Screenshots Gallery

Selected screenshots of regulatory documents

Annotated Case Report Form (Source: Zanamivir trial NAI30031, ACRF Contact, PDF p. 6)

GlaxoWellcome CONFIDENTIAL FINAL - 26 APR 00

Protocol code	Session number	Subject number
NAI30031	1	

Demography / Concurrent Medications
Screening

Date of assessment (day / month / year) VSDT R (D7)

Date of birth (day / month / year) BTHDT R (D8)

Sex

Male M SEX R (A1)

Female F [NSEX]

Race, ✔ *one:*

ETHORI R (A1) [NETHORI]

White W *Origins in the original peoples of Europe, the Middle East, Western Russia, Afghanistan, or the white racial groups of Africa.*

Black B *Origins in any of the black racial groups of Africa.*

Asian A *Origins in the original peoples of the Indian subcontinent, the Far East, Southeast Asia, or the Pacific islands.*

American Hispanic H *Hispanics of North, Central, or South American origin.*

Other X *People whose racial group is not represented above, or whose predominant origin cannot be determined.*

[DEMOG]

Current smoker Yes Y No N SBSMK R (A1) [VYNALL]

Concurrent Medications

Enter any concurrent medications the subject is currently taking on the CONCURRENT MEDICATIONS page if appropriate. DNE ✔ *if done*

SESSION Ø

TMTSGPL R (N3) = 1

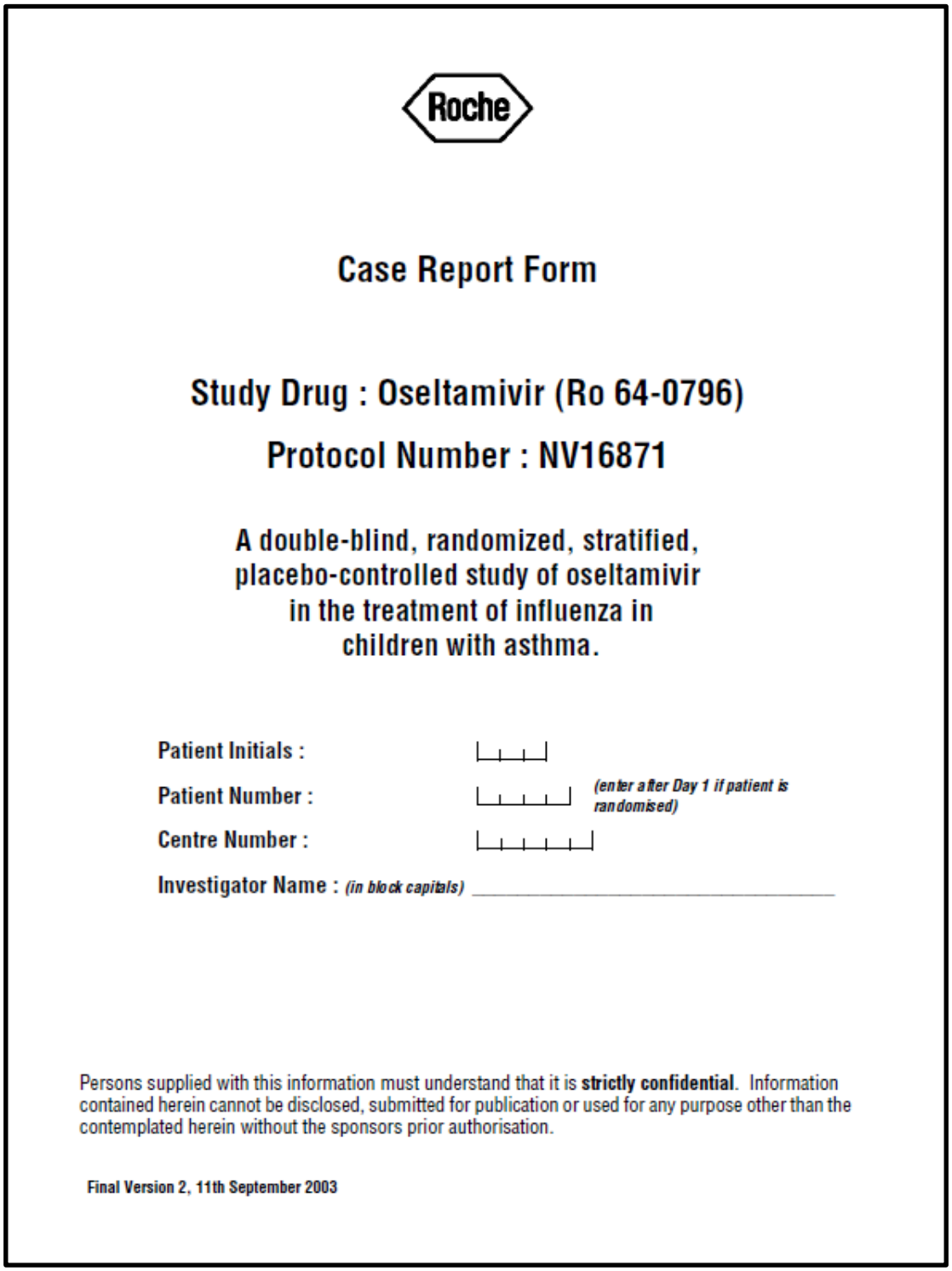
TMTSGSL R (A13) = 1

TMTSTDT R (D7) = VSDT

p.101

[TMTLOG]

Blank Case Report Form (Source: Oseltamivir trial NV16871 PDF pp. 336-527)



Roche

Case Report Form

Study Drug : Oseltamivir (Ro 64-0796)

Protocol Number : NV16871

A double-blind, randomized, stratified, placebo-controlled study of oseltamivir in the treatment of influenza in children with asthma.

Patient Initials : ⌊_ _ _⌋

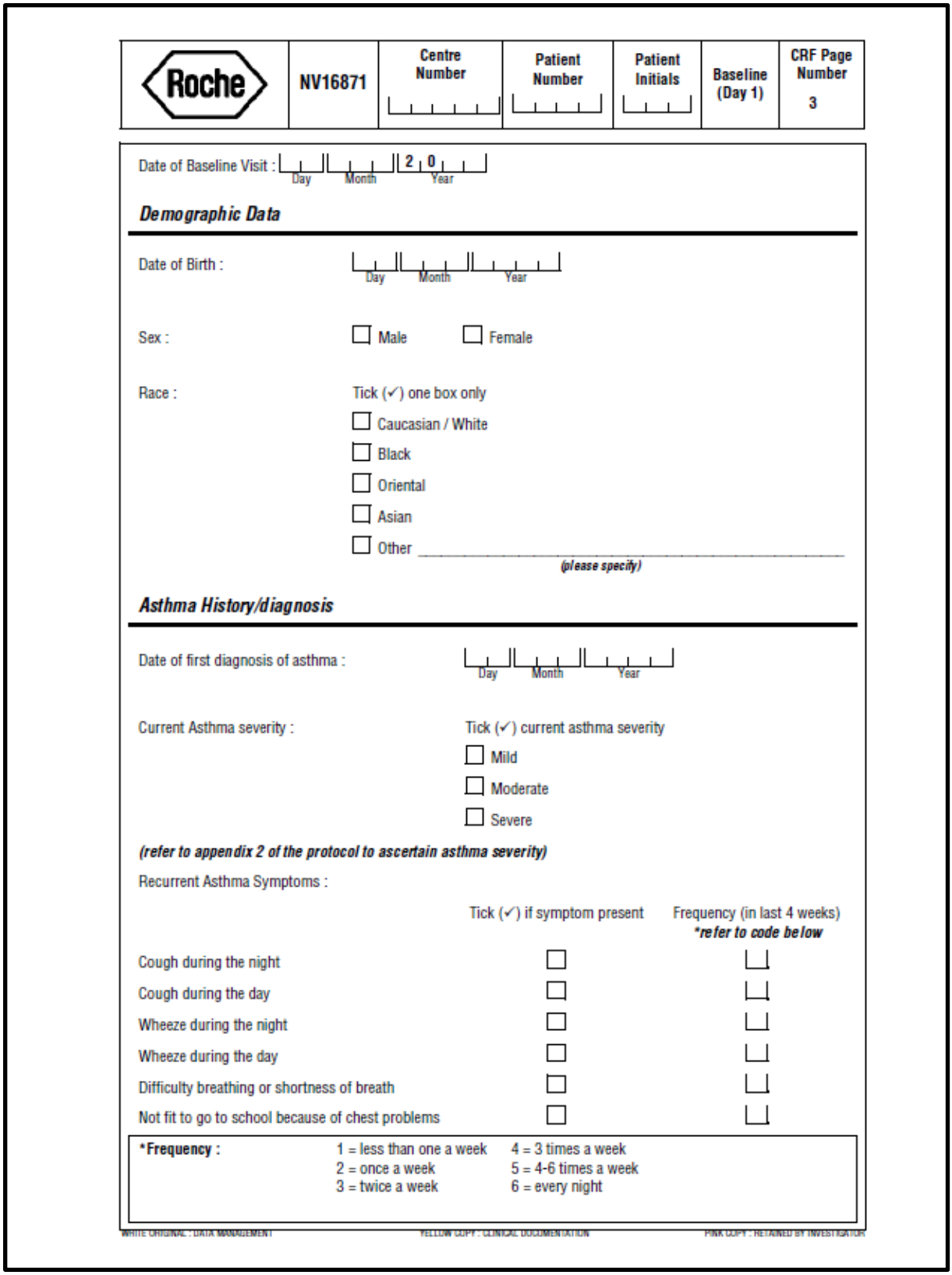
Patient Number : ⌊_ _ _ _⌋ *(enter after Day 1 if patient is randomised)*

Centre Number : ⌊_ _ _ _ _⌋

Investigator Name : *(in block capitals)* _____

Persons supplied with this information must understand that it is **strictly confidential**. Information contained herein cannot be disclosed, submitted for publication or used for any purpose other than the contemplated herein without the sponsors prior authorisation.

Final Version 2, 11th September 2003



Roche	NV16871	Centre Number	Patient Number	Patient Initials	Baseline (Day 1)	CRF Page Number 3

Date of Baseline Visit : Day Month 2 0 Year

Demographic Data

Date of Birth : Day Month Year

Sex : ☐ Male ☐ Female

Race : Tick (✓) one box only

- ☐ Caucasian / White
- ☐ Black
- ☐ Oriental
- ☐ Asian
- ☐ Other _____ *(please specify)*

Asthma History/diagnosis

Date of first diagnosis of asthma : Day Month Year

Current Asthma severity : Tick (✓) current asthma severity

- ☐ Mild
- ☐ Moderate
- ☐ Severe

(refer to appendix 2 of the protocol to ascertain asthma severity)

Recurrent Asthma Symptoms :

	Tick (✓) if symptom present	Frequency (in last 4 weeks) **refer to code below*
Cough during the night	☐	☐
Cough during the day	☐	☐
Wheeze during the night	☐	☐
Wheeze during the day	☐	☐
Difficulty breathing or shortness of breath	☐	☐
Not fit to go to school because of chest problems	☐	☐

***Frequency :**

1 = less than one a week
2 = once a week
3 = twice a week
4 = 3 times a week
5 = 4-6 times a week
6 = every night

WHITE ORIGINAL : DATA MANAGEMENT YELLOW COPY : CLINICAL DOCUMENTATION PINK COPY : RETAINED BY INVESTIGATOR

Case Report Form (Source: Arthronat trial MA-CT-10-002 PDF pp. 3988-3989)

PROTOCOL NO. MA-CT-10-002	SITE ID	SUBJECT INITIAL	SUBJECT ID
	001	M-V	001

SCREENING (V1 / -14 to -1 days)

SMOKING HISTORY

☒ 1 Non smoker		
☐ 2 Smoker, Date started :	___ ___ ___/___ ___ ___ ___ (mmm / yyyy)	Duration : ☐☐.☐☐ years
☐ 3 Ex-smoker, Date stopped :	___ ___ ___/___ ___ ___ ___ (mmm / yyyy)	Duration : ☐☐.☐☐ years

OSTEOARTHRITIC HISTORY

Date of onset of symptoms:	02/FEB/2010 (dd / mmm / yyyy)
Date of Diagnosis :	06/APR/2010 (dd / mmm / yyyy)
Joints affected *(check all that apply)* :	☐ 1 Hip ☐ 2 Knee ☒ 3 Shoulder ☐ 4 Wrist ☐ 5 Neck ☐ 6 Other, specify : _____

Index Joint *(check only one)* :	AREA	SIDE	
	☐ 1 Hip	☐ 1 Left	☒ 2 Right
	☐ 2 Knee		
	☒ 3 Shoulder		
	☐ 4 Wrist		
	☐ 5 Neck		

Treatment for OA *(check all that apply)* :	☐ 0 NA ☐ 1 Corticosteroids ☐ 2 Hyaluronic Acid ☒ 3 NSAIDs ☐ 4 Other

If Corticosteroid or Hyaluronic Acid is checked, please provide all details in the Prior Concomitant Medication page and exclude the subject from the study.
If NSAIDs or Other is checked, please provide the details in Prior Concomitant Medication page.

PROTOCOL NO. MA-CT-10-002	SITE ID	SUBJECT INITIALS	SUBJECT ID
	001	N-V	001

SCREENING (V1 / -14 to -1 days)

MEDICAL AND SURGICAL HISTORY

Does the subject have any past or ongoing medical / surgical history? ☒ 1 Yes ☐ 2 No If 'Yes', please provide details below :

Description	Start Date (dd / mmm / yyyy)	Stop Date (dd / mmm / yyyy)	Ongoing	Any Past/Ongoing medications recorded?
Type II Diabetes Mellitus	UK/UK/1990	__/__/____	☒	☐
Hypertension	UK/UK/1995	__/__/____	☒	☐
Underwent Surgery for Kidney Stones	UK/UK/2007	UK/UK/2007	☐	☐
	__/__/____	__/__/____	☐	☐
	__/__/____	__/__/____	☐	☐
	__/__/____	__/__/____	☐	☐

**If past / ongoing medication is recorded, then please provide details in Prior Concomitant Medication page.*

☐ 1 *Check this box if supplementary page is used.*

Certificate of analysis (Source: Tamiflu (Oseltamivir) trial WP16263 PDF pp. 422-3)

Placebo Capsules
Ro 64-0796/V16

Roche

Prepared by: [redacted]
Approved by:
Date: 21.09.9

CERTIFICATE OF ANALYSIS

No. 07039556 Batch: G MZ 0163

Date of manufacture: August 1999
Batch size: 104'827 capsules
Place of manufacture: Hoffmann-la Roche Ltd, Basle, Switzerland
Date of analysis: September 1999
Retest date: 08.2002

Capsule size	No. 2
Colour of the capsules	
Body	grey, opaque
Cap	ivory, opaque
Capsule contents	
Appearance	powder
Colour	white
Identity of	
Ro 64-0796	negative
Dehydrocholic acid	corresponds

Clinical Study Report (source: Tamiflu (Oseltamivir) trial M76001 PDF p.13)

FINAL STUDY REPORT MODULES

This report consists of 5 modules

Those not supplied in this submission are obtainable from the sponsor on request

MODULE I: CORE REPORT AND STUDY PUBLICATIONS
- Introduction
- Rationale
- Objectives
- Methodology
- Efficacy Results
- Safety Results
- Discussion / Conclusions
- Appendices

MODULE II: PRESTUDY DOCUMENTS AND STUDY METHODOLOGY
- Protocol and Amendment History
- Blank CRF
- Patient Information Sheet
- Glossary of Original and Preferred Terms
- Randomization List
- Reporting Analysis Plan (RAP)
- Certificates of Analysis
- List of Investigators
- List of Responsible Ethics Committees

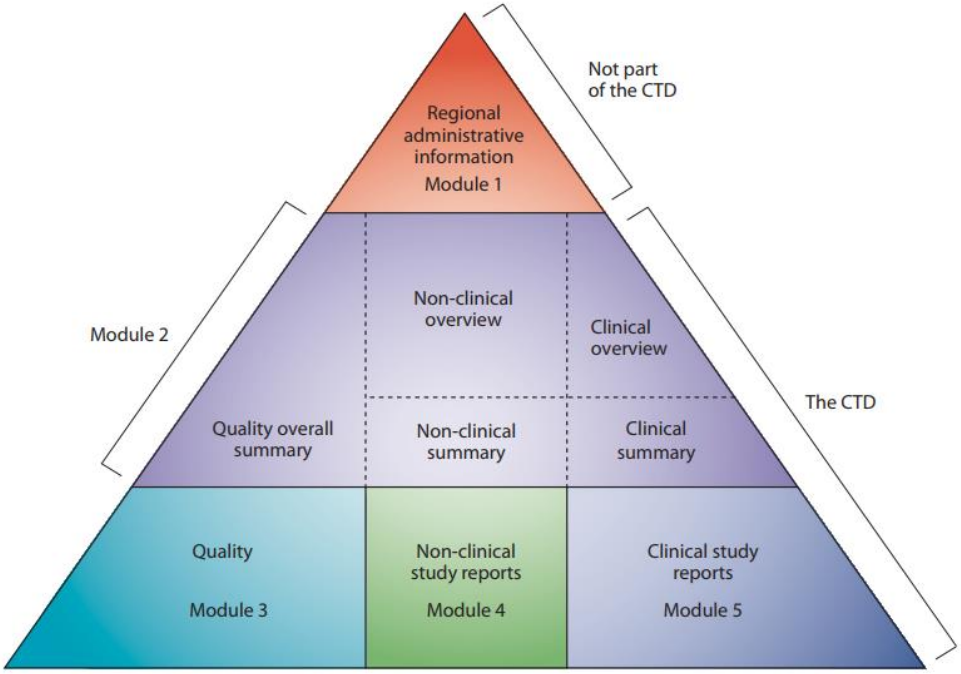
MODULE III: INDIVIDUAL PATIENT LISTINGS OF DEMOGRAPHIC AND EFFICACY DATA
- Demographic Data Listings
- Previous and Concomitant Diseases
- Previous and Concomitant Medications
- Efficacy Listings

MODULE IV: INDIVIDUAL PATIENT LISTINGS OF SAFETY DATA
- Laboratory Parameters
- Vital Signs Data

MODULE V: STATISTICAL REPORT

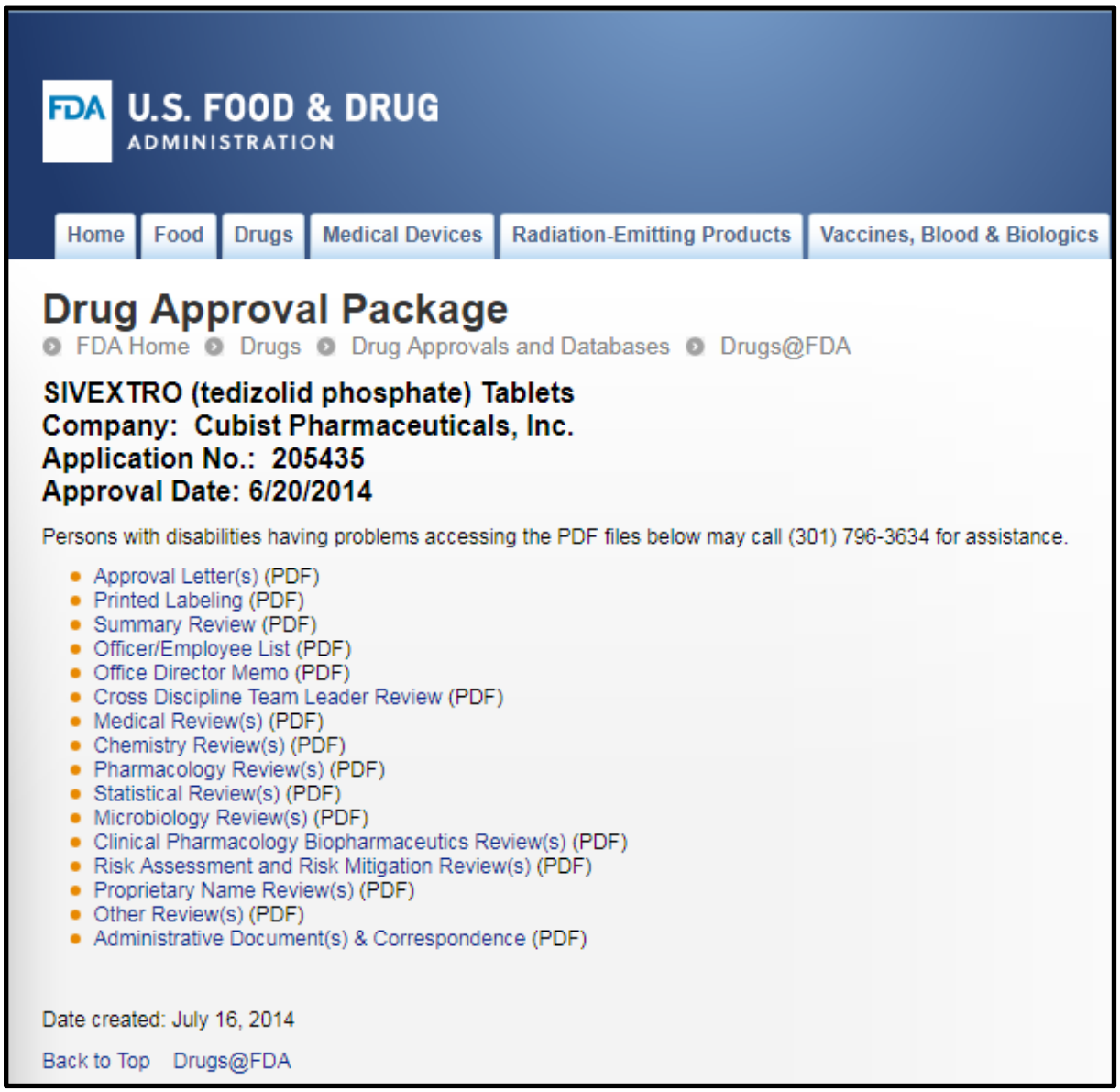
Common Technical Document (Source: ICH website)

CTD Triangle



The CTD triangle. The Common Technical Document is organized into five modules. Module 1is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

Drug Approval Package (Source: FDA website)



Drug Label (Source)

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DALVANCE® safely and effectively. See full prescribing information for DALVANCE.

DALVANCE (dalbavancin) for injection, for intravenous use
Initial U.S. Approval: 2014

----------RECENT MAJOR CHANGES----------

- Dosage and Administration (2) 01/2016

----------INDICATIONS AND USAGE----------

DALVANCE is indicated for acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms. (1.1)

To reduce the development of drug-resistant bacteria and maintain the effectiveness of DALVANCE and other antibacterial drugs, DALVANCE should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. (1.2)

----------DOSAGE AND ADMINISTRATION----------

- Dosage in patients with normal or impaired renal function (2.1, 2.2):

Estimated CrCl	Single Dose Regimen	Two-Dose Regimen
≥ 30 mL/min or on regular hemodialysis	1500 mg	1000 mg followed one week later by 500 mg
< 30 mL/min and not on regular hemodialysis	1125 mg	750 mg followed one week later by 375 mg

- Administer by intravenous infusion over 30 minutes (2.1, 2.3)
- See Full Prescribing Information for instructions on reconstitution of lyophilized powder and preparation of injection (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

For injection: 500 mg of lyophilized powder in a vial for reconstitution (3)

----------CONTRAINDICATIONS----------

Hypersensitivity to dalbavancin (4)

----------WARNINGS AND PRECAUTIONS----------

- Serious hypersensitivity (anaphylactic) and skin reactions have been reported with glycopeptide antibacterial agents, including DALVANCE; exercise caution in patients with known hypersensitivity to glycopeptides. (5.1)
- Rapid intravenous infusion of glycopeptide antibacterial agents can cause reactions. (5.2)
- ALT elevations with DALVANCE treatment were reported in clinical trials. (5.3)
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including DALVANCE. Evaluate if diarrhea occurs. (5.4)

----------ADVERSE REACTIONS----------

The most common adverse reactions in patients treated with DALVANCE were nausea (4.7%), headache (3.8%), and diarrhea (3.4%). (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Durata Therapeutics, Inc. at 1-855-387-2825 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------USE IN SPECIFIC POPULATIONS----------

Dosage adjustment is required in patients whose creatinine clearance is less than 30 mL/min and who are not receiving regularly scheduled hemodialysis. (2.2, 8.6)

See 17 for PATIENT COUNSELING INFORMATION

Revised 01/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

---

European Public Assessment Report (Source: website and document)

Olazax

olanzapine

About | Authorisation details | Product information | Assessment history

Next tab »

This is a summary of the European public assessment report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach its recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis for the CHMP recommendations, read the scientific discussion (also part of the EPAR).

Expand all items in this list

- **What is Olazax?**
- **What is Olazax used for?**
- **How is Olazax used?**
- **How does Olazax work?**
- **How has Olazax been studied?**
- **What are the benefit and risk of Olazax?**
- **Why has Olazax been approved?**
- **Other information about Olazax**

Name	Language	First published	Last updated
Olazax : EPAR - Summary for the public	EN = English GO	29/01/2010	15/09/2014

This EPAR was last updated on 19/04/2017 .

More detail is available in the summary of product characteristics

European Medicines Agency
Evaluation of Medicines for Human Use

Doc.Ref.: EMEA/774081/2009

ASSESSMENT REPORT
FOR

OLAZAX

International Nonproprietary Name: **olanzapine**

Procedure No. EMEA/H/C/1087

Assessment Report as adopted by the CHMP with
all information of a commercially confidential nature deleted.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

Medical Officer Review (Source)

Clinical Review
Sarah M. Connelly, MD
NDA 205834
Ledipasvir/Sofosbuvir Fixed-Dose Combination

Table of Contents

Table 3 Overview of Phase 2 and Pivotal Phase 3 LDV/SOF Trials

Trial Number	Trial Design	Population	Regimen and Duration	Number Enrolled	Primary Efficacy Endpoint
Pivotal Phase 3 LDV/SOF Trials					
GS-US-337-0102 (ION-1)	Randomized, open-label, international, multicenter trial	GT 1 Treatment-naïve ≤20% may have had cirrhosis at screening	**LDV/SOF:** 12 or 24 weeks **LDV/SOF+RBV**: 12 or 24 weeks	865	SVR12
GS-US-337-0109 (ION-2)	Randomized, open-label, multicenter trial	GT 1 Treatment-experienced, including prior PI-failures ≤ 20% may have had cirrhosis at screening	**LDV/SOF:** 12 or 24 weeks **LDV/SOF+RBV**: 12 or 24 weeks	440	SVR12
GS-US-337-0108 (ION-3)	Randomized, open-label, multicenter trial	GT 1 Treatment-naïve, non-cirrhotic	**LDV/SOF:** 8 or 12 weeks **LDV/SOF+RBV**: 8 weeks	647	SVR12
Phase 2 LDV/SOF Trials					
GS-US-337-0118 (LONESTAR)	Open-label Single center trial	GT 1 Treatment-naïve and Treatment-experienced, including prior PI-failures; ≤50% of treatment-experienced subjects may have had cirrhosis at screening	**LDV/SOF:** 8 or 12 weeks **LDV/SOF+RBV:** 8 or 12 weeks	100	SVR12
GS-US-337-0122 (ELECTRON-2; Cohort 2, Groups 3 and 4)	Open-label Two center trial (New Zealand)	GT 3 Treatment-naïve Subjects may have had cirrhosis	**LDV/SOF:** 12 weeks **LDV/SOF+RBV**: 12 weeks	51	SVR12
P7977-0523 (ELECTRON; Part 4, Groups 12 and 13; Part 6, Groups 16-18, 20, and 21)	Open-label Two center trial (New Zealand)	GT 1, 2 or 3 Treatment-naïve and Treatment-experienced Subjects may have had cirrhosis at screening	**LDV+SOF:** 12 weeks **LDV/SOF:** 12 weeks **LDV/SOF+RBV**: 6 or 12 weeks	102	SVR12

Patient Information Leaflet (Source)

Package leaflet: Information for the patient

Xydalba 500 mg powder for concentrate for solution for infusion
dalbavancin

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effect(s) you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Xydalba is and what it is used for

Xydalba contains the active substance dalbavancin, which is an **antibiotic** of the glycopeptide group.

Xydalba is used to treat **adults with infections of the skin or in the layers of flesh below the skin.**

Xydalba works by killing certain bacteria, which can cause serious infections. It kills these bacteria by interfering with the formation of bacterial cell walls.

If you also have other bacteria that cause your infection, your doctor may decide to treat you with other antibiotics in addition to Xydalba.

2. What you need to know before you are given Xydalba

Do not use Xydalba if you are **allergic** to dalbavancin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given Xydalba:
- If you have or have had **kidney problems**. Depending on the condition of your kidney, your doctor may have to reduce your dose.
- If you are suffering from **diarrhoea**, or you have previously suffered from diarrhoea when being treated with antibiotics.
- If you are **allergic** to other antibiotics such as vancomycin or teicoplanin.

Diarrhoea during or after treatment

If you develop **diarrhoea during** or **after** your treatment, tell your doctor **at once**. Do not take any medicine to treat your diarrhoea without first checking with your doctor.

Statistical Officer Review (Source)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA #:	022526 / N0062
Drug Name:	Addyi™ (Flibanserin 100 mg q.h.s.)
Indication(s):	Treatment of hypoactive sexual desire disorder (HSDD) in premenopausal women
Applicant:	Sprout Pharmaceuticals, Inc.
Date(s):	Submission: 02/18/2015 PDUFA: 08/18/2015
Review Priority:	Resubmission class2
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Kate Dwyer, Ph.D.
Concurring Reviewers:	Mahboob Sobhan, Ph.D.
Medical Division:	Division of Bone, Reproductive and Urologic Products, HFD-580
Clinical Team:	Catherine Sewell, MD, Clinical Reviewer Olivia Easley, MD, Clinical Reviewer Christina Chang, MD, Clinical Team leader
Project Manager:	Jennifer Mercier

Keywords: NDA review, ROC analysis

Table of Contents

Study Protocol (Source)

SmithKline Beecham Pharmaceuticals
Clinical Research & Development
1250 South Collegeville Road
P.O. Box 5089
Collegeville, PA 19426-0989

STUDY DRUG : BRL 29060/PAROXETINE (PAXIL)

A MULTI-CENTER, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

PROTOCOL NUMBER 29060/329

PROTOCOL	August 20, 1993	Date of approval:	August 26, 1993
Amendment #1:	March 24, 1994	Date Amendment Approved:	April 17, 1994
Amendment #2:	October 2, 1996	Date Amendment Approved:	October 29, 1996

Protocol Table of Contents

Summary of Product Characteristics (Source)

1. NAME OF THE MEDICINAL PRODUCT

Olazax 5 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg olanzapine.

Excipient with known effect: Each tablet contains 0.23 mg aspartame

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL form

Tablet
Yellow coloured circular flat bevelled edge tablets with 'B' debossed on one side.

4. Clinical particulars

4.1 Therapeutic indications

Adults
Olanzapine is indicated for the treatment of schizophrenia.

Olanzapine is effective in maintaining the clinical improvement during continuation therapy in patients who have shown an initial treatment response.

Olanzapine is indicated for the treatment of moderate to severe manic episode. In patients whose manic episode has responded to olanzapine treatment, olanzapine is indicated for the prevention of recurrence in patients with bipolar disorder (see section 5.1).

4.2 Posology and method of administration

Adults
Schizophrenia: The recommended starting dose for olanzapine is 10 mg/day.

Manic episode: The starting dose is 15 mg as a single daily dose in monotherapy or 10 mg daily in combination therapy (see section 5.1).

Preventing recurrence in bipolar disorder**:**
The recommended starting dose is 10 mg/day.

For patients who have been receiving olanzapine for treatment of manic episode, continue therapy for preventing recurrence at the same dose. If a new manic, mixed, or depressive episode occurs, olanzapine treatment should be continued (with dose optimisation as needed), with supplementary therapy to treat mood symptoms, as clinically indicated.

During treatment for schizophrenia, manic episode and recurrence prevention in bipolar disorder, daily dosage may subsequently be adjusted on the basis of individual clinical status within the range 5-20 mg/day. An increase to a dose greater than the recommended starting dose is advised only after appropriate clinical reassessment and should generally occur at intervals of not less than 24 hours. Olanzapine can be given without regards for meals as absorption is not affected by food. Gradual tapering of the dose should be considered when discontinuing olanzapine.