STATISTICAL ANALYSIS PLAN

Protocol Title:	A Phase 2a, Open Label, Proof-of-Concept Trial of Daxdilimab for the Treatment of Moderate-to-Severe Alopecia Areata
Name of Test Drug:	Daxdilimab (HZN-7734)
Protocol Number:	HZNP-DAX-201
Protocol Version (Date):	07-Jan-2022
Analysis Type:	All Planned Analyses
Analysis Plan Version:	v1.0
Analysis Plan Author(s):	[redacted]

NOTICE OF CONFIDENTIAL AND PROPRIETARY INFORMATION

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LIST OF ABBREVIATIONS

AA	alopecia areata
ADA	anti-drug antibodies
AE	adverse event
AESI	adverse event of special interest
[redacted]	[redacted]
ALT	alanine aminotransferase
AST	aspartate aminotransferase
BMI	body mass index
[redacted]	[redacted]
CSR	clinical trial report
IP	investigational product
MedDRA	Medical Dictionary for Regulatory Activities
PD	pharmacodynamics
pDC	plasmacytoid dendritic cell
PK	pharmacokinetics
PT	preferred term
Q1, Q3	first quartile, third quartile
Q4W	once every 4 weeks
QTc	QT interval corrected for heart rate
QTcB	QT interval corrected for heart rate using Bazett's formula
QTcF	QT interval corrected for heart rate using Fridericia's formula
SAE	serious adverse event
SALT	severity of alopecia tool
SAP	statistical analysis plan
SAS	Statistical Analysis Software
SD	standard deviation
SOC	system organ class
SPP	statistical programming plan
TEAE	treatment-emergent adverse event
ULN	upper limit of normal
WHO-DD	World Health Organization Drug dictionary

SAP REVISION

Revision Date (DD MMM YYYY)	Section	Summary of Revision	Reason for Revision

1 INTRODUCTION

This document describes the statistical analysis for protocol HZNP-DAX-201, a phase 2a, open label, proof-of-concept trial of daxdilimab for the treatment of moderate-to-severe alopecia areata (AA).

2 TRIAL OVERVIEW

2.1 Trial Objectives and Endpoints

The objectives and corresponding endpoints are listed in Table 1 below:

Table 1 Trial Objectives and Endpoints

Primary Objectives	**Endpoints**
To evaluate the effect of daxdilimab on reducing hair loss at Week 24 in participants with AA.	Percent change from baseline in Severity of Alopecia Tool (SALT) score at Week 24.
Secondary Objectives	**Endpoints**
To evaluate the effect of daxdilimab on reducing hair loss through 9 months of treatment in participants with AA.	• Percent change from baseline in SALT score at Weeks 12-20; 28-36. • Proportion of participants who achieve ≥50% reduction in SALT from baseline at Weeks 12-36. • Proportion of participants with absolute SALT score ≤ 10, 20, 30, 50 at Weeks 12-36.
To evaluate the post-treatment duration effect of daxdilimab on reducing hair loss in participants with AA.	• Percent change from baseline in SALT score at Weeks 40-48. • Proportion of participants who achieve ≥50% reduction in SALT from baseline at Weeks 40-48. • Proportion of participants with absolute SALT score ≤ 10, 20, 30, 50 at Weeks 40-48.
To characterize the PK, PD, and immunogenicity of daxdilimab.	• Daxdilimab concentrations. • Change from baseline in plasmacytoid dendritic cells (pDCs). • Anti-drug antibody (ADA) rate.
To evaluate the safety and tolerability of daxdilimab.	Incidence of adverse events (AEs), serious adverse events (SAEs), and adverse events of special interest (AESIs).
[redacted]	[redacted]
[redacted]	[redacted]

Table 1 Trial Objectives and Endpoints

To characterize the PD of daxdilimab.	Change from baseline in blood biomarkers.

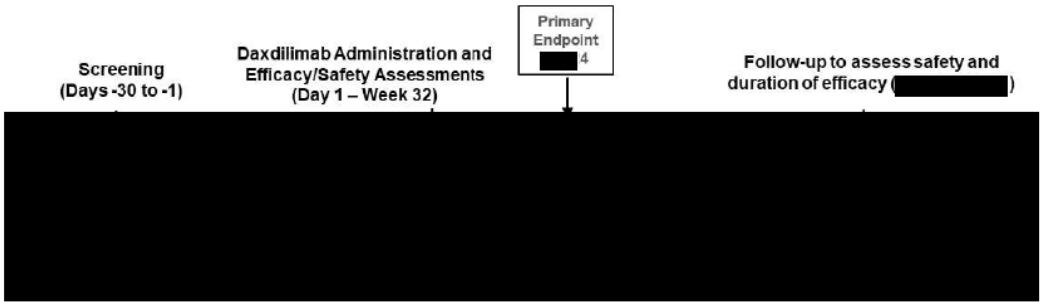
Abbreviations:
AA, Alopecia Areata; ADA, anti-drug antibody; AE, adverse event; AESI, adverse event of special interest; [redacted] PD, pharmacodynamic; pDC, plasmacytoid dendritic cell; PK, pharmacokinetic; SAE, serious adverse event; SALT, Severity of Alopecia Tool.

2.2 Trial Design

This is a Phase 2a, multicenter, open-label, proof-of-concept trial to assess the preliminary efficacy, safety, tolerability, PK, and PD of daxdilimab in participants with moderate to-severe AA.

The trial will comprise of a screening period of up to 30 days with enrollment on Day 1. Participants will be treated with daxdilimab [redacted] mg [redacted]. The primary endpoint assessment will occur during the Week 24 visit. All participants will have a follow-up period of 16 weeks (through Week 48) to evaluate long-term safety and to observe the duration of efficacy following the treatment period. The basic study flow diagram is presented in Figure 1. Refer to Protocol for detailed trial design.

Figure 1 Study Flow Diagram



2.3 Sample Size

A total of up to 30 participants will receive daxdilimab in the trial. The sample size was determined by the need to evaluate potential efficacy, safety and tolerability, and PK/PD. No formal power calculation was performed.

The mean percent reduction from baseline in SALT score was 58% in 4 mg group at Week 36 in Eli Lilly's phase 2 AA trial (n=28) (King B, Ko J, Forman S, et al., 2021). The lower bound of the 95% confidence interval was about 42%. With 30 participants, if we observe a mean percent reduction from baseline in SALT score of 58% at Week 24, there is about 98% confidence that the mean percent reduction from baseline is at least 42%. The estimated confidence level that true mean percent reduction from baseline in SALT score is above a cutoff for an observed mean is provided in Table 2.

Table 2 Confidence level that true mean percent reduction from baseline in SALT score is above a cutoff for an observed mean

	Observed	Confidence that mean is		
n	Mean % reduction	≥35%	**≥42%**	≥45%
30	50%	0.97	**0.85**	0.74
	55%	>0.99	**0.95**	0.90
	58%	>0.99	**0.98**	0.95

The proportion of patients achieving SALT ≤20 at Week 36 in 4 mg group was 33% and 35% in two Eli Lilly's phase 3 AA trials. The lower bound of the 95% confidence interval was about 27%. The estimated confidence level that true proportion of participants achieving SALT ≤20 is above 27% and other cutoffs for an observed response rate is provided in Table 3.

Table 3 Confidence level that true proportion of participants achieving SALT ≤20 is above a cutoff for an observed response rate.

	Observed	Confidence that response rate is		
n	response rate	≥20%	≥25%	**≥27%**
30	9 (30%)	0.87	0.67	**0.58**
	11(36.7%)	0.97	0.89	**0.84**
	12(40%)	0.99	0.95	**0.92**
	13(43.3%)	0.99	0.98	**0.96**
	15(50%)	0.99	0.99	**0.99**

3 PLANNED ANALYSES

3.1 Primary Analysis

The primary analysis will be performed when all participant have completed Week 24 or withdraws prior to the scheduled Week 24 visit. All available data on or before the data cut-off (including data collected after Week 24) will be included in the primary analysis.

3.2 Final Analysis

The final analysis will be performed when all participants have completed trial.

4 STATISTICAL METHODS

4.1 General Considerations for Data Analyses

All statistical calculations will be primarily performed using SAS® System Version 9.4 or higher. Analysis results will be presented using descriptive statistics. For categorical variables, the number and percentage of participants in each category will be presented; for continuous variables, the number of participants (n), mean, standard deviation (SD), median, first quartile (Q1), third quartile (Q3), minimum, and maximum will be presented.

For additional details on data presentation, refer to the Statistical Programming Plan (SPP).

4.1.1 Definition of Baseline

Unless otherwise specified, baseline is defined as the last non-missing valid observation prior to the first dose of investigational product (IP). In cases where baseline measurements are taken on the same day as IP and no times are reported, it will be assumed that these measurements are taken prior to IP being administered.

4.1.2 Analysis Windows

Analysis visit windows will be used for all visit-based assessments to map longitudinal observations to scheduled visits and thereby allow for by-visit analyses, since not all assessments are performed on the scheduled day. Unless otherwise specified, all longitudinal efficacy, safety, and biomarker data analyses will be based on the analysis visit windows. The analysis visit windows will be calculated by bisecting the interval between adjacent scheduled visit days except for the first post-treatment visit. The first post-treatment visit will start at Day 2. The detailed analysis visit windows will be specified in SPP.

The actual assessment day will be mapped to the windows defined for each scheduled study visit with following rules:

- If more than one assessment falls within a visit window, the closest non-missing assessment to the scheduled day will be used in the analysis.
- If 2 non-missing assessment actual dates are equidistant from the target day, the later visit will be used in the analysis.
- For retest values of laboratory data, the retest value will be chosen.

All observations will be included in data listings.

4.1.3 Missing Data

In general, missing data will not be imputed unless methods for handling missing data are specified.

4.2 Protocol Deviations

The protocol deviations are reviewed and categorized as major and minor prior to the database lock. The number and percentage of participants with major protocol deviations by

deviation reason (eg, nonadherence to study drug, violation of select inclusion/exclusion criteria) will be summarized. A by-participant listing will be provided for all protocol deviations.

A by-participant listing will be provided for those participants who did not meet at least one eligibility (inclusion or exclusion) criterion. The listing will present the eligibility criterion (or criteria if more than one deviation) that participants did not meet and related comments, if collected.

4.3 Analysis Sets

4.3.1 Safety Analysis Set

The safety analysis set is defined as participants who received any dose of daxdilimab. The efficacy, safety, pharmacodynamics (PD) and immunogenicity analyses will be based on the safety analysis set.

4.3.2 Pharmacokinetic Analysis Set

The Pharmacokinetic (PK) analysis set is defined as participants who received any dose of daxdilimab and have at least one measurable PK concentration post dose. The PK analyses will be based on PK analysis set.

4.4 Subject Disposition

A summary of subject disposition will be presented using the categories presented below.

- Screened
- Screen failed with reasons
- Enrolled
- Enrolled but not treated
- Enrolled and treated
- Completed treatment
- Discontinued treatment with reasons
- Completed trial
- Discontinued trial with reasons

4.5 Investigational Product Exposure

The number of doses received, amount of the investigational product (IP) received, durations of the IP exposure, and treatment compliance will be summarized for the safety analysis set. The number and percentage of participants treated ≥ 4 weeks, ≥12 weeks, ≥ 24 weeks, and ≥ 36 weeks will also be provided.

- Durations of the study drug exposure = last dose date + 28 – first dose date + 1.

- The amount of study drug exposure: if a participant received partial dose at a dosing visit, then the amount of IP at that dosing visit will be estimated based on the actual volume administered.
- Treatment compliance for an individual participant = [Total number of doses received]/[Total number of doses planned per protocol] ×100%.

4.6 Demographics, Baseline Characteristics, and Medical History

The demographics (age, gender, race, ethnicity, height, weight, and body mass index) will be summarized.

Participant background information, including baseline SALT, [redacted]

Significant medical history finding will be summarized by MedDRA system organ class (SOC) and preferred term (PT).

4.7 Efficacy Analyses

4.7.1 Primary Efficacy Endpoint and Analysis

4.7.1.1 Primary Efficacy Endpoint

The primary efficacy endpoint is the percent change from baseline in SALT score at Week 24.

4.7.1.2 Primary Efficacy Analysis

The primary efficacy endpoint of percent change from baseline in SALT score at Week 24 will be summarized using descriptive statistics. A 2-sided 95% confidence interval will be calculated for the mean.

4.7.1.3 Handling Plan for Prohibited Medication Use and Treatment Discontinuation

The results after administration of the prohibited medications that are considered to be effective for treatment of AA, will be imputed using the worst observation on or prior to administration of the prohibited medications including baseline. The prohibited medications that are considered to be effective for treatment of AA will be identified and finalized by medical monitor before database lock of each planned analysis.

Participants who discontinue treatment early will be asked to come to scheduled evaluations until the end of the study unless participants withdraw consent of trial participation or are lost to follow-up. The data collected after discontinuation of study treatment will be included in the analysis.

4.7.1.4 Handling Plan for Missing Data

Missing visits, due to skipped visits or early dropout of study, will be imputed using the last observation carried forward (LOCF).

4.7.1.5 Sensitivity Analysis of the Primary Efficacy Endpoint

The sensitivity analysis of the primary efficacy endpoint will be performed using all available data in the same way as the primary analysis. The data collected after administration of the prohibited medications or discontinuation of study treatment will be included in the analysis. No data will be imputed for missing visits.

4.7.2 Secondary Efficacy Endpoints and Analyses

4.7.2.1 Secondary Efficacy Endpoints

The secondary efficacy endpoints are as follows:

- Percent change from baseline in SALT score at Weeks 12-20, 28-36, and Weeks 40-48.
- Proportion of participants who achieve ≥ 50% reduction in SALT from baseline at Weeks 12-36 and Weeks 40-48.
- Proportion of participants with absolute SALT score ≤ 10, 20, 30, 50 at Weeks 12-36 and Weeks 40-48.

4.7.2.2 Secondary Efficacy Analyses

The continuous secondary efficacy endpoints will be summarized in the same way as the primary efficacy endpoint, including handling plan for prohibited medication use, treatment discontinuation and missing data (Section 4.7.1.3 and Section 4.7.1.4). Spaghetti plots of SALT score by participant over time will be presented. In addition, percent change from baseline in SALT score over time will be analyzed by baseline IFN gene signature levels (high versus low).

The binary secondary efficacy endpoints will be summarized descriptively using frequencies and percentages. A 2-sided 95% confidence interval will be calculated for the percentage. The participants will be considered non responder after administration of the prohibited medications that are considered to be effective for treatment of AA. The data collected after discontinuation of study treatment will be included in the analyses. Missing visits due to skipped visits will be imputed using the last observation carred forward (LOCF), and the participants will be considered non-responders after early dropout of study.

4.7.2.3 Sensitivity Analysis of the Secondary Efficacy Analyses

The sensitivity analysis for the continuous endpoints will be performed in the same way as the sensitivity analysis for the primary efficacy endpoint (Section 4.7.1.2).

The sensitivity analysis will be performed for the binary efficacy endpoints using all available data with the same method as the secondary efficacy analyses. Data collected after administration of prohibited medications or after discontinuation of study treatment will be

included in the analysis. Missing visits due to skipped visits will be imputed using last observation carried forward (LOCF). Participants after early dropout of study will be considered as non-responders.

4.8 Safety Analyses

4.8.1 Adverse Events

In general, if an adverse event (AE) onset is on or after the first dose of IP, the AE will be considered as a treatment-emergent adverse event (TEAE). Otherwise, the AE will be considered as a non-TEAE.

AEs will be coded using the most recent version of MedDRA. All TEAEs will be summarized overall and by MedDRA system organ class (SOC) and preferred term (PT), by severity and by relationship to daxdilimab. Specific AEs will be counted once for each participant for calculating rates, but all events will be presented in participant listings. In addition, if the same AE occurs multiple times within a particular participant, the highest severity and level of causality will be reported.

An overall summary table will be showing the number and percentage of participants with at least one event in any of the following categories:

- TEAE
- Treatment-emergent serious adverse event (TESAE)
- TEAE resulting in death
- Grade 3 or higher TEAE

- TEAE leading to discontinuation of daxdilimab
- Serious and/or grade 3 or higher TEAE
- Daxdilimab related TEAE
- Daxdilimab related TESAE

The following AE summaries will also be provided by SOC and PT:

- TEAEs resulting in death
- Grade 3 or higher TEAEs
- TEAE leading to discontinuation of daxdilimab
- Daxdilimab related TEAE
- TESAEs
- Daxdilimab related TESAE
- Treatment-emergent adverse events of special interest (AESI, refer to protocol for detailed definition of AESI)

TESAEs will be summarized by serious adverse event (SAE) criteria as well. In addition, a summary of TEAEs sorted by frequency will be presented by PT. Listings will be provided for all TEAEs and non-treatment emergent AEs.

4.8.2 Clinical Laboratory Evaluations

The following summary will be provided for hematology and chemistry.

- Observed values and changes from the baseline by visit
- Worst toxicity grade
- At least 2-grade shift from baseline to worst toxicity
- Shift from the baseline relative to the normal range

In addition, the number and percentage of participants with the following liver-related abnormalities will be summarized if meet the following criteria at any post-baseline visit.

- AST or ALT: (a) $\geq 3 \times$ ULN; (b) $\geq 5 \times$ ULN; (c) $\geq 8 \times$ ULN
- Total bilirubin: $\geq 2 \times$ ULN
- ALT or AST ≥ 3 x ULN and total Bilirubin $\geq 2 \times$ ULN
- ALT or AST $\geq 5 \times$ ULN for more than 2 weeks

The following summary will be provided for urinalysis.

- Observed values and changes from the baseline
- Shift from the baseline relative to the normal range

Listings will be provided for all clinical laboratory evaluations.

4.8.3 Vital Signs

The observed values, along with the changes from baseline, will be summarized for systolic blood pressure, diastolic blood pressure, body temperature, heart rate, and respiratory rate. In

addition, a summary of participants with clinically significant vital signs values (meeting any of following criteria) will also be provided.

- Systolic blood pressure: < 90 mmHg, > 160 mmHg
- Diastolic blood pressure: < 60 mmHg, > 100 mmHg
- Heart rate: < 50 beats/min, > 100 beats/min
- Respiratory rate: < 12 breaths/min, > 23 breaths/min
- Temperature: < 36°C, >38°C

4.8.4 Prior and Concomitant Medications

Medications collected at screening and during the trial will be coded using the current version of the World Health Organization Drug dictionary (WHO-DD). Number (%) of participants who received prior medications and concomitant medications will be summarized by WHO-DD Anatomical Therapeutic Chemical (ATC) category and PT. At each level of summarization, a participant is counted once if the participant reported one or more medications at that level. The prior and concomitant medications are defined as below.

- Prior medications are defined as medications with a stop date occurring before the IP administration date.
- Concomitant medications are defined as medications with a start date on or after the IP administration date or stop date occurring on or after the IP administration date.

The number and percentage of participants who take prohibited medications that are considered to be effective for treatment of AA will also be summarized by WHO-DD ATC category and PT.

The missing start/stop date will be imputed as appropriate and the details of the imputation will be included in the SPP.

4.8.5 Electrocardiogram Results

The observed values, along with the changes from baseline, will be summarized for ventricular heart rate, PR interval, QRS duration, QT interval, and the corrected QT interval (QTc). The number (%) of participants meeting the following criteria will be summarized:

- QTc > 450 msec
- QTc > 480 msec
- QTc > 500 msec
- QTc increases from baseline > 30 msec
- QTc increases from baseline > 60 msec

Corrected QT (QTc) intervals will be derived using Fridericia's correction (QTcF) and Bazett's correction (QTcB). In addition, the overall clinical evaluation of electrocardiogram results (normal, abnormal, not clinically significant abnormal, clinically significant abnormal) will also be summarized.

4.8.6 Other Safety Measures

4.8.6.1 Overdose

The incidence of TEAEs associated with overdose will be summarized by MedDRA SOC and PT, if applicable.

4.8.6.2 Physical Examination and Weight

Significant physical examination findings will be summarized. The observed values and the changes from baseline in the weight and body mass index (BMI) will be summarized.

4.8.6.3 Local injection tolerability

The incidence of TEAEs associated with local injection tolerability will be summarized by MedDRA SOC and PT, if applicable.

4.9 Pharmacokinetic (PK) Analyses

The PK components of the clinical study report (CSR) will be generated and reported by the PK group.

Serum concentrations will be summarized descriptively by visit.

Individual serum concentration vs. actual time profiles for each participant, as well as the mean (±SD) serum concentration versus scheduled time profiles, will be presented graphically.

Additional PK analyses may be conducted as appropriate and reported separately from the clinical study report.

4.10 Pharmacodynamics

Descriptive summaries will be presented by visit for the following:

- pDC levels (DC flow cytometry)
- whole blood transcriptomics (eg. IFN gene signature)

Descriptive statistics will be presented for PBMC assays as well as serum IFN-a and other serum/plasma biomarkers or factors that may be associated with the daxdilimab mechanism of action or AA disease pathways when applicable and if data allows.

4.11 Immunogenicity

The ADA status will be summarized for the safety analysis set by the categories defined in Table 4. The ADA incidence rate may also be summarized, where the incidence is the proportion of the participants with ADA positive post-baseline only or boosted their pre-existing ADA during the study period. The cutoff for the boosted ADA will be determined before the database lock for the primary analysis. If data allow, the ADA titer for the ADA positive participants will be summarized, and the impact of ADA on PK, efficacy and safety will be evaluated.

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted] induced ADA positive at ≥ 2 post [redacted] assessments (with ≥ 16 weeks between first and last positive) or [redacted]
[redacted]	[redacted]

[redacted]

5 REFERENCES

King B, Ko J, Forman S, et al., 2021

King B, Ko J, Forman S, et al. Efficacy and safety of the oral Janus kinase inhibitor baricitinib in the treatment of adults with alopecia areata: Phase 2 results from a randomized controlled study. J Am Acad Dermatol. 2021;85(4):847-853.

6 SOFTWARE

SAS® Software Version 9.4. SAS Institute Inc., Cary, NC, USA.

APPENDIX 1 APPROVALS

Confirmation by the study biostatistician (or designee), biostatistics management (or designee), and the study clinical colleague or therapeutic lead (or designee) that the review of this statistical analysis plan is complete, and there is agreement on the content.

[redacted]
Sr Manager, Biostatistics

DocuSigned by:
[redacted]
Signer Name: [redacted]
Signing Reason: I am the author of this document
Signing Time: 18-Apr-2022 | 14:14 CDT
34B59A5A28654B75A8EBE3E29B2A4F66

18-Apr-2022 | 14:14 CDT

Name,
Title

Signature/Date

[redacted]
Sr Director, Biometrics

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[redacted]
Signer Name: [redacted]
Signing Reason: I approve this document
Signing Time: 18-Apr-2022 | 14:16 CDT
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18-Apr-2022 | 14:16 CDT

Name,
Title

Signature/Date

[redacted]
Sr Scientific Director, R&D Clinical Development

DocuSigned by:
[redacted]
Signer Name: [redacted]
Signing Reason: I approve this document
Signing Time: 18-Apr-2022 | 14:45 CDT
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18-Apr-2022 | 14:45 CDT

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Title

Signature/Date

DocuSign

Certificate Of Completion

Envelope Id: 6F70B34252894E43A6E142670A590674
Subject: Please DocuSign: HZNP-DAX-201 Statistical Analysis Plan Final v1.0.docx
Source Envelope:
Document Pages: 24
Certificate Pages: 2
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-06:00) Central Time (US & Canada)

Signatures: 3
Initials: 0

Status: Completed

Envelope Originator:
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1 Horizon Way
Deerfield, 60015
[redacted]
IP Address: 12.163.207.11

Record Tracking

Status: Original
4/18/2022 2:11:19 PM

Holder: [redacted]

Location: DocuSign

Signer Events	Signature	Timestamp
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Electronic Record and Signature Disclosure: Not Offered via DocuSign		
[redacted] Security Level: Email, Account Authentication (Required)	[redacted] Signature Adoption: Pre-selected Style Signed by link sent to [redacted] Signature ID: 94348E43-E051-4584-8D3D-CFDE0A20F5C3 Using IP Address: 12.163.207.11 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 4/18/2022 2:13:34 PM Viewed: 4/18/2022 2:15:55 PM Signed: 4/18/2022 2:16:35 PM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		

Signer Events	Signature	Timestamp
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Electronic Record and Signature Disclosure: Not Offered via DocuSign		

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	4/18/2022 2:13:34 PM
Certified Delivered	Security Checked	4/18/2022 2:13:56 PM
Signing Complete	Security Checked	4/18/2022 2:14:26 PM
Completed	Security Checked	4/18/2022 2:45:36 PM

Payment Events	Status	Timestamps