The road to Esther Race:
Freelance Medical Writer

...and what it’s like now I’m here

Esther Race: Freelance Medical Writer
A twisted road to medical writing...

- Plymouth Poly - BSc (Hons), Biological Sciences
- Various lab technician jobs
- London Hospital Medical College
  - PhD: Development of a whole inactivated HIV vaccine
  - Retroscreen (now “hvivo”)
- Roche Products – team leader (3 yrs)
  - Saquinavir NDA and market support
- INSERM U13 (Bichat Hospital), Paris (4 yrs)
  - Viralliance - Operations Director (now ONXEO)

...
A scenic trip through agency life

**Where/what**

- Medical Writer (Home/London)
- Chief Medical Writer (Home/London)
- Untitled (Oxford)
- Scientific Advisor (Oxford)
- Company Director (Home)

**Learned/liked/disliked...**

- What Med Comms is about
- Adapting to the audience
- Taking the s@*t (red pen and process)
- Extending the message
- The thrills and spills of on site
- Conflict houses and company growing pains
- The impact of a flat structure
- New therapy areas are not difficult
- What those client services people do...
- Big office/little office
- Changing landscape of med comms
- Enough of “working for the man”
- Freelance is much easier than you think
- It’s a small world
- When to say no
Abstract

OBJECTIVE: Faldaprevir is a potent, once-daily hepatitis C virus (HCV) NS3/4A protease inhibitor. STARTVerso4 assessed the efficacy and safety of faldaprevir and response-guided pegylated interferon α-2a/ribavirin (PegIFN/RBV) in individuals with HCV/HIV co-infection.

DESIGN: A phase 3 open-label study (NCT01399619).

METHODS: Individuals (N=308) co-infected with HCV genotype 1 (treatment-naive or prior interferon relapsers) and HIV (96% on antiretroviral therapy (ART)) received faldaprevir 120mg (N=123) or 240mg (N=185) and PegIFN/RBV. Those receiving a protease inhibitor or efavirenz ART were assigned to faldaprevir 120 or 240mg, respectively. Individuals achieving early treatment success (ETS; HCV RNA <25 IU/ml at week 4 and undetectable at week 8) were randomized to 24 or 48 weeks of PegIFN/RBV. The primary endpoint was sustained virologic response 12 weeks after treatment (SVR12).

RESULTS: SVR12 was achieved in 221 (72%) individuals, and the rates were comparable across faldaprevir doses. ETS was achieved in 80%, and of these 86% achieved SVR12, with comparable rates with 24 and 48 weeks of PegIFN/RBV (87 and 94%, respectively). In multivariate analysis, age below 40 years, IL28B CC genotype, and baseline HCV RNA below 800,000IU/ml were associated with SVR12 (P=0.027, P<0.0001, and P=0.0002, respectively), whereas treatment (ART regimen and faldaprevir dose), liver cirrhosis, and genotype 1 subtype were not. The safety profile was comparable to that of faldaprevir in HCV-monoinfected individuals.

CONCLUSIONS: High SVR12 rates were achieved with faldaprevir and PegIFN/RBV in HIV/HCV co-infected individuals, regardless of faldaprevir dose and background ART, HCV genotype 1 subtype, or cirrhosis status. SVR rates mirrored those obtained with similar regimens in HCV monoinfected individuals.
Bread and butter Clinical study publications

**Clinical Study Protocol**
- Advisory boards
- Clinical study kit
- Investigator meetings
- Investigator updates

**Results**
- Internal data review
- Abstract
- Poster/oral
- Manuscript

**Internal communications**
- Internal news letters
- Internal Q & A
- Objection handler
- Training slides

**Wider external communications**
- Press release
- Conference materials/symposia
- Sub-analyses
- Review papers
STARTVerso4: CSR to publication

• CSR

3857 pages  
(without appendices)
STARTVerso4: CSR to publication

- CSR
- Data review meeting
- Abstracts (interim analysis, final analysis, subanalyses..)
  - Kick-off meeting
STARTVerso4: CSR to publication

- CSR
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- Abstracts (interim analysis, final analysis, subanalyses..)
- Kick-off meeting
- Draft, review – wordsmith
- Submission

Proposed abstract category: 500 HCV Therapy and Trials: New Agents (phase 2 – 3)

Word limits: Title: 255 characters (currently 171); Main body: 2700 characters, including spaces (currently 2070) (Table counted as 50 characters per row = 300)

STARTVerso4-Phase III trial of faldaprevir plus peg-interferon alpha 2a and ribavirin (PR) in patients with HIV and HCV genotype 1T results: end of treatment response

Jurgen Kurt Rockstroh1, Mark Nelson1, Vincenzo Sorano2, Kazemehr Aresteh2, Josef Guarinola3, Sanjay Bhagani3, Jose Malillas4, Cristina Turr1, Massimo Puet1, Patrice Ingiliz1, Manuel Battegay1, Maria K. Jain5, Marine Nunez5, Kilian Marks6, Jens Kort1, Jerry Stern5, Richard Vinski1, Montserrat Manero4, Douglas Gienshardt7

1University of Bonn, Bonn, Germany; 2Chelsea and Westminster Hospital, London, UK; 3Hospital Carlos III, Madrid, Spain; 4EINFED, Monza, Bergamo, Italy; 5Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; 6Royal Free Hospital, London, UK; 7Hospital Clinic, Barcelona, Spain; 8Hospital Universitari Germans Trias i Pujol, Barcelona, Spain; 9IO Grillo Hospital, Genoa, Genoa, Italy; 10Medizinisches Institut, Berlin (MIB), Berlin, Germany; 11Division of Infectious Diseases and Hospital Epidemiology, Basel, Switzerland; 12UT Southwestern Medical Center, Dallas, TX, USA; 13Wake Forest University, Winston-Salem, NC, USA; 14Wall-Cornell Medical College, New York, NY, USA; 15Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, USA; 16Boehringer Ingelheim, Espasa S.A., Barcelona, Spain; 17Mount Sinai School of Medicine, New York, NY, USA

Background

Faldaprevir (FDV) is a potent, once-daily HCV NS3/4A protease inhibitor. The objective of the STARTVerso4-5 study is to assess efficacy and safety of FDV plus PR and evaluate a 24-week (T14) shortened treatment duration in HIV patients co-infected with chronic HCV genotype 1T.

Methods

SV1 is an open-label, sponsor-blinded study in HIV/HCV co-infected patients who were HCV treatment-naive (T14) or relapsed after previous HCV therapy. Arm A: patients received FDV 120 mg OD and PR for 24 weeks; Arm B: patients received FDV 240 mg OD plus PR for 12 weeks...
STARTVerso4: CSR to publication

- CSR
- Data review meeting
- Abstracts (interim analysis, final analysis, subanalyses..)
  - Kick-off meeting
  - Draft, review, submission
- Slides and posters
  - Kick-off meeting
  - Drafts, review, submission/presentation
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  • Drafts, review, submission/presentation
• Manuscript
  • Outline
  • First draft
  • Second draft........xth draft
  • Submission draft (formatting, figures, reference updates)
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- Manuscript
  - Outline
  - First draft
  - Second draft........xth draft
  - Submission draft (formatting, figures, reference updates)
  - Reviewers comments, resubmission, page proofs
STARTVerso4: CSR to publication
Dear Author,

During the preparation of your manuscript for submission, some queries have arisen. These are listed below. Please check your typescript carefully and mark any corrections in the margin. As usual, as many as possible, or complete them as a separate list. This form should then be returned with your marked proofs list of corrections to the Production Editor.

1. Query: As a style, the short title should be limited to 65 characters including spaces and author names, and abbreviations or acronyms are not allowed. Please check the suggested running head for abbreviations and ensure that no expansion is exceeding the permissible character limit.

   Response: As per note, study names should not appear in article titles. Please provide an alternative title without the study name. Please provide the full terms of the following acronyms: PEP, SPF, EASL, and UCL.

2. Query: Please provide complete bibliographic details such as volume, year of publication, and page range for Refs. 8 and 14.

   Response: Please update Ref. 8, if possible, by providing complete publication details such as volume, year of publication, and page range.

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Jam – nice and/or sticky

- Objection handlers and Q and As
- Conference reports
- Symposia and stand alone meetings
  - Concept, agenda, content
  - Meeting in a box
- Internal review papers/reports
- E-learning
- Websites
- Proofing and data checking
...and what it’s like now I’m here

Benefits
• Flexibility
• Variety
  • Field, project, client
• Comfort and challenge
• Work-life balance

Risks
• Flexibility
• Isolation
• Deadline pile up
• Work-life balance

Questions?