

## Contract

between

**THREEWIRE GmbH**

**Eschersheimer Landstrasse 14, 60322 Frankfurt am Main, Germany**

- hereinafter referred to as THREEWIRE -

and

**Kyjov 1225**

**Nemocnice Kyjov, příspěvková organizace, Strážovská 1247/22, 697 01 Kyjov**

- hereinafter referred to as STUDY SITE –

### **PREAMBLE**

This concerns the following A PHASE 3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLINDED STUDY TO EVALUATE THE EFFICACY, SAFETY, AND TOLERABILITY OF A CLOSTRIDIUM DIFFICILE VACCINE IN ADULTS 50 YEARS OF AGE AND OLDER (hereinafter the STUDY), Sponsor: Pfizer Inc. 235 East 42nd Street NY, NY 10017, The United States of America (hereafter referred to as the “Sponsor”)

### **IN CONSEQUENCE THEREOF, THE PARTIES HAVE AGREED AS FOLLOWS:**

#### **§ 1 - Object**

1.1 The object of this agreement (the “Contract”) is that the STUDY SITE allocates a qualified person (ENROLMENT ASSISTANT) to the STUDY SITE in order to provide it with needed assistance regarding to the services described herein.

1.2 The STUDY SITE assures that the ENROLMENT ASSISTANT holds the required skills, qualifications, diplomas and authorisations to practice as such in the country where the STUDY SITE is located and to provide the services described in Section 2 below.

#### **§ 2 - Services**

The ENROLMENT ASSISTANT shall provide to the STUDY SITE the services as set forth in Annex 1 (the “Services”),

#### **§ 3 - Compliance**

3.1 The parties shall comply with all applicable national laws, regulations, and guidelines when performing this Contract.

3.2 The STUDY SITE shall ensure that all access to patient files, collecting and processing of confidential patient information shall be in accordance with all applicable rules and guidelines of data privacy as demanded by the STUDY SITE.

3.3 the STUDY SITE assures that the ENROLMENT ASSISTANT will not sign patients on an informed consent form.

#### **§ 4 - Instructions and Supervision**

4.1 The parties to this Contract agree that the ENROLMENT ASSISTANT works for the STUDY SITE and is exclusively subject to the instructions and supervision of the STUDY SITE with regards to the Services, in particular with regard to the access, review, and processing of data, documents, dossiers and other patient records or files.

4.2 The Study Site agrees to charge THREEWIRE exclusively for the provision of the Services described in this Contract.

#### **§ 5 - General Obligations of the STUDY SITE**

5.1 The STUDY SITE is obligated to make all the necessary arrangements so that the ENROLMENT ASSISTANT can carry out the Services in accordance with this Contract.

For this purpose, the STUDY SITE shall make a suitable workplace available for the ENROLMENT ASSISTANT, where patient-related data, dossiers and other records or files can be reviewed and examined by the ENROLMENT ASSISTANT. The STUDY SITE shall assure that the ENROLMENT ASSISTANT has access to his/her workplace and the relevant data and documents during the STUDY SITE'S normal business hours.

5.2 The STUDY SITE will control all personal data of patients collected and processed by the ENROLMENT ASSISTANT. Before the ENROLMENT ASSISTANT starts providing the Services, the STUDY SITE shall conclude with the ENROLMENT ASSISTANT a data processing agreement and a confidentiality agreement in accordance with the applicable rules on data privacy. The STUDY SITE appoints:

Contact person: 

as the contact person for the ENROLMENT ASSISTANT, who shall support the ENROLMENT ASSISTANT especially for questions about technical issues and arrangements.

5.3 The STUDY SITE shall report on a weekly basis to THREEWIRE the outcome of each Potential Study Participant.

5.4 The STUDY SITE shall add the ENROLMENT ASSISTANT's details to Sponsor Site Delegation Logs and any other logs and reports.

#### **§ 6 - General Obligations of the ENROLMENT ASSISTANT**

6.1 The ENROLMENT ASSISTANT is not authorised to remove data, documents, dossiers or other information media from the assigned workplace. The ENROLMENT ASSISTANT does not have permission to make copies, etc. unless the STUDY SITE has given prior explicit permission.

6.2 With regards to handling patient files and data, the ENROLMENT ASSISTANT is subject to the instructions and supervision of the STUDY SITE. The ENROLMENT ASSISTANT agrees to comply with the instructions from, and the internal regulations that are applicable at, the STUDY SITE.

6.3 The ENROLMENT ASSISTANT shall report each week to THREEWIRE about how the Services are progressing (as set forth in Annex 1 hereinafter "Services").

6.4 The ENROLMENT ASSISTANT is not authorised to sign patients on the Informed Consent. This is the sole obligation of the STUDY SITE.

### **§ 7 - Compensation**

The parties to the Contract agree that THREEWIRE shall provide compensation as specified in Annex 2 hereto, which forms part of this Contract.

### **§ 8 - Confidentiality**

8.1 THREEWIRE, the ENROLMENT ASSISTANT and the STUDY SITE are mutually obligated to maintain in strict confidence any information of which they become aware whilst implementing this Contract. This applies, in particular, to the personal data of the patients of which the ENROLMENT ASSISTANT becomes aware in relation to and during his/her Services in accordance with this Contract.

8.2 The STUDY SITE acknowledges and agrees that, in accordance with applicable legislation, the ENROLMENT ASSISTANT is not permitted to collect, process or use the personal data of which he/she becomes aware in relation to and whilst performing the Services for any purpose other than for the correct performance of his/her Services under this Contract. In particular, the transmission of personal data to third parties is not permitted.

All documents, which contain or may contain personal data, must be stored in such a way that they are protected against access by unauthorised persons.

Furthermore, the ENROLMENT ASSISTANT shall observe all other data protection and safety regulations and instructions which are given by the STUDY SITE, are contained in the data processing Agreement, or are applicable in the STUDY SITE.

The STUDY SITE shall assure that the ENROLMENT ASSISTANT has been trained in how to treat confidential patient data as well as on the applicable statutory regulations before proceeding with such identification.

8.3 The above commitments shall also continue to apply for a period of 30 years after the provision of all the Services or the termination of the present Contract.

### **§ 9 - No Guarantee**

Neither THREEWIRE nor the STUDY SITE warrant or guarantee that the work of the ENROLMENT ASSISTANT will lead to the identification of Potential Study Participants.

### **§ 10 - Term and Termination**

10.1 This Contract is initially concluded for a period of 24 weeks. The Contract comes into effect on signature date.

10.2 This contract covers a maximum of 192 hours for conducting the following. The parties to this Contract may extend the term of the Contract by written agreement before the expiration of the initial contractual term.

10.3 The Parties to the Contract may terminate this contract with a 7 day written notice.

10.4 The right to termination of the Contract for material breach remains unaffected. Any notice shall be served by registered letter.

10.5 Should the THREEWIRE terminate this Contract because of circumstances that are caused by the ENROLMENT ASSISTANT or his/her behaviour, the STUDY SITE shall have the opportunity to appoint a different ENROLMENT ASSISTANT within a period of 14 calendar days, who will take the place of the ENROLMENT ASSISTANT working under the present Contract.

10.6 In the event that the present Contract is terminated, then the ENROLMENT ASSISTANT shall:

- Submit a report to the STUDY SITE that documents the results of the ENROLMENT ASSISTANT'S Services up to the time that the termination comes into effect. The ENROLMENT ASSISTANT will inform THREEWIRE of the submission date of this report to the STUDY SITE and of the number of patients that were identified as Potential Study Participants.
  
- Warrant to the STUDY SITE and to THREEWIRE by means of a written declaration that no personal data obtained in relation to and during the implementation of this Contract, are in the possession of the ENROLMENT ASSISTANT. This also applies to such personal data recorded by the ENROLMENT ASSISTANT as part of his/her own note, regardless of the type of note. The ENROLMENT ASSISTANT will warrant to the STUDY SITE and THREEWIRE in writing that such notes have been destroyed.

10.7 If required, this contract will come to Term only after Approval or Confirmation of Receipt is received by a competent Ethics Committee.

## **§ 11 No inducement to Prescribe or Purchase**

The parties confirm that the conclusion of this Contract has no influence on sales transactions and, in particular, with regards to procurement processes/pricing in connection with the STUDY SITE and that there are also no expectations in this regard. Furthermore, the parties confirm that the conclusion of this Contract and the services being delivered thereunder are not intended as an incentive for a preferred prescription and/or use and/or recommendation of certain medicines and/or other products.

## **§ 12 Miscellaneous**

No failure or delay by a Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise

of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

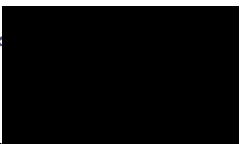
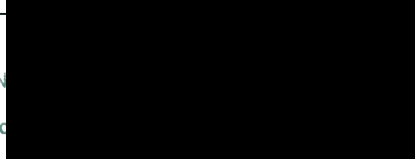
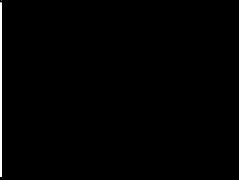
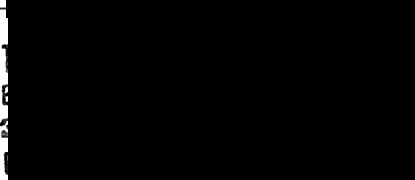
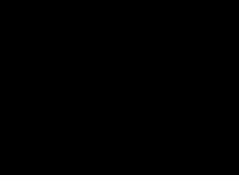
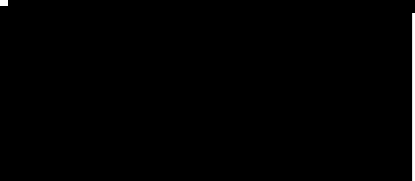
Should one or more provision of this Agreement become invalid, the remaining provisions shall remain valid and in full force and effect. The Parties agree to replace such an invalid provision by a valid one which takes the originally intended economic, legal and other objectives of the Parties with regards to this Agreement into account.

This Agreement, including all attachments and appendices, constitutes the entire Agreement between the Parties with respect to the subject matter hereof and supersedes and extinguishes all previous Agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter. Any amendments of or supplements to this Agreement must be made in writing to be valid; this requirement may solely be waived in writing.

This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be subject to German law without regard to any provisions referring to the law of another country. The venue for disputes emanating from this Agreement shall be Frankfurt/Main, Germany. Notwithstanding the prior sentence, the parties agree to resolve any disputes between them in connection to this Agreement through binding arbitration conducted in the English language before a single arbitrator in Frankfurt/Main, Germany. It is highlighted that either party may conduct such arbitration via tele/video-conferencing, or physical appearance by the Party and/or his representative is not required.

The Parties hereby declare that they have read through this Agreement prior to signature thereof and that it has been concluded following mutual discussion, freely and of their own volition, definitively and solemnly, and that they have the **full authority to sign this contract on behalf of their organizations**, in witness whereof they have hereunto set their signatures.

**DATE AND SIGNATURES**

	BY:	DATE:	SIGNATURE:
STUDY SITE:		26 MAR 2018	
THREEWIRE:		4April2018	
PRINCIPAL INVESTIGATOR (acknowledgment only):		26 MAR 2018	

## Annex I

The ENROLMENT ASSISTANT shall provide the following services:

### **A. General Services**

1. Identify, according to the STUDY SITE request and on the basis of all the documents provided by it, patients of the STUDY SITE who can be eligible for participation in the STUDY (the 'Potential Study Participants');
2. Create a full database of Potential Study Participants (the 'Patients Database');
3. Providing phone Screening to patients who can be eligible for participation in the STUDY (the 'Potential Study Participants') this may include patients who are already included in the STUDY SITE database or self-referred patients from community hospitals or media outreach;
4. Correspondingly to the STUDY SITE request, scheduling screening meetings and enter the information collected therefrom the Patients Database into the my-patient.com or into any other alternative data conservation program provided to them;
5. Provide a reminder to Study Participants regarding screening meetings attendance as well as alternative site visits, all which in addition to a complete study related reports and logs.
6. Assist and advice the Study Participants in the completion of study related documentation and compliance with study procedures.
7. Communicating with referral sites in the vicinity of the Study site in order to facilitate referrals of Potential Study Participants. The mentioned above may include phone reminders, visits and distribution of approved Study Materials.
8. Coordinating the process of transferring patients from a referral site to the STUDY SITE.
9. At the request of the STUDY SITE, the ENROLMENT ASSISTANT shall examine patient-related data, documents, dossiers, and other records or files, which are made available to him/her by the STUDY SITE, with the objective of determining whether the patients can be eligible for participation in the STUDY (the 'Potential Study Participants').

### **B. Patients Database**

1. After having identified Potential Study Participants pursuant to Section 4 above, the ENROLMENT ASSISTANT shall enter certain of their personal data into a patient database to be held at the STUDY SITE (the "Patients Database"). This Patients Database will include for each Potential Study Participant: the name, gender, birth date, address, city or town of residence and contact data (general patient information) as well as the state of health and any existing illnesses (health-related patient information).
2. The results of the ENROLMENT ASSISTANT'S work shall be made available exclusively to the STUDY SITE, in the form of the Patients Database.

3. The ENROLMENT ASSISTANT shall generate, at regular intervals, progress reports allowing THREEWIRE to monitor progress in the provision of the Services. The STUDY SITE and the ENROLMENT ASSISTANT shall assure that these reports only contain aggregated data without any personal data and that no conclusions can be drawn at any time about the identity of individual persons.

### **C. Pre-Screening of Potential Study Participants**

1. The ENROLMENT ASSISTANT will contact Potential Study Participants at the request of the STUDY SITE and record in the Patients Database whether they can be eligible for the STUDY. The ENROLMENT ASSISTANT shall record the date and time of any contact with a Potential Study Participant. He/she shall also record whether the Potential Study Participant being approached has an interest in participating in the STUDY and, if the Potential Study Participant does not have such interest, the reason for this decision.

2. At the request of and in coordination with the STUDY SITE, the ENROLMENT ASSISTANT shall make an appointment between the STUDY SITE and the Potential Study Participants who have shown interest in participating in the STUDY, for the purpose of determining whether they should be included in the STUDY. The date of the appointment shall be entered into the Patients Database.

3. The outcome of this exercise to determine inclusion shall be documented in the Patients Database. If inclusion in the STUDY is not possible based on the outcome of the above exercise, the ENROLMENT ASSISTANT shall then record the reasons thereof into the Patients Database.

### **D. Communicate and coordinate recruitment related activities with referral physicians.**

1. ENROLMENT ASSISTANT will at the request of the study site will coordinate recruitment activities with referral practices. These tasks will include informing referral physicians regarding the Study providing informational materials to referral physicians and visiting referral physicians.

2. ENROLMENT ASSISTANT will not review patient confidential information at referral hospitals without receiving Patient consent. ENROLMENT ASSISTANT and STUDY SITE assure that only approved study materials are used.

## Annex 2

The parties to the Contract agree that THREEWIRE shall compensate the STUDY SITE and the STUDY SITE shall compensate the ENROLMENT ASSISTANT for the Services performed by him/her in accordance with the Contract.

1. THREEWIRE agrees to pay the following amount:

€ [18] (in words: [eighteen] Euro) per hour for work excluding statutory VAT.

€ [17] (in words: [seventeen] Euro) per hour as overhead costs excluding statutory VAT.

**Total of € [35] (in words: [thirty-five] Euro) per hour excluding statutory VAT**

2. The amount has to be paid by THREEWIRE within 30 days after receiving the invoice to the following bank account:

**Account holder: Nemocnice Kyjov, příspěvková organizace**

**Bank: Komerční banka, a.s.**

**Bank code:** [REDACTED]

**Account No.:** [REDACTED]

**SWIFT No.:** [REDACTED]

3. The ENROLMENT ASSISTANT acknowledges and agrees that he/she is not entitled to any compensation from THREEWIRE/ for the Services provided under this Contract and, in particular, that is not entitled to any compensation from the THREEWIRE over and above the defined in this Contract.
4. The STUDY SITE/ is solely responsible for the payment of all federal, state, and local taxes or fees.
5. No compensation will be provided to the ENROLMENT ASSISTANT for activities/hours reported prior to full execution of this contract, as determined by the signatures/dates of all parties involved.



### ThreeWire Enrollment Assistant Scope and Responsibilities Document

Study Site Name & ID: Nemocnice Kyjov 1225 Study Site Location: Kyjov

Principal Investigator: [REDACTED] Study Coordinator: [REDACTED]

The purpose of this document is to outline the roles and responsibilities of a ThreeWire Enrollment Assistant™ (EA) based on the needs of the study site listed above. Additional duties beyond this scope require prior approval from the ICON-Pfizer team.

**A. Role of the Enrollment Assistant to be performed by:**

- ThreeWire provided EA
  - Nurse
  - Other Healthcare Professional (describe): \_\_\_\_\_
- Study site identified resource
  - Existing site employee to work additional hours, evening or weekends
  - Existing site employee to dedicate a portion of existing working hours to this program
  - Temporary additional resource retained by the study site
- Other: \_\_\_\_\_

**B. The planned services to be performed by the Enrollment Assistant include (select all applicable):**

- Chart Review
  - Electronic/paper - on site
  - Review at a referral clinic
- Pre-Screening and Follow-up
  - Pre-screening for eligibility to protocol
  - Mailings to pre-qualified patients
  - Medical record retrieval
  - Scheduling appointments
  - Appointment reminders
  - Other— please describe: \_\_\_\_\_
- Media Referral Follow-up
- Community Outreach
  - Community awareness by posting approved study materials in appropriate locations
  - Plan and coordinate community outreach events
  - Attend community outreach events
  - Connect with community members to generate referrals and raise awareness of the study
- Other: \_\_\_\_\_

C. Hours and Duration of Support (*initial allotment 192 hours*)

- Planned hours per week: max 15 hours \_\_\_\_\_
- Planned days per week: \_\_\_\_\_

D. Facility information: Please answer the following (applicable to ThreeWire provided EAs):

- Is a work station with a computer and a phone available? yes \_\_\_\_\_
- Is EMR access required? (*If chart review is a duty*) yes \_\_\_\_\_
- Is a badge required for access into the building? no \_\_\_\_\_

E. Training Requirements and Responsibilities

All EA's will be trained by ThreeWire on indices I, III and V.  
The study site is responsible for indices II and IV.

Index	Area of Training	Training to be Provided and/or Documented by:		
		ThreeWire	Study Site	Sponsor
I	Good Clinical Practices	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
II	Patient Privacy	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
III	Study Protocol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
IV	Site specific training & Study operations and logistics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
V	Reporting	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please complete and sign the respective section below to acknowledge that you have been informed of and agree to the plan described above for Enrollment Assistant support for the B5091007 protocol at this study site:

\_\_\_\_\_

**Study Site Representative**

MURP

\_\_\_\_\_

**Title**

\_\_\_\_\_

**Signature**

26 MAR 2018

\_\_\_\_\_

**Date**

\_\_\_\_\_

**ThreeWire, GmbH. Representative**

\_\_\_\_\_

**Title**

\_\_\_\_\_

**Signature**

\_\_\_\_\_

**Date**