

RECORD OF TELEPHONE CONVERSATION

Submission Information

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| Application Type | BLA |
| STN | 125428/0.0 |
| Review Office | OVRR |
| Applicant | Dynavax Technologies Corporation / Lic. # 1883 |
| Product | Hepatitis B Vaccine (Recombinant), Adjuvanted |
| Trans-BLA Group: | No |

Telecon Details

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|---------------------------------|-----------------------------------|
| Telecon Date/Time | 28-SEP-2016 09:52 AM |
| Author | SAID, MARIA |
| EDR | No |
| Post to Web | No |
| Outside Phone Number | |
| FDA Originated? | Yes |
| Communication Categories | IR - Information Request |
| Related STNs | None |
| Related PMCs | None |
| Telecon Summary | IR Post Marketing Study questions |
| FDA Participants | Katherine Berkhausen |
| Applicant Participants | Elaine Alambra |

Telecon Body:

From: Berkhausen, Katherine

Sent: Wednesday, September 28, 2016 9:52 AM

To: Alambra, Elaine

Cc: Daemer, Richard J.

Subject: IR post marketing study

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Dear Elaine,

We have the following information request and ask that you provide your response within a week.

1. The Phase 4 Post-Marketing Study Concept (Appendix 1 of the Risk Management Plan, STN 125428/0.42, module 1.16) states that “it is estimated that the study duration will be approximately 8 years in duration including protocol development and study preparation, subject accrual and collection of safety events, data analysis, and report writing.” Please provide the number of years that will be needed specifically for subject accrual as well as an explanation and justification for this time estimate. What rate of vaccination uptake are you expecting?

2. The Phase 4 Post-Marketing Study Concept (Appendix 1 of the Risk Management Plan, STN 125428/0.42, module 1.16) states that a sample size of 20,000 subjects per group will achieve 90% power to detect a 2.5 fold increase in the incidence of most immune-mediated diseases. Please describe:

- what is meant by “most immune-mediated diseases”.
- the calculation used to determine this sample size, including the background incidence rate and the rationale for using this background incidence rate.

Kind regards,

Katherine

Katherine Berkhausen
CAPT., US Public Health Service

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