

Impact of a community pharmacy based information program on type 2 diabetic patients' adherence to their oral treatment

Submission date 03/03/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/04/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/05/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a lifelong (chronic) condition that causes a person's blood sugar level to become too high. A survey found that although 80% of patients with type 2 diabetes say they are well informed, 71% would like other additional information. Only 17% of the same patients report receiving instruction in addition to their treatment. Pharmacists could exert a major effect on treatment adherence in chronic disease. The aim of this study to assess the impact of information provided by community pharmacists on patients' adherence to treatment.

Who can participate?

Patients aged over 18 with type 2 diabetes

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in one group attend interviews with a pharmacist three times over 6 months (once every 2 months) covering diet, drug treatment and the complications of diabetes. Each interview lasts about thirty minutes and involves general monitoring of the patient and then giving the patient a brochure which is an opening for a discussion between the pharmacist and the patient. Participants in the other group receive treatment as usual. The impact on treatment adherence is assessed in both groups after 6 months by the pharmacist counting the tablets remaining in the treatment packs delivered to the patient during the previous visit.

What are the possible benefits and risks of participating?

The benefits for the patient are a better knowledge of diet and the complications of diabetes, as well as better management of their treatment. There are no expected risks for the participants.

Where is the study run from?

182 pharmacies in France

When is the study starting and how long is it expected to run for?

March 2014 to December 2016

Who is funding the study?
Merck (USA)

Who is the main contact?
Dr Yves Michiels

Contact information

Type(s)
Scientific

Contact name
Dr Yves Michiels

Contact details
1 rue Guynemer
Longvic
France
21600

Additional identifiers

Protocol serial number
012014

Study information

Scientific Title
Impact of a community pharmacy based information program on type 2 diabetic patients' adherence to their oral treatment (IPhODia): a randomized cluster study vs usual practice

Acronym
IPhODia

Study objectives
Diabetes is a prime example of a chronic disease which is increasingly prevalent in France (38% in 7 years) and accounts for nearly 10% of our health spending. The many complications associated with diabetes contribute substantially to this spending and occur when diabetes is insufficiently controlled. The current therapeutic objective of the treatment is measured by the level of HbA1C which should be < 7% as defined by NHANES.

In France, despite significant improvements in the follow up of type 2 diabetes patients, the last results of Entred 2007-2010 are showing an insufficient level of control with too many patients with HbA1C>7%. This epidemiological study points to improved control of cardiovascular risk factors (lipid profile, high blood pressure) but still inadequate control of glycaemia. Some 41% of people with type 2 diabetes have HbA1c levels above 7% and 15% have levels above 8%.

These figures, testifying to failed therapy, are the source of many hospitalizations especially as glycaemic balance is not achieved. Alongside this, the costs of cover are proportional to this

absence of control. The annual cost of a diabetic patient rises from \$2 792 for an HbA1c < 7% to \$6 759 for an HbA1c of 10%. Several additional measures should be contemplated to make therapy more efficacious. Adherence or rather non-adherence is inherent in chronic drug treatment and for diabetes, many studies are increasingly highlighting adherence as a factor for successful or unsuccessful drug treatment. Adherence seems to be one of the key points for the successful treatment of a chronic diseases like diabetes.

General practitioners remain the prime point-of-contact for diabetic patients, in spite of regular controls, physicians encounter difficulties correctly informing their patients mainly due to a lack of time and means. Diabetic patients must, in the majority (90%) of cases, go to the pharmacy for their treatment to be renewed and dispensed. This should be a useful opportunity for detecting and correcting any decline in adherence. Pharmacists, who are par excellence specialists in medication, are an essential actor and thanks to their expertise, their large number and their accessibility, pharmacists could play a beneficial role in patient adherence.

The IPhODia study aims to assess the impact on adherence of specific information provided by community pharmacists.

Ethics approval required

Old ethics approval format

Ethics approval(s)

In France a clinical trial such as IPhODia does not require ethics approval

Study design

Prospective multicentre randomised controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Diabetes

Interventions

The intervention consists of three different pharmaceutical interviews during 6 months (one every 2 months) covering thematic information on diabetes, namely diet for diabetics, monitoring drug treatment and the complications of diabetes. Each interview is composed of two parts and lasts about 30 minutes. It involves first general monitoring of the diabetic patient and then giving the patient a thematic information brochure which is an opening for a discussion between the pharmacist and the patient.

In order to demonstrate the effectiveness of this intervention, a randomised study is performed with two groups of patients, one receiving information from the pharmacists according to the program, the other receiving treatment as usual. Impact on adherence will be assessed using the Medication Possession Ratio (MPR) at 6 months.

Intervention Type

Other

Primary outcome(s)

Medication Possession Ratio (MPR), measured by the pharmacist by counting tablets remaining in the treatment packs delivered to the patient during the previous visit, at 6 months

Key secondary outcome(s)

1. HbA1c level, measured by laboratory analysis at 6 months
2. Adherence, measured by a specific questionnaire (TOP) at 6 months
3. Patient's knowledge acquisition, measured by a specific questionnaire developed by the scientific committee at 6 months
4. Patient's satisfaction, measured by a specific questionnaire developed by the scientific committee, for the patients in group A at 6 months

Completion date

31/12/2016

Eligibility**Key inclusion criteria**

1. Men or women
2. Age >18 years
3. Diabetics with less four oral antidiabetics medications
4. HbA1c > 6.7%
5. Patient present at pharmacy for more than 6 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Cancer
2. Patients with insulin treatment or anti-diabetics injectables

Date of first enrolment

01/03/2014

Date of final enrolment

01/09/2016

Locations

Countries of recruitment

France

Study participating centre

PHARMACIE NGHIEM

France

91600

Study participating centre

PHARMACIE BONNET

France

34000

Study participating centre

PHARMACIE GOULET

France

76620

Study participating centre

PHARMACIE SUEUR

France

80230

Study participating centre

PHARMACIE HENRY

France

18120

Study participating centre

PHARMACIE BOUDON

France

15120

Study participating centre

PHARMACIE BERTHOLOM

France

29910

Study participating centre

PHARMACIE LAIR-MARTIN-LONGUESSERRE

France

31260

Study participating centre

PHARMACIE STAHL

France

88290

Study participating centre

PHARMACIE BERTOUX-FORESTIER

France

80134

Study participating centre

PHARMACIE BERA

France

38114

Study participating centre

PHARMACIE DERAM

France

62220

Study participating centre

PHARMACIE RENUCCI

France

84210

Study participating centre

PHARMACIE SCHAUB

France

73230

Study participating centre

PHARMACIE GERMES-CANEPA

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Study participating centre

PHARMACIE LOUBRIEU

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Study participating centre

PHARMACIE OSTER-HILD

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67400

Study participating centre

PHARMACIE LAFORTUNE

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Study participating centre

PHARMACIE BIZON

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Study participating centre

PHARMACIE VAURY

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91670

Study participating centre

PHARMACIE THOUVEREY

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71500

Study participating centre

PHARMACIE MINGEAU

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58150

Study participating centre

PHARMACIE BOUTINET-DJILANI

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17650

Study participating centre

PHARMACIE VITOUX-GILLET

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59550

Study participating centre

PHARMACIE MOUTIER-DUMAS

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87130

Study participating centre

PHARMACIE LEPINE

France

87220

Study participating centre

PHARMACIE DRIOUT

France

41500

Study participating centre

PHARMACIE TROUSSELLE

France

49000

Study participating centre

PHARMACIE TARODO DE LA FUENTE

France

81240

Study participating centre

PHARMACIE RAYMOND-TAUGOURDEAU

France

49112

Study participating centre

PHARMACIE BEGLIA JOEL

France

13200

Study participating centre

PHARMACIE SCHAUB

France

73230

Study participating centre

PHARMACIE BREYSSE

France

81200

Study participating centre

PHARMACIE MALLIS

France

62440

Study participating centre

PHARMACIE BONCHRISTIANI-ANDREANI

France

13013

Study participating centre

PHARMACIE BERGEZ-BEVALOT

France

25000

Study participating centre

PHARMACIE RODIER CABANIS

France

30420

Study participating centre

PHARMACIE DODIN-MOTTE

France

95290

Study participating centre

PHARMACIE DECLOITRE

France

33000

Study participating centre

PHARMACIE MILLERET-VERNAY

France

21250

Study participating centre

PHARMACIE DOUCET

France

45260

Study participating centre

PHARMACIE BEL

France

31340

Study participating centre

PHARMACIE GIRARD-PLANTE-VIEITEZ

France

31660

Study participating centre

PHARMACIE LHOYER

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60160

Study participating centre

PHARMACIE SENEZ VANGHELUE

France

60840

Study participating centre

PHARMACIE COUFFIGNAL-BONNY

France

94370

Study participating centre

PHARMACIE AATEF-VINAY

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Study participating centre

PHARMACIE HENRY

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Study participating centre

PHARMACIE EDUS

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90170

Study participating centre

PHARMACIE BIZON

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Study participating centre

PHARMACIE CHARTIER SEBASTIEN

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Study participating centre

PHARMACIE LECUGY-VINCENT

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Study participating centre

PHARMACIE NOLL

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PHARMACIE BLAISE-GRASMICK

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PHARMACIE BERA

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PHARMACIE COGNARD-LOURADOUR

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PHARMACIE GUILLEBOT-VERGARA

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PHARMACIE DERAM

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PHARMACIE DESERICOURT-PEREZ

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Study participating centre

PHARMACIE LOUBRIEU

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PHARMACIE KARAYAN

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60700

Study participating centre

PHARMACIE GUILLEBOT-VERGARA

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PHARMACIE DODIN-MOTTE

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Study participating centre

PHARMACIE LE BAIL

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PHARMACIE GIANNECCHINI

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PHARMACIE VIVIEN-MINIGHETTI

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Study participating centre

PHARMACIE BERA

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38114

Study participating centre

PHARMACIE MAGNIEN

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21240

Study participating centre

PHARMACIE FABERT

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Study participating centre

PHARMACIE MAGNIEN

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PHARMACIE PENNE-LESPIAU

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PHARMACIE DERAM

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Study participating centre

PHARMACIE VIVIEN-MINIGUETTI

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Study participating centre

PHARMACIE HAMON-PALLU

France

56800

Study participating centre

PHARMACIE OSTER-CHILD

France

67400

Study participating centre

PHARMACIE LAFORTUNE

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91390

Study participating centre

PHARMACIE DESACHY-DAVERAT

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40360

Study participating centre

PHARMACIE TIVOLLIER-GOBILLOT

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Study participating centre

PHARMACIE VIVIEN-MINIGHETTI

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Study participating centre

PHARMACIE FACQ

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60160

Study participating centre

PHARMACIE MALLIS

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Study participating centre

PHARMACIE BROUSSEAU

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44100

Study participating centre

PHARMACIE OSTER-HILD

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Study participating centre

PHARMACIE GABRIELLNI-DURAND-BRESSAC

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13012

Study participating centre

PHARMACIE POTHELUNE

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72190

Study participating centre

PHARMACIE PERONNE-DETRIN

France

80000

Study participating centre

PHARMACIE FRANCK

France

93220

Study participating centre

PHARMACIE LEBAIL

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Study participating centre

PHARMACIE AUCLAIRE

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Study participating centre

PHARMACIE MATHEVET

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Study participating centre

PHARMACIE TROUILLOT-MAURIN-FAURY-VAZQUEZ

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Study participating centre

PHARMACIE MOUTIER-DUMAS

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PHARMACIE RETAILLEAU

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Study participating centre

PHARMACIE LEFEBRVRE-RICQUEBOURG

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Study participating centre

PHARMACIE POLETTI-REPELLIN

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Study participating centre

PHARMACIE PERONNE-DETRIN

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Study participating centre

PHARMACIE BONCHRISTIANI-ANDREANI

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Study participating centre

PHARMACIE HAMON-PALLU

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PHARMACIE MEUNIER

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Study participating centre

PHARMACIE PENICAUT-BECHADE

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PHARMACIE CAMY

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PHARMACIE LE BAIL

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PHARMACIE AGRA

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PHARMACIE SICARD

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PHARMACIE POTHELUNE

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Study participating centre

PHARMACIE LECUGY-VINCENT

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PHARMACIE MIR-RABILLER

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PHARMACIE CHAU

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PHARMACIE MALLIS

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PHARMACIE CHIEP

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PHARMACIE LAIR-MARTIN-LONGUESSERRE

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PHARMACIE GIMENO-BUSSON

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Study participating centre

PHARMACIE OSTER-HILD

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PHARMACIE DE GRAEVE-MASSIP

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PHARMACIE COUTINHO DE ALMEIDA

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PHARMACIE FAURY

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PHARMACIE BORDAT

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PHARMACIE LEPINE

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PHARMACIE ROUSSEAU

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Study participating centre

PHARMACIE LAFFLY

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Study participating centre

PHARMACIE CORGNE

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PHARMACIE COUTINHO DE ALMEIDA

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PHARMACIE STAHL

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PHARMACIE BAFFOUX - ROUET

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PHARMACIE LE BAIL

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PHARMACIE VAURY

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PHARMACIE MONTAGNY-WELLHOFF

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PHARMACIE VAURY

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PHARMACIE BAUDIN-CIMETIERE

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PHARMACIE LAFORTUNE

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PHARMACIE THOMAS

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PHARMACIE LEFEBVRE-RICQUEBOURG

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PHARMACIE SCHREVEL

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PHARMACIE GERMES - CANEPA

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PHARMACIE THOUVEREY

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PHARMACIE LOUBRIEU

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PHARMACIE OSTER-HILD

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PHARMACIE ENJALBERT - LAMASSIAUDE

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Study participating centre

PHARMACIE LEFEBVRE-RICQUEBOURG

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PHARMACIE SAHUGUET

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Study participating centre

PHARMACIE COGNARD - LOURADOUR

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Study participating centre

PHARMACIE HENRY

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PHARMACIE HAMON - PALLU

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Study participating centre

PHARMACIE SEGUIN

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Study participating centre

PHARMACIE BONNIN - JOUANNIN

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Study participating centre

PHARMACIE LAIR -MARTIN -LONGUESSERRE

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Study participating centre

PHARMACIE SOL-GIRAL

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43110

Study participating centre

PHARMACIE DECLOITRE

France

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Study participating centre

PHARMACIE COGNARD - LOURADOUR

France

87920

Study participating centre

PHARMACIE BARBE - LECLERCQ

France

89110

Study participating centre

PHARMACIE VIVIEN - MINIGHETTI

France

13200

Study participating centre

PHARMACIE TIVOLLIER - GOBILLOT

France

51000

Study participating centre

PHARMACIE LEYENDECKER

France

67130

Study participating centre

PHARMACIE SEGUIN

France

69290

Study participating centre

PHARMACIE BOUREL - EQUINET

France

80090

Study participating centre

PHARMACIE DOUCET

France

45260

Study participating centre

PHARMACIE LESOIF-GRIMAULT

France

53500

Study participating centre

PHARMACIE BEGLIA JOEL

France

13200

Study participating centre

PHARMACIE MOUSSLY

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51230

Study participating centre

PHARMACIE BOURDY-DUBOIS-CHANEL

France

58640

Study participating centre

PHARMACIE VIVIEN - MINIGHETTI

France

13200

Study participating centre

PHARMACIE HENRY

France

18120

Study participating centre

PHARMACIE COHARD

France

86540

Study participating centre

PHARMACIE LESOIF-GRIMAULT

France

53500

Sponsor information

Organisation

Observia

Organisation

MSD France

Funder(s)

Funder type

Industry

Funder Name

Merck

Alternative Name(s)

Merck & Co., Inc., Merck & Co.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Laura Romengas (laura.romengas@observia-group.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	01/05/2020	Yes	No