from baseline at month 12, per eye, per approved retinal indication and per product

Key Secondary and Exploratory Objectives

- To evaluate the **effectiveness** of faricimab and the PDS for their approved retinal indications on VA at specified intervals up to **5 years**
- To describe **retinal treatment patterns**
- To evaluate **changes in VA over time** in relation to:
  - Number of treatments/**treatment patterns**
  - Investigator-determined **disease activity**
  - Presence/location of **fluid**
  - Additional **nAMD- and DMO-specific** anatomical changes, such as fibrosis, atrophy and DRIL
    - The proportion and location of **anatomical features**

Safety Objective

To evaluate **ocular and systemic safety and tolerability** of faricimab and the PDS in their approved retinal indications in the real-world setting

DMO, diabetic macular oedema; DRIL, disorganisation of retinal inner layers; ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery System with ranibizumab; VA, visual acuity.

5. EMR to EDC (E2e): *An Automated Solution to Collect VOYAGER Study Data*

Data Entry Challenges Experienced in Conventional Studies

Data entry **time burden**

Data susceptible to **transcription errors, duplications and missing data**

The EMR to EDC (E2e) Solution

An automated solution that takes selected pre-existing medical information from a consented patient's EMR and automatically enters the data into the EDC



Data That Will be Automatically* Transferred

Baseline Visit
Demographic characteristics
Prior anti-VEGF treatment
Other treatment or procedure
Non-ocular medical history
Other ocular medical history

Baseline and Observational Visits
DMO/nAMD lesion characteristics
VA score
Image assessments

Observational Visits
HbA1c
Current treatment/management

* Subject to short delay, depending on local clinical workflow. DMO, diabetic macular oedema; E2e, EMR to EDC; EDC, electronic data capture; EMR, electronic medical records; HbA1c, haemoglobin A1c; nAMD, neovascular age-related macular degeneration; VA, visual acuity; VEGF, vascular endothelial growth factor.

6. The EMR to EDC Pilot Study: *A Small-Scale Pilot Study in 2 NHS Sites in VOYAGER*

Aim

To establish if the EMR to EDC solution:
- Can **reduce site data entry burden**
- Is **viewed as beneficial** by study site staff

Success Metrics

1. **Percentage of data points** in study EDC that are pre-populated by E2e vs manually entered
2. **Site staff time spent on data entry** for E2e pre-populated patients vs manually entered
3. **Site staff perception of E2e solution**, collected by short survey at 2 points in pilot

Potential Benefits

1. Reduction in data entry burden
2. Early access to EMR to EDC
3. Access to updated EMR
4. Involvement in publications
5. Collaborate with Roche/IQVIA/Medisoft on future EMR to EDC studies

Details About the EMR to EDC Set-up:

- **No extra Hardware/Software is required to be installed at study sites**
- **EMR to EDC capabilities built in to mediSIGHT EMR (V1.21+)**
- **Manually entered data will not be overwritten by pre-populated data**
- **Pre-populated data can be overwritten by manually entered data**

E2e, EMR to EDC; EDC, electronic data capture; EMR, electronic medical records; NHS, National Health Service.

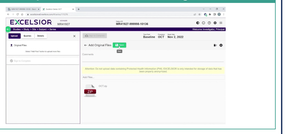
7. VOYAGER Ecosystem

Investigator Interface ⇄ **Navigates to eCRF to add new patient or add data to existing patient** ⇐ **EMR data is transferred automatically into the CRF (pilot at 2 UK sites using mediSIGHT EMR)**

Visualise longitudinal data



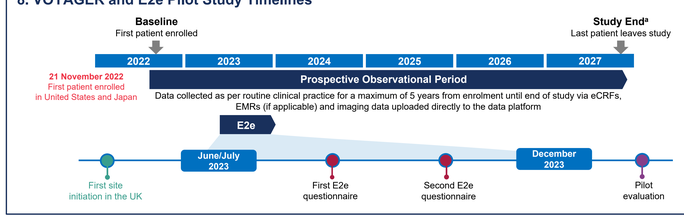
Upload OCTs and other images[a]



Collaboration Network:
A community of investigators who collaborate and initiate new sub-studies (globally, regionally, nationally)

[a] Images collected for future AI analytic tools and assessments include: colour fundus photography, fundus fluorescein angiography, indocyanine green angiography, spectral-domain OCT, spectral-domain OCT angiography, swept-source OCT, swept-source OCT angiography.
AI, artificial intelligence; eCRF, electronic case report form; EMR, electronic medical records; OCT, optical coherence tomography.

8. VOYAGER and E2e Pilot Study Timelines



[a] Study end: Study completion or end of termination defined as death, loss to follow-up, withdrawal of consent, participation in an investigational ophthalmology clinical trial, early termination of the study, or discontinuation of the study site, whichever occurs first.
E2e, EMR to EDC; eCRF, electronic case report form; EDC, electronic data capture; EMR, electronic medical record.

Introduction

- Vision gains achieved with anti–vascular endothelial growth factor agents in clinical practice often fall short of those achieved in clinical trials[1]
- Potential reasons for this disparity include:
  - Inadequate treatment frequency[2]
  - Inability to replicate clinical trial protocols[3]
  - Greater diversity in real-world populations[4]
  - Variable interpretation of disease activity[5] and implementation of treatment approaches[6]
- VOYAGER (NCT05476926) is an observational, prospective, multinational, multicentre study designed to collect primary functional, anatomic, imaging and safety data, and to gain clinical insights into real-world treatment patterns and outcomes in patients receiving faricimab and the PDS for their approved indications

Methods

- Patients who are currently receiving or initiating treatment with faricimab or the PDS for their approved retinal indications in routine clinical practice will be observed for 2–5 years
- Patient visits will be conducted according to routine local clinical practice and data will be recorded on electronic case report forms and stored in a research database
- Variables being collected include visual acuity (VA), imaging assessments, clinical decisions/management, treatment patterns and safety events
- Routinely captured images, including optical coherence tomography, will be uploaded to evaluate retinal fluid and anatomical biomarkers impacting VA
- Two UK sites using mediSIGHT EMR will pilot an innovative data entry solution, which auto-transcribes consented data from EMR to EDC (E2e), over approximately 6 months

References

1. Falcão M. *Ophthalmologica*. 2020;243:243-254. **2.** Ciulla TA et al. *Br J Ophthalmol*. 2021;105(2): 216-221. **3.** Giocanti-Aurégan A et al. *Patient Prefer Adherence*. 2022;16:587-604. **4.** Ziemssen F et al. *BMC Ophthalmol*. 2017;17(1):7. **5.** Neely DC et al. *JAMA Ophthalmol*. 2017;135(6):570-575. **6.** Hahn P, Garg SJ. 2022. ASRS Global Trends in Retina. Accessed November 25, 2022. https://www.asrs.org/content/ documents/2022-asrs-global-trends-in-retina-survey.pdf. **7.** Regula JT et al. *EMBO Mol Med*. 2016;8(11):1265-1288, with erratum in Regula JT et al. *EMBO Mol Med*. 2019;11(5):e10666. **8.** Vabysmo [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2023. **9.** Vabysmo [SMPC]. Grenzach-Whylen, Germany: Roche Pharma AG; 2022. **10.** Holekamp NM et al. *Ophthalmology*. 2022;129(3):295-307. **11.** Susvimo [prescribing information]. South San Francisco, CA: Genentech, Inc.; 2022.

Acknowledgements

The authors would like to thank Laia Vidal, Juliet Ellis, Jaroslaw Turowski, Alicja Stempa, Marcin Okula, Michael Krupnick (all IQVIA employees), and Medisoft Limited for their contributions.

Disclosures

CB: Consultant: Alimera Sciences, Bayer, Boehringer Ingelheim, Janssen, Novartis, Roche; **MB, SS:** Employee: F. Hoffman-La Roche Ltd.; **UC:** Consultant: Apellis, Boehringer Ingelheim, Iveric Bio, Novartis, Roche; Data and Safety Monitoring Committee: Bayer; Former Chair: Photon, Pulsar; Visiting Chair: Roche; **GC:** Genentech, Inc.; **RP:** Employee: Roche Products Ltd.; **AW:** Employee: IQVIA; **MD:** Employee: Medisoft; **RG:** Consultant: Apellis, Bayer, Belite Bio, Boehringer Ingelheim Pharmaceuticals, Character Bioscience, Novartis, Ocular Therapeutix, Roche/Genentech, Inc.

Study and Product Disclosures

- Faricimab is approved for the treatment of neovascular age-related macular degeneration and diabetic macular oedema in multiple countries worldwide and is not currently approved for use outside these indications
- The Port Delivery System with ranibizumab (PDS) has been approved by the US Food and Drug Administration for the treatment of nAMD in adults who have previously responded to ≥ 2 anti-VEGF injections. Please note that the PDS has not been approved for use outside of the United States
  - **Roche/Genentech has voluntarily recalled the PDS (Susvimo) Ocular Implant and Insertion Tool Assembly, including the ranibizumab drug vial and initial fill needle (lot numbers 3499188 and 3523071), which are sold together, and paused implantations including in ongoing global clinical trials**
- **The US Food and Drug Administration has issued a boxed warning for the PDS because it has been associated with a 3-fold higher rate of endophthalmitis compared with monthly intravitreal injections of ranibizumab[7]**
- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation

- Funding was provided by F. Hoffmann-La Roche Ltd. for the study and third-party writing assistance, which was provided by Nicole Tom, PhD, of Envision Pharma Group