An international, multicentre, observational, prospective, longitudinal cohort study to assess the impact of integrated upper limb spasticity management including the use of bont-A injections on patient-centred goal attainment in real life practice – ULIS III

SECONDARY IDENTIFICATION NUMBER
Y-79-52120-206

SCIENTIFIC TITLE
An international, multicentre, observational, prospective, longitudinal cohort study to assess the impact of integrated upper limb spasticity management including the use of bont-A injections on patient-centred goal attainment in real life practice – ULIS III

PROJECT DESCRIPTION
To assess the longitudinal attainment of patient centred and function related goals after botulinum toxin A (BoNT-A) injection (including following repeated injection cycles where these occur) alongside integrated spasticity management used in real life settings over a period of 2 years.

PROJECT DURATION

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Duration in Months</th>
<th>Target Completion Date</th>
<th>Actual Completion Date</th>
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</thead>
</table>

PROJECT STATUS
Completed

REASON FOR PROJECT PENDING/SUSPENSION/TERMINATION
Unspecified

IMPLEMENTING AGENCY (PRIMARY SPONSOR)

<table>
<thead>
<tr>
<th>Institution</th>
<th>Classification</th>
<th>Region</th>
<th>LTO #</th>
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<tbody>
<tr>
<td>Ipsen Innovation S.A.S.</td>
<td>Private Business</td>
<td>France</td>
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COOPERATING AGENCY (SECONDARY SPONSOR)

<table>
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<tr>
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<tr>
<td>Covance Scientific Services and Solutions, Inc</td>
<td>Private Business</td>
<td>Philippines</td>
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FUNDING AGENCY (SOURCES OF MONETARY OR MATERIAL SUPPORT)

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<td>France</td>
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CONTACT FOR PUBLIC QUERIES

<table>
<thead>
<tr>
<th>Name</th>
<th>E-Mail</th>
<th>Phone Number</th>
<th>Institution and Institution Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richard Bungay</td>
<td><a href="mailto:Richard.Bungay@covance.com">Richard.Bungay@covance.com</a></td>
<td>+639175575867</td>
<td>Covance Scientific Services and Solutions, Inc., 12th Floor One Corporate Centre Office Condominium Julia Vargas corner</td>
</tr>
</tbody>
</table>
CONTACT FOR SCIENTIFIC QUERIES

<table>
<thead>
<tr>
<th>Name</th>
<th>E-Mail</th>
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<th>Institution and Institution Address</th>
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<tbody>
<tr>
<td>Helen Altarejos</td>
<td><a href="mailto:helen.altarejos@covance.com">helen.altarejos@covance.com</a></td>
<td>+65 6568 6764</td>
<td>Covance (Asia) Pte Ltd 1 International Business Park #01-01 The Synergy Singapore 609917</td>
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IMPLEMENTING AGENCY (PRIMARY SPONSOR)

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise</th>
<th>Affiliation</th>
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<tbody>
<tr>
<td>Mary Jeanne Flordelis, MD</td>
<td>Internal Medicine</td>
<td>Perpetual Succour Hospital</td>
</tr>
<tr>
<td>Raymond L. Rosales, MD</td>
<td>Neurology</td>
<td>Metropolitan Medical Center</td>
</tr>
</tbody>
</table>

RESEARCH CLASSIFICATION

Clinical Trial

HEALTH CONDITION(S) OR PROBLEM(S) STUDIED

INTEGRATED UPPER LIMB SPASTICITY

PRIMARY OUTCOMES

To assess the longitudinal attainment of patient centred and function related goals after botulinum toxin A (BoNT-A) injection (including following repeated injection cycles where these occur) alongside integrated spasticity management used in real life settings over a period of 2 years

KEY SECONDARY OUTCOMES

- To describe baseline characteristics (demographic data, aetiology, severity and distribution of spasticity (focal or regional), severity of impairment, presence of severe weakness, time since onset of the event leading to upper limb spasticity (ULS), time between onset of the event and first BoNT-A injection) of patients with ULS.- To describe real life practice in the use of BoNT-A injection(s) (BoNT-A preparation, dose, time intervals between injections, injection points, and injection guidance: electromyography (EMG), electrostimulation (ES), or ultrasound (US)).- To describe and quantify the concomitant therapies (e.g. specific interventions by physiotherapists and occupational therapists) given in real life practice using the Upper Limb Focal Spasticity Therapy Recording Schedule (ULSTR).- To assess the longitudinal attainment of patient centred goals by goal area, including the attainment of treatment goals after each cycle of BoNT-A injections, using the Goal Attainment Scaling Evaluation of Outcomes for Upper Limb Spasticity (GASeous) tool and goal related standardised measures within the Upper Limb Spasticity Index (ULS-Index).- To assess the percentage achievement of treatment goals per goal area after repeated BoNT-A injections.- To describe the evolution of goals across the study and changes from baseline in standardised outcome measures.- To describe the correlations between patient centred goal attainment and standardised measures directed by the primary goal areas after each BoNT-A injection cycle.- To assess the effectiveness of BoNT-A on upper limb passive function: hygiene, dressing, limb position and pain; the four domains of the Disability Assessment Scale (DAS), as well as the Principal Target of Treatment (PTT).- To assess global assessment of benefits by both the investigator and the caregiver and/or patient.- To assess the change in Quality of Life (using the EuroQol 5 Dimensions, 5 Levels (EQ-5D 5L) and Spasticity Related Quality of Life Tool (SQoL-6D)) in a subpopulation of native English-speaking patients in Anglophone countries.

RECRUITMENT STATUS

Completed

COUNTRIES OF RECRUITMENT

Australia, Austria, Brazil, France, Germany, Hong Kong, Italy, Mexico, Philippines, Poland, Portugal, Russia, Taiwan, United Kingdom, United States

FDA DOCUMENT TRACKING NUMBER

Contact #: (+632) 8377534, (+632) 8377537, (+632) 8372071-80 loc. 2117, 2112 Saliksik Building, DOST Compound, Gen. Santos Ave., Bicutan Taguig City 1631 Philippines
20150226141644

FDA APPROVAL DATE
2015-04-27

ERC APPROVAL DATE
0000-00-00

FIRST ENROLMENT DATE
2015-04-27

TARGET SAMPLE SIZE (PHILIPPINES)
30

ACTUAL SAMPLE SIZE (PHILIPPINES)
38

REASON FOR THE DIFFERENCE BETWEEN TARGET & ACTUAL SAMPLE SIZES
due to patient potential

DATE OF FIRST ENROLMENT
2015-04-27

KEY INCLUSION AND EXCLUSION CRITERIA (CT)

All patients enrolled must fulfil the following criteria:
- Adults (aged more than 18, 20 or 21 years, according to local legislation).
- Patients with ULS, in whom a decision has already been made to inject BoNT-A.
- Patient has provided written informed consent for collection of the data (or patient participation must be validated in accordance with local policy/guidelines).

Exclusion Criteria
A patient will not be included in the study if they meet any of the following criteria:
- Participation in any interventional clinical study of ULS within the 12 weeks prior to the Inclusion visit (Visit 1).
- Patient has already been included in the current study, but was subsequently withdrawn.

STUDY TYPE
Observational

INTERVENTION NAME
Unspecified

INTERVENTION DESCRIPTION
Unspecified

AMENDMENT APPROVAL DATE/REASONS

Contact #: (+632) 8377534, (+632) 8377537, (+632) 8372071-80 loc. 2117, 2112
Saliksik Building, DOST Compound, Gen. Santos Ave., Bicutan Taguig City 1631 Philippines
METHOD OF ALLOCATION

Randomized

MASKING / BLINDING

N/A

MASKING DETAILS

Unspecified

ASSIGNMENT

Single

PURPOSE

To assess the longitudinal attainment of patient centred and function related goals after botulinum toxin A (BoNT-A) injection (including following repeated injection cycles where these occur) alongside integrated spasticity management used in real life settings over a period of 2 years

PHASE

Phase IV

RESEARCH UTILIZATION

<table>
<thead>
<tr>
<th>Utilization</th>
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<tbody>
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<td>Publication</td>
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<td>Oral Presentation</td>
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<tr>
<td>Drug Literature</td>
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<td>Posters</td>
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<td>Others</td>
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