The road to

RacEditorial Ltd

…and what I learned along the way

Esther Race: Freelance Medical Writer

The road to RacEditorial Ltd

- How I got here
- What I do
- Why I like it (…or…)

The road to RacEditorial Ltd

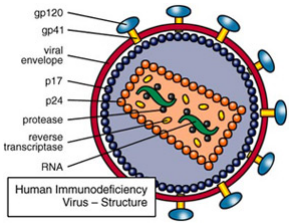
- How I got here – a bit about me

A twisted road to medical writing…

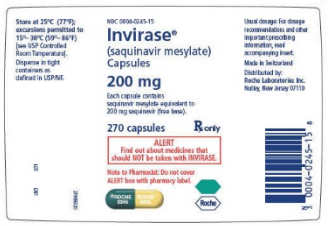
1984

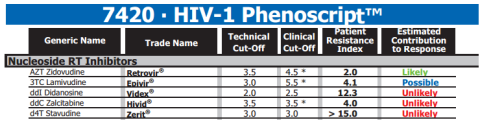
- Plymouth Poly - BSc (Hons), Biological Sciences
- Various lab technician jobs

- London Hospital Medical College
  - PhD: Development of a whole inactivated HIV vaccine



- Team leader, Roche Products, WGC (3 yrs)
- INSERM U13 (Bichat Hospital), Paris (2 yrs)
- Co-founder, Viralliance, Paris (2 yrs)





7420 · HIV-1 Phenoscript™

Generic Name	Trade Name	Technical Cut-Off	Clinical Cut-Off	Patient Resistance Index	Estimated Contribution to Response
Nucleoside RT Inhibitors					
AZT Zidovudine	Retrovir®	3.5	4.5 *	**2.0**	Likely
3TC Lamivudine	Epivir®	3.0	5.5 *	**4.1**	Possible
ddI Didanosine	Videx®	2.0	2.5	**12.3**	Unlikely
ddC Zalcitabine	Hivid®	3.5	3.5 *	**4.0**	Unlikely
d4T Stavudine	Zerit®	3.0	3.0	**> 15.0**	Unlikely

2002

INTERNATIONAL MEDICAL PRESS

?

A trip through agency life

Where/what	Learned/liked/disliked…
• Medical Writer (Home/London)	• What Med Comms is about • Adapting to the audience • Taking the s@*t (red pen and process)
• Chief Medical Writer (Home/London)	• Extending the message • The thrills and spills of on site • Conflict houses and company growing pains
• Untitled (Oxford)	• The impact of a flat structure • New therapy areas are not difficult • What those client services people do
• Scientific Advisor (Oxford)	• Big office/little office • Changing landscape of med comms • A corporate life is not for me
• Company Director (Home)	• Freelance is much easier than you think • It's a small world • When to say no

The road to RacEditorial Ltd

- How I got here
- What I do – a case study

What I do: STARTVerso4, from concept to primary publication

Abstract ▾ Send to: ▾

AIDS. 2015 Mar 13;29(5):571-81. doi: 10.1097/QAD.0000000000000579.

Faldaprevir and pegylated interferon α-2a/ribavirin in individuals co-infected with hepatitis C virus genotype-1 and HIV.

Dieterich D[1], Nelson M, Soriano V, Arastéh K, Guardiola JM, Rockstroh JK, Bhagani S, Laguno M, Tural C, Ingiliz P, Jain MK, Stern JO, Manero M, Vinisko R, Kort J; STARTVerso4 study group.

⊕ **Author information**

15 named authors

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 <25IU/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).

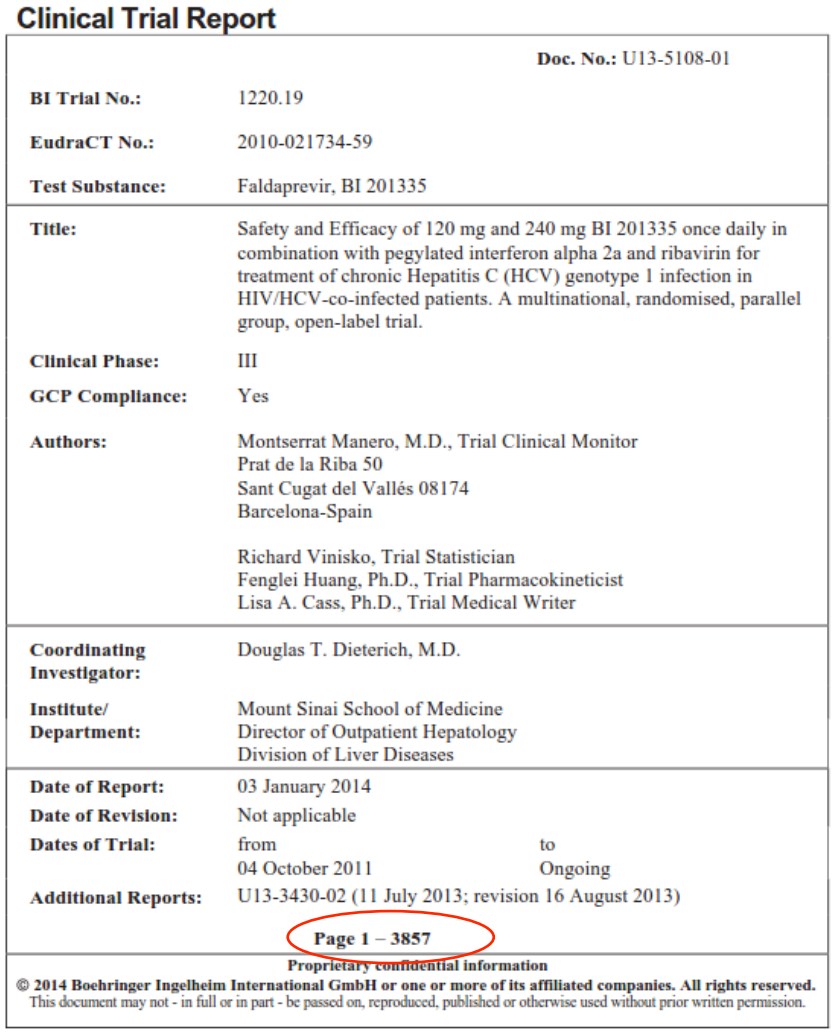
RESULTS: SVR12 was achieved in 221 (72%) individuals, and the rates were comparable across faldaprevir doses. ETS was achieved in 80%, and of these 86% achieved SVR12, with comparable rates with 24 and 48 weeks of PegIFN/RBV (87 and 94%, respectively). In multivariate analysis, age below 40 years, IL28B CC genotype, and baseline HCV RNA below 800000IU/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.

STARTVerso4
From concept to primary publication

- CSR

3857 pages
(without appendices)



Clinical Trial Report

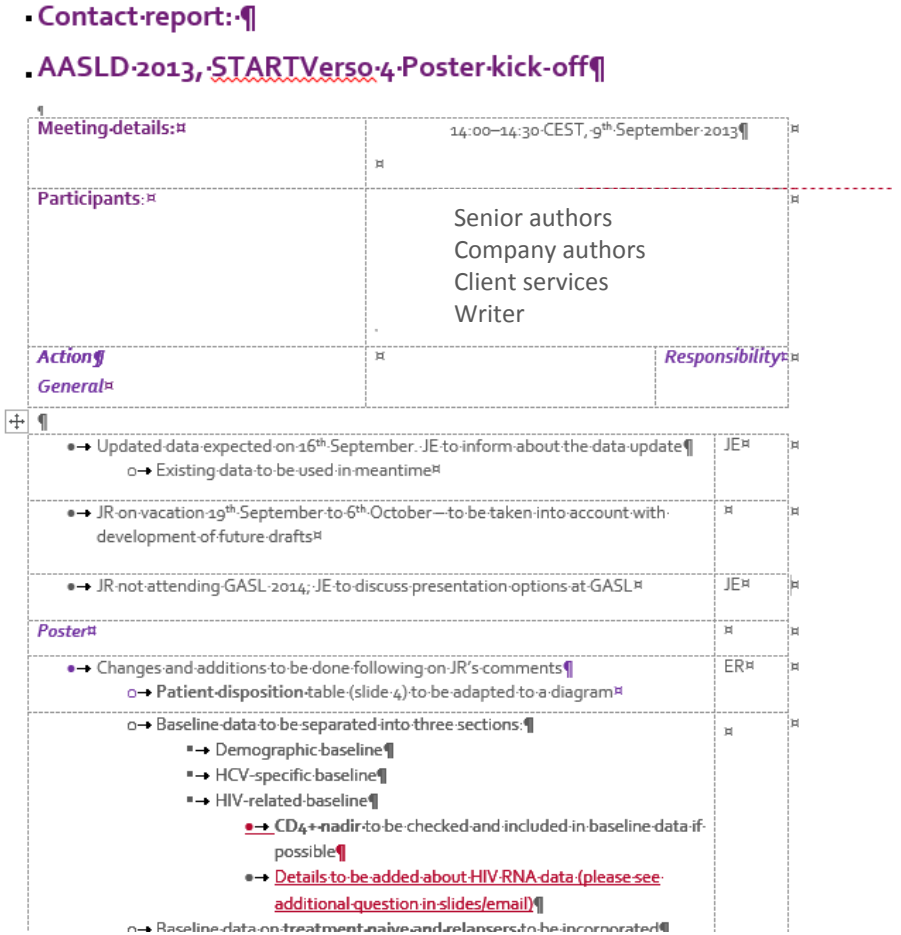
Doc. No.: U13-5108-01

BI Trial No.:	1220.19
EudraCT No.:	2010-021734-59
Test Substance:	Faldaprevir, BI 201335
Title:	Safety and Efficacy of 120 mg and 240 mg BI 201335 once daily in combination with pegylated interferon alpha 2a and ribavirin for treatment of chronic Hepatitis C (HCV) genotype 1 infection in HIV/HCV-co-infected patients. A multinational, randomised, parallel group, open-label trial.
Clinical Phase:	III
GCP Compliance:	Yes
Authors:	Montserrat Manero, M.D., Trial Clinical Monitor Prat de la Riba 50 Sant Cugat del Vallés 08174 Barcelona-Spain Richard Vinisko, Trial Statistician Fenglei Huang, Ph.D., Trial Pharmacokineticist Lisa A. Cass, Ph.D., Trial Medical Writer
Coordinating Investigator:	Douglas T. Dieterich, M.D.
Institute/ Department:	Mount Sinai School of Medicine Director of Outpatient Hepatology Division of Liver Diseases
Date of Report:	03 January 2014
Date of Revision:	Not applicable
Dates of Trial:	from 04 October 2011 to Ongoing
Additional Reports:	U13-3430-02 (11 July 2013; revision 16 August 2013)

Page 1 – 3857

STARTVerso4
From concept to primary publication

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



Contact report:

AASLD 2013, STARTVerso 4 Poster kick-off

Meeting details:	14:00–14:30 CEST, 9th September 2013	
Participants:	Senior authors Company authors Client services Writer	
Action		***Responsibility***
General		
• Updated data expected on 16th September. JE to inform about the data update ○ Existing data to be used in meantime		JE
• JR on vacation 19th September to 6th October—to be taken into account with development of future drafts		
• JR not attending GASL 2014; JE to discuss presentation options at GASL		JE
Poster		
• Changes and additions to be done following on JR's comments ○ **Patient disposition** table (slide 4) to be adapted to a diagram		ER
○ Baseline data to be separated into three sections: ▪ Demographic baseline ▪ HCV-specific baseline ▪ HIV-related baseline • **CD4+ nadir** to be checked and included in baseline data if possible • Details to be added about HIV RNA data (please see additional question in slides/email) ○ Baseline data on **treatment naive and relapsers** to be incorporated		

STARTVerso4
From concept to primary publication

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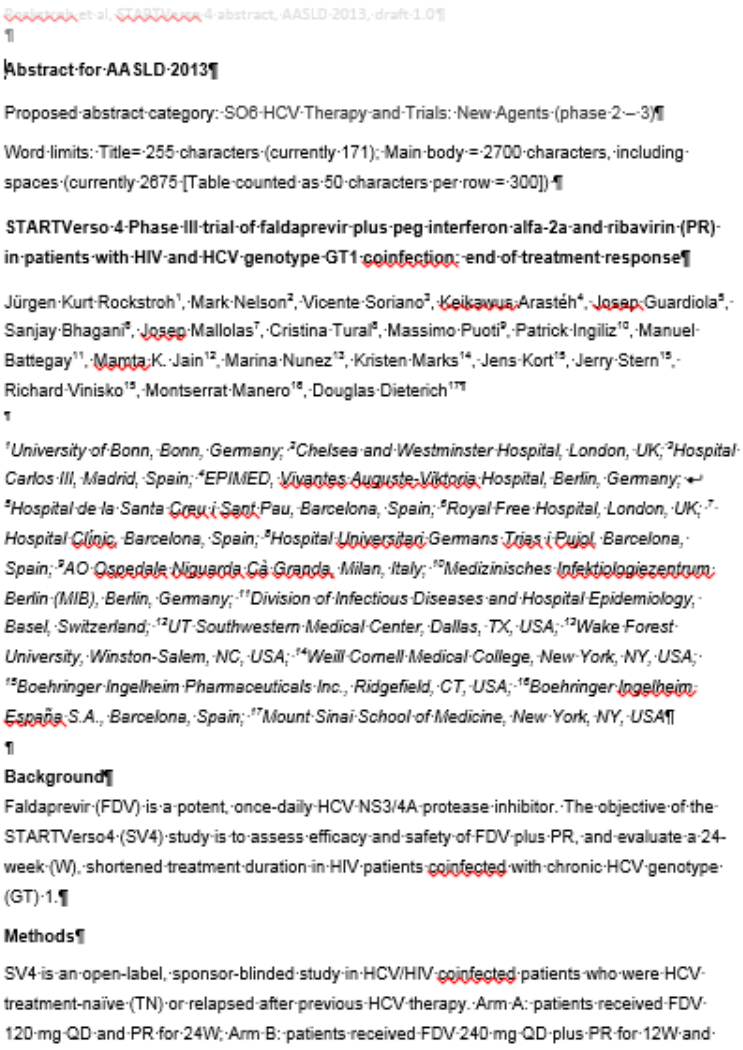
  - Kick-off meeting
  - Draft, review, submission



et al. STARTVerso 4 abstract, AASLD 2013, draft 1.0¶

¶

Abstract for AASLD 2013¶

Proposed abstract category: SO6 HCV Therapy and Trials: New Agents (phase 2 – 3)¶

Word limits: Title= 255 characters (currently 171); Main body = 2700 characters, including spaces (currently 2675 [Table counted as 50 characters per row = 300]) ¶

STARTVerso 4 Phase III trial of faldaprevir plus peg interferon alfa 2a and ribavirin (PR) in patients with HIV and HCV genotype GT1 coinfection: end of treatment response¶

Jürgen Kurt Rockstroh[1], Mark Nelson[2], Vicente Soriano[3], Keikawus Arasteh[4], Josep Guardiola[5], Sanjay Bhagani[6], Josep Mallolas[7], Cristina Tural[8], Massimo Puoti[9], Patrick Ingiliz[10], Manuel Battegay[11], Mamta K. Jain[12], Marina Nunez[13], Kristen Marks[14], Jens Kort[15], Jerry Stern[15], Richard Vinisko[15], Montserrat Manero[16], Douglas Dieterich[17]¶

¶

[1]University of Bonn, Bonn, Germany; [2]Chelsea and Westminster Hospital, London, UK; [3]Hospital Carlos III, Madrid, Spain; [4]EPIMED, Vivantes Auguste-Viktoria Hospital, Berlin, Germany; [5]Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; [6]Royal Free Hospital, London, UK; [7]Hospital Clinic, Barcelona, Spain; [8]Hospital Universitari Germans Trias i Pujol, Barcelona, Spain; [9]AO Ospedale Niguarda Cà Granda, Milan, Italy; [10]Medizinisches Infektiologiezentrum Berlin (MIB), Berlin, Germany; [11]Division of Infectious Diseases and Hospital Epidemiology, Basel, Switzerland; [12]UT Southwestern Medical Center, Dallas, TX, USA; [13]Wake Forest University, Winston-Salem, NC, USA; [14]Weill Cornell Medical College, New York, NY, USA; [15]Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, USA; [16]Boehringer Ingelheim España S.A., Barcelona, Spain; [17]Mount 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 (SV4) study is to assess efficacy and safety of FDV plus PR, and evaluate a 24 week (W), shortened treatment duration in HIV patients coinfected with chronic HCV genotype (GT) 1.¶

Methods¶

SV4 is an open label, sponsor blinded study in HCV/HIV coinfected patients who were HCV treatment naïve (TN) or relapsed after previous HCV therapy. Arm A: patients received FDV 120 mg QD and PR for 24W; Arm B: patients received FDV 240 mg QD plus PR for 12W and

STARTVerso4
From concept to primary publication

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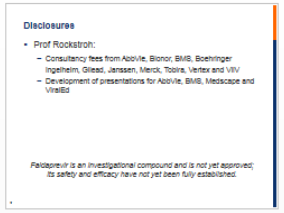
  - Draft, review, submission
- Slides and posters
  - Kick-off meeting
  - Drafts, review, submission/presentation

STARTVerso4
From concept to primary publication

1



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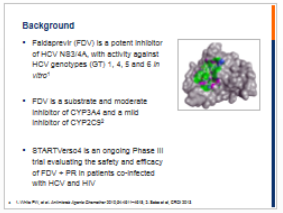

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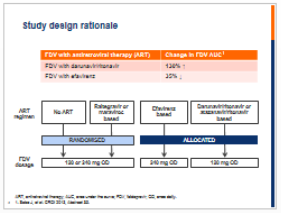

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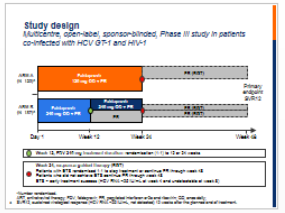

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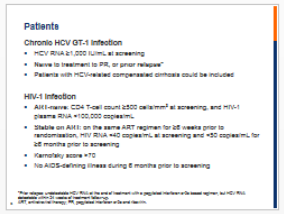

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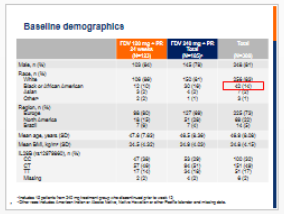

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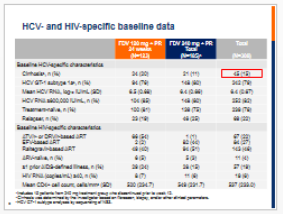

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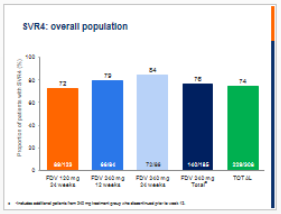

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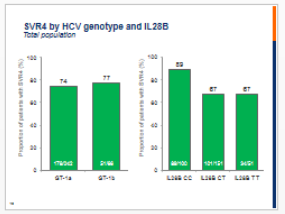

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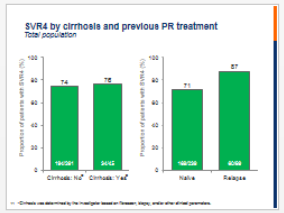

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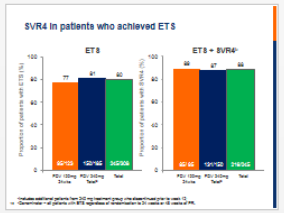

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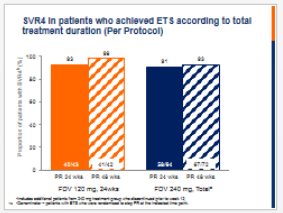

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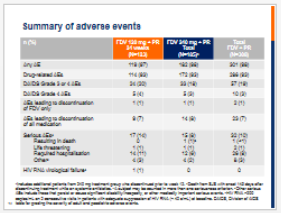

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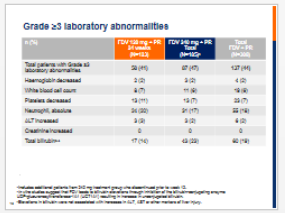

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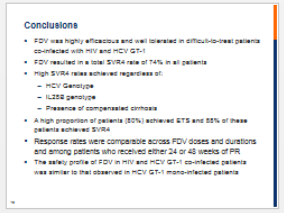

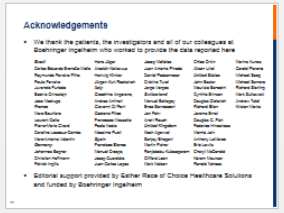

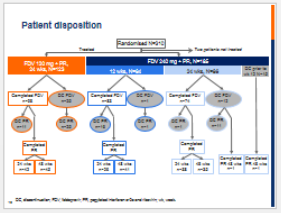

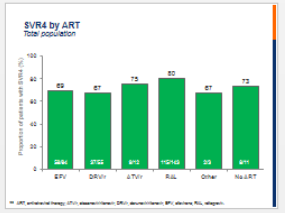

STARTVerso4
From concept to primary publication

Boehringer Ingelheim

STARTVERSO4 PHASE III TRIAL OF FALDAPREVIR PLUS PEGYLATED INTERFERON α-2A AND RIBAVIRIN (PR) IN PATIENTS WITH HIV AND HCV GENOTYPE GT1 CO-INFECTION

1099

LEAD AUTHOR NAME

BACKGROUND

METHODS

STUDY DESIGN

KEY INCLUSION CRITERIA

ANALYSES

RESULTS

PATIENTS

EFFICACY

SAFETY

PHARMACOKINETICS

SUMMARY

CONCLUSIONS

DISCLOSURES

ACKNOWLEDGEMENTS

STARTVerso4

The 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), November 1–5, 2013, Washington, DC.

STARTVerso4
From concept to primary publication

- CSR
- Data review meeting
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  - Kick-off meeting
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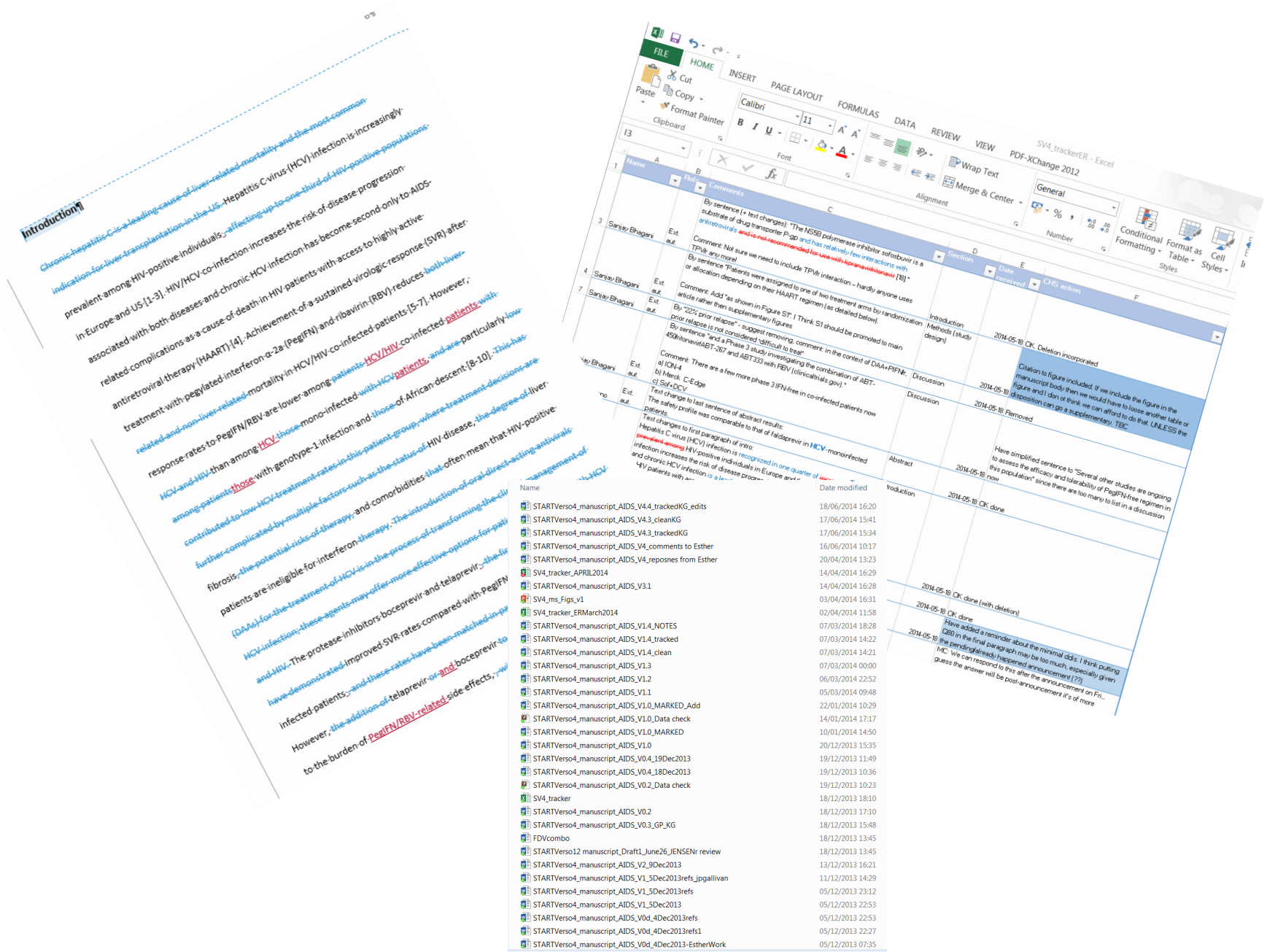
- Slides and posters
  - Kick-off meeting
  - Drafts, review, submission/presentation
- Manuscript
  - Outline
  - First draft
  - Second draft……xth draft……copy edit, data check….



Introduction¶

Chronic hepatitis C is a leading cause of liver-related mortality and the most common indication for liver transplantation in the US. Hepatitis C virus (HCV) infection is increasingly prevalent among HIV-positive individuals, affecting up to one third of HIV-positive populations in Europe and US [1-3]. HIV/HCV co-infection increases the risk of disease progression associated with both diseases and chronic HCV infection has become second only to AIDS-related complications as a cause of death in HIV patients with access to highly active antiretroviral therapy (HAART) [4]. Achievement of a sustained virologic response (SVR) after treatment with pegylated interferon-α-2a (PegIFN) and ribavirin (RBV) reduces both liver-related and non-liver related mortality in HCV/HIV co-infected patients [5-7]. However, response rates to PegIFN/RBV are lower among patients HCV/HIV co-infected patients with HCV and HIV than among HCV those mono-infected with HCV patients, and are particularly low among patients those with genotype-1 infection and those of African descent [8-10]. This has contributed to low HCV treatment rates in this patient group, where treatment decisions are further complicated by multiple factors such as the status of HIV disease, the degree of liver fibrosis, the potential risks of therapy, and comorbidities that often mean that HIV-positive patients are ineligible for interferon therapy. The introduction of oral direct-acting antivirals (DAAs) for the treatment of HCV is in the process of transforming the cl… HCV infection; these agents may offer more effective options for pati… and HIV. The protease inhibitors boceprevir and telaprevir, the fir… have demonstrated improved SVR rates compared with PegIFN… infected patients, and these rates have been matched in pa… However, the addition of telaprevir or and boceprevir to… to the burden of PegIFN/RBV-related side effects, …wi…

Name	Date modified
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STARTVerso4
From concept to primary publication

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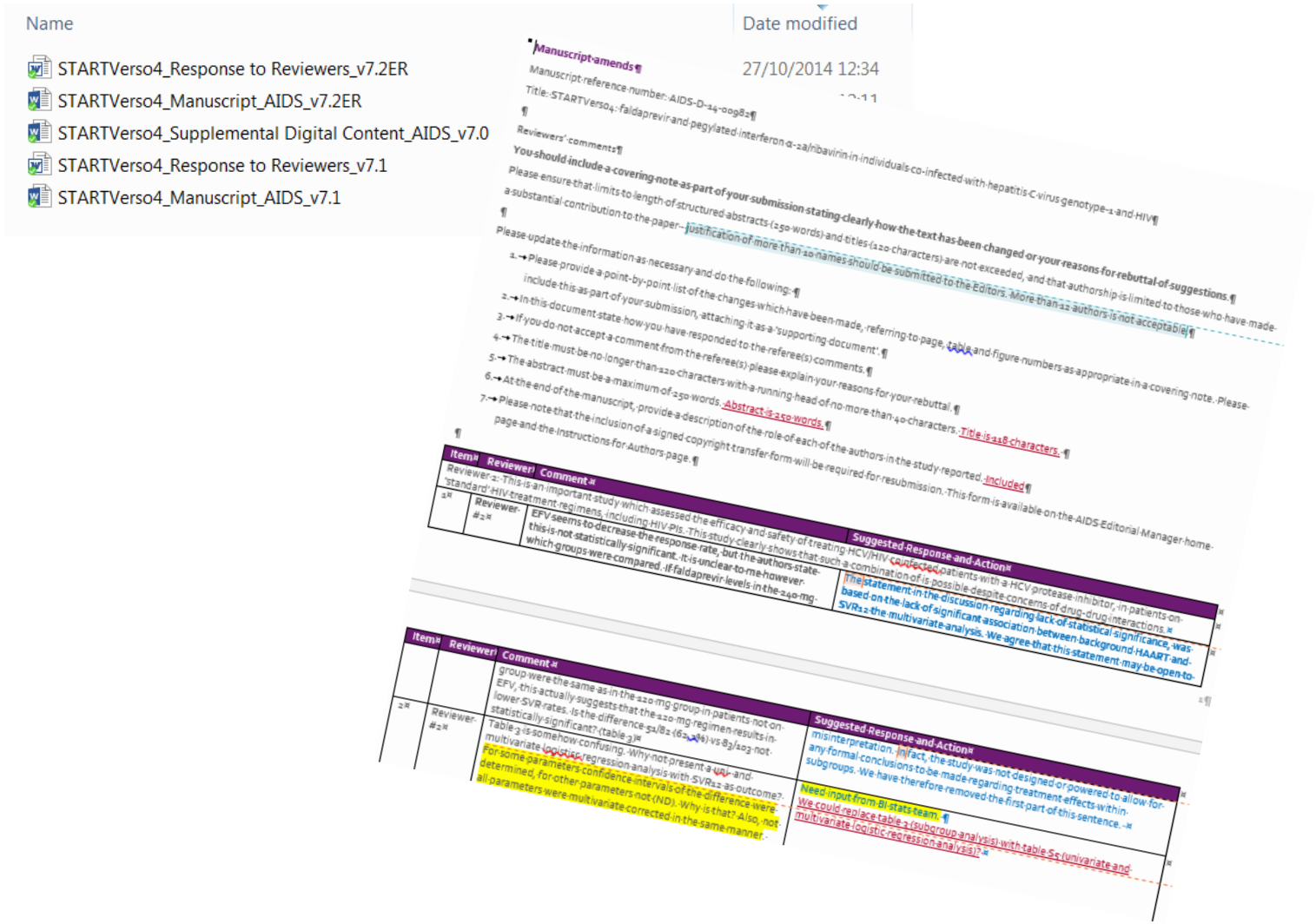
- Manuscript
  - Outline
  - First draft
  - Second draft……xth draft……copy edit, data check….
  - Submission draft (formatting, figures, reference updates)

STARTVerso4: CSR to publication



Dear Author,

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AQ2 **STARTVerso4: faldaprevir and pegylated interferon α-2a/ribavirin in individuals co-infected with hepatitis C virus genotype-1 and HIV**

Douglas Dieterich[a], Mark Nelson[b], Vicente Soriano[c], Keikawus Arasteh[d], Josep M. Guardiola[e], Jürgen K. Rockstroh[f], Sanjay Bhagani[g], Montserrat Laguno[h], Cristina Tural[i], Patrick Ingiliz[j], Mamta K. Jain[k], Jerry O. Stern[l], Montserrat Manero[m], Richard Vinisko[l], Jens Kort[l], on behalf of the STARTVerso4 study group

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-naïve or prior interferon relapsers) and HIV (96% on antiretroviral therapy (ART)) received faldaprevir 120 mg ($N = 123$) or 240 mg ($N = 185$) and PegIFN/RBV. Those receiving a protease inhibitor or efavirenz ART were assigned to faldaprevir 120 or 240 mg, 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 800 000 IU/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.

thank Anne-Marie Quinson for data interpretation and development and critical review of the manuscript. Medical writing assistance, supported financially by Boehringer Ingelheim, was provided by Esther Race of Choice Healthcare Solutions during the preparation of this manuscript. This trial is registered with Clinical-Trials.gov (NCT01343888).

Clinical study publications: more than just a manuscript

Clinical Study Protocol

- Advisory boards
- Clinical study kit
- Investigator meetings
- Investigator updates

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

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- Internal Q & A
- Objection handler
- Training slides
- e-learning

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