Statistical Analysis Plan (SAP)

Study No. D-PLEX 310

A Phase II, Prospective, Multicenter, Randomized, Controlled, Two-arm, Single Blind, Study to Assess Safety and Efficacy of D-Plex Administered Concomitantly with the Standard of Care (SOC), Compared to SOC Treated Control Arm, in Prevention of Post-Abdominal Surgery Incisional Infection

Version 1.1

October 30, 2019

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Approval Page

By entering into this Statistical Analysis Plan (SAP), the parties acknowledge and agree that this SAP shall be incorporated into and subject to the terms of the Master Services Agreement (MSA). Any changes requested by Client to this SAP shall be subject to Section I.C of the MSA requiring a mutually agreed upon "Change Order" prior to any modification of the procedures set forth herein.

I agree to the format and content of this document.

Approved by:

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Revision History

Version 1.0 to 1.1

- Add Tables 4-6
    - Add additional analysis of number and proportion of subjects who experience SSI or mortality within 30 days by treatment group
- Add Tables 16-18, 25-27
    - Add additional analysis of total ASEPSIS score by treatment group
- Figure 5
    - Add additional PK analysis figure for median doxycycline concentration levels
- Selected tables were modified to remove analysis by visit

Table of Contents

1.0 Synopsis of Study Design Procedures

This study is a prospective, multicenter, randomized, controlled, two arm, single blind, study to assess safety and efficacy of D-PLEX administered concomitantly with the standard of care (SOC) in prevention of post abdominal surgery incisional infection, compared to SOC treated control arm. The objectives of this Phase II study are as follows:

- To assess the anti-infective efficacy of D-PLEX (in addition to SOC) over a period of 30 days post operation, by preventing surgical site infection (SSI) defined as superficial and deep abdominal wall surgical incision infection, compared to the SOC treated control arm.
- To assess the safety of D-PLEX.

1.1 Design and Treatment

Subjects will be randomized on day 0 to either the investigational arm (SOC + D-PLEX) or to the control arm (SOC only) at a 1:1 ratio. Randomization will be balanced by gender, age (18-40, 41-65, 66 and above), type of surgery (open laparotomy or laparoscopic), and inclusion of colostomy (yes/no). Investigational product (IP) will be administered under single-blind conditions such that the subject does not know if they are receiving D-PLEX + SOC or just the SOC.

SOC + D-PLEX (amount based on size of incision) or SOC alone will be applied during the abdominal surgery at the stage of closure of the abdominal wall surgical target incision. The total dose applied at the surgical site will be determined based on surgical incision length with a maximum of three vials (15g) being administered. Dosage will be administered as follows:

Surgical Incision Length (cm)	Number of Vials to Apply
5-10	1
11-20	2
≥21	3

1.2 Study Procedures

The study includes procedures at screening (within 21 days of surgery), pre-application of D-PLEX (Day 0), procedure (Day 0), and post-application (Day 1, 5, 14, 30, and 60).

Visit 1: Screening Period (Day -21 to Day 0)

Patient will be screened for study eligibility at the clinic within 21 days prior to surgery (Day -21 to 0). The following screening assessments will be performed:

- Sign an Informed Consent form before any of the study related procedures are performed
- Assign (from the eCRF) a sequentially ordered patient number for the site. If a patient is withdrawn from the study or fails to undergo the treatment procedure, the patient number cannot be reassigned
- Record demographics (including age, gender, etc.)
- Record medical history
- Complete allergy questionnaire
- Record concomitant medications
- Measure vital signs (height, weight, temp., heart rate & blood pressure)
- Perform physical examination
- Perform blood laboratory tests*
- Perform 12-lead ECG**
- Perform Urinalysis*
- Perform a rectal swab for bacteriology
- Record baseline safety (any future planned elective procedure should be recorded so it will not be counted later on as an adverse event (AE) or serious adverse event (SAE) as applicable)
- Eligibility determination according to inclusion and exclusion criteria

* Blood tests and Urinalysis done at the medical center's lab within 21 days prior to surgery may be used for eligibility determination.

** ECG done within the last 90 days prior to surgery can be used for eligibility determination.

Visit 2: Surgery – Index Procedure (Day 0)

- Randomization*** (randomization is patient specific, if a patient is withdrawn from the study or fails to undergo the treatment procedure, the randomization number cannot be reassigned)
- Vital signs
- Pre-application Doxycycline PK sampling (for applicable subjects)
- Abdominal Surgery
- D-PLEX administration at the stage of closure of the abdominal wall surgical incision
- Post-application Doxycycline PK sampling (at 2h, 4h, 6h, 8h & 12h)
- AEs assessment and recording
- Concomitant Medication Review

*** For surgery planned for early morning time, randomization via the eCRF could be done a day in advance.

Visits 3 – 6: Follow up Visits (Days 1, 5, 14 & 30 post-surgery)

Post-operative care will be performed per SOC. Post-operative resumption of activity are at the discretion of investigator based on subject medical condition.

The subsequent follow up visits will take place at Day 1, Day 5 and Day 14 post-surgery. These visits are usually performed after this type of surgery.

The additional follow up visit will take place at Day 30 post-surgery and is required by the study, i.e. in addition to the routine visits usually performed after this kind of surgery.

During all the above-mentioned visits, the following procedures will be performed:

- Vital signs
- Assessment of surgical site wound healing – Including visual examination and wound assessment questionnaire
- Laboratory examinations
- Post-application Doxycycline PK sampling
- AE assessment and recording
- Concomitant Medication Review
- Physical examination [at Day 30]
- Perform a rectal swab for comparable bacteriology [at Day 30]

Urinalysis will be performed only at the discretion of the Investigator.

Bacteriology cultures will be taken if there is wound discharge.

Visit 7: End of Study (Day 60 post-surgery)

- Vital signs
- Assessment of surgical site
- Laboratory examinations
- Adverse Events assessment and recording
- Concomitant Medication Review
- Physical examination

1.3 Sample Size

The study will enroll a total of [redacted] subjects, with [redacted] subjects allocated to each treatment group. The sample size was chosen by the Sponsor to collect adequate data for evaluating the primary study objectives. This study is not powered to test formal statistical hypotheses; however, exploratory sample size calculations show that a sample of [redacted] subjects provides 80% power to detect an 80% decrease in the SSI rate (15% versus 3%) at a two-sided α=0.10 level of significance.

A blinded non-comparative sample size reassessment to evaluate infection rate will be conducted after a total of [redacted] and [redacted] have been assessed for primary efficacy endpoint. The maximal sample size allowed to upsize is about [redacted] subjects.

2.0 Data Analysis Considerations

2.1 Types of Analyses

Analyses will consist of summarizing efficacy and safety data. Unless otherwise stated, two-sided p-values <0.10 will be considered as statistically significant.

The following standards will be applied for the analyses unless otherwise specified. Simple summary statistics (descriptive statistics) for continuous data are: n (number of non-missing observations), mean, median, standard deviation, minimum, and maximum. The frequency count and percentage will be used to summarize categorical data. Summary statistics will be presented by treatment.

Statistical tests of each efficacy endpoint will be conducted as described in Section 4.2.

All data collected will be presented in the by-subject data listings, sorted by subject and by time point, where appropriate.

2.2 Analysis Populations

The following analysis populations will be defined for the study:

Intention to Treat (ITT): The ITT analysis set will consist of all subjects who have been randomized to receive either D-PLEX or SOC. In this analysis set, treatment will be assigned based on the treatment to which subjects were randomized, regardless of which treatment they actually receive.

Safety: The safety analysis set will consist of all subjects who have been randomized and treated. In this population, treatment will be assigned based upon the treatment subjects actually receive, regardless of the treatment to which they were randomized.

Modified Intent to Treat (mITT): The mITT analysis set is a subset of the ITT set and will consist of all subjects randomized and treated with D-PLEX or SOC, for whom there is at least valid post-surgical observations on the primary endpoint and meet all inclusion/exclusion criteria. The exclusion from the mITT population will be determined prior to database lock.

Per Protocol (PP): The PP analysis set will include all ITT subjects who have completed the study without any major protocol deviations. The exclusion from the PP population will be determined prior to database lock.

Pharmacokinetic (PK): The PK analysis set will consist of all subjects who have been randomized, treated with D-PLEX, and have had PK sampling.

The analysis of primary efficacy endpoints will be performed on the ITT, mITT and PP populations as listed in Section 8.0. Analyses performed on the PP population are secondary to the analyses conducted on the ITT and mITT populations. Any additional analysis will be done on the populations as specified in Appendix B.

Analyses of safety will be performed on the safety population. Baseline subject characteristics and demographics will be summarized for the ITT population.

Analysis of pharmacokinetic variables will be performed on the PK population.

2.2.1 Subgroup Definitions

Analyses will be presented by treatment (D-PLEX or control), dose group (number of vials of D-PLEX), and type of surgery (open laparotomy or laparoscopic) as indicated below and shown in Appendix B.

2.3 Missing Data Conventions

Missing data for the primary efficacy endpoint will be imputed for the ITT analysis set. Deaths occurring within 30 days post abdominal surgery will be counted as treatment failures in the calculation of the primary efficacy endpoint for each treatment group. Subjects who have missing primary efficacy endpoint data due to other reasons will also be counted as treatment failures in the calculation of the primary efficacy endpoint for each treatment group.

There will be no imputation of missing data for the mITT analysis of the primary endpoint, and there will be no imputation of missing data for all other study endpoints (i.e., a complete case analysis will be used).

2.4 Interim Analyses

A blinded non-comparative sample size reassessment to evaluate the infection rate precision assumptions will be conducted after a total of [redacted] subjects have been assessed for the primary efficacy endpoint. The maximal sample size allowed to upsize is about [redacted] subjects.

Refer to the separate Interim Analysis Plan (IAP) for further details on the interim analyses.

2.5 Study Center Considerations in the Data Analysis

A study center is defined as a treatment administration site or group of treatment administration sites under the control and supervision of the same Principal Investigator (PI).

There will be no selective pooling of study centers in the analysis. All calculations will be made on the combined results of all centers.

2.6 Documentation and Other Considerations

The data analyses will be conducted using SAS® Software, version 9.4 or later.

3.0 Analysis of Baseline Subject Characteristics

Baseline and demographic characteristics will be summarized by treatment and overall for all subjects in the ITT population. Continuous variables will be displayed via summary statistics (mean, median, sample size, standard deviation, minimum, and maximum). Categorical variables will be summarized via counts and percentages.

A detailed listing of demographics data for each subject will also be provided as shown in Appendix B.

4.0 Analysis of Efficacy

4.1 Description of Efficacy Variables

4.1.1 Primary Efficacy Variables

The primary efficacy variable for the study is the following:

- Combined infection and mortality rate which is measured by the number and proportion of subjects with either an SSI event (as determined by the blinded and independent adjudication committee, within 30 days post

abdominal surgery) or mortality for any reason within 30 days post index surgery.

SSI is composed of Deep Incisional Surgical Site Infection (DSSI) and Superficial Incisional Surgical Site Infection (SSSI). A SSSI is an infection that involves only skin and subcutaneous tissue of the incision and does not include diagnosis/treatment of cellulitis, a stitch abscess alone or a localized stab wound or pin site infection. A DSSI is an infection that involves deep tissues, such as fascia and muscle layers; this also includes infection involving both superficial and deep incision sites. The calculations and analyses pertaining to each of the above variables are shown in Section 4.2.2.

4.1.2 Key Secondary and Exploratory Efficacy Variables

Key secondary efficacy variables:

- Number of hospitalization days post colorectal surgery due to SSI
- Average ASEPSIS assessment score during 30 days post-surgery
- Number of surgical interventions due to SSI
- Mortality rate within 30 days post abdominal surgery

Additional efficacy variables:

- Infection rate as measured by the proportion of subjects with an SSI event, as determined by the blinded and independent adjudication committee, within 30 days post abdominal surgery
- Incidence of SSSI rates during 30 days post-surgery
- Incidence of DSSI rates during 30 days post-surgery
- Mortality rate within 60 days post abdominal surgery
- Determination of susceptibility to Doxycycline of any organisms recovered from an abdominal surgery incisional infection site
- Number of overall hospitalization days within 60 days post-surgery
- Number of subjects who were hospitalized due to SSI
- Number of re-admissions due to surgical site infection
- Number of antibiotic treatment days due to abdominal incisional surgical site infection
- Number of subjects who received antibiotics due to SSI
- Time to surgical site infection post-surgery
- Number of non-confirmed SSI by adjudication
- Number of any SSI (confirmed and non-confirmed)

4.2 Analysis of Efficacy Variables

4.2.1 Primary Efficacy Analysis

The number and proportion of subjects with at least one SSI, as determined by a blinded and independent adjudication committee, within 30 days post abdominal surgery, or mortality for any reason within 30 days post index surgery, will be tabulated per treatment group and surgery type. If a subject is presented to the blinded and independent adjudication committee, the SSI will be considered to have taken place within 30 days of treatment. A 95% confidence interval using exact binomial methods will be constructed for each proportion. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups and surgery types. The same analysis will be performed by treatment group only.

This analysis of the primary efficacy variable will be performed on the ITT population and a secondary analysis of the primary efficacy variable will be performed on the mITT and PP populations.

Missing data for the primary efficacy endpoint will be imputed according to the methods described in section 2.3

4.2.2 Secondary and Exploratory Efficacy Analyses

Secondary efficacy analyses will be conducted on the ITT and mITT population. Selected analyses will also be performed on the PP population, as stated below.

4.2.2.1 Key Secondary Efficacy Analyses

Hospitalization Days Due to SSI
For both initial and additional hospitalization events, the number of hospitalization days due to surgical site infection will be summarized by treatment group using descriptive statistics. A Wilcoxon Rank Sum Test will be conducted to assess for treatment group differences.

Average ASEPSIS Assessment Scores
The total ASEPSIS assessment score will be summarized by treatment group and visit, and by treatment group only, using descriptive statistics. Additionally, the cumulative ASEPSIS assessment score (includes all scores within 30 days of treatment) will also be summarized by treatment group using descriptive statistics. An additional analysis of the subset of subjects who experience at least one SSI will also be summarized by treatment group and visit using descriptive statistics. All descriptive statistics will include data from both scheduled and unscheduled visits. A Wilcoxon Rank Sum Test will be conducted to assess for treatment group differences for both the total and cumulative ASEPSIS assessment scores.

Surgical Interventions Due to SSI

The number of surgical interventions due to surgical site infection will be summarized by treatment group using descriptive statistics. A Wilcoxon Rank Sum Test will be conducted to assess for treatment group differences.

Mortality Rate within 30 Days
The number and proportion of subjects who experience death for any reason within 30 days post abdominal surgery will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups.

4.2.2.2 Additional Secondary Efficacy Analyses

Infection Rate
The number and proportion of subjects with at least one SSI, as determined by a blinded and independent adjudication committee, within 30 days post abdominal surgery will be tabulated per treatment group. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups.

Incidence of SSSI Rate
The number and proportion of subjects who experience at least one SSSI within 30 days post abdominal surgery will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups.

Incidence of DSSI Rate
The number and proportion of subjects who experience at least one DSSI within 30 days post abdominal surgery will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups.

Mortality Rate within 60 Days
The number and proportion of subjects who experience death for any reason within 60 days post abdominal surgery will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups.

Bacterial Growth Susceptibility to Doxycycline
The number of subjects who have bacterial growth analyzed will be summarized by treatment group. The number and proportion of subjects who experience bacterial growth will be summarized by treatment group, isolate and sensitivity to Doxycycline. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the infection proportions between treatment groups for isolate and bacterial growth presence.

Overall Hospitalization Days

The number of overall hospitalization days within 60 days post-surgery will be summarized by treatment group using descriptive statistics. Hospitalization days will be counted as aggregated overall hospitalization days (including post-operation hospitalizations and hospitalizations due to SAEs) per subject. A Wilcoxon Rank Sum Test will be conducted to assess for treatment group differences.

Subject Hospitalization

The number and proportion of subjects who were hospitalized due to SSI within 30 days and within 60 days post-surgery will be presented separately by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the proportions between treatment groups. This analysis will be performed on the ITT, mITT, and PP populations.

Re-admission Due to Surgical Site Infection

The number and proportion of subjects who experience re-admission due to SSI will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the re-admission proportions between treatment groups.

Antibiotic Treatment Days

The number of antibiotic treatment days due to abdominal incisional surgical site infection (SSI) will be summarized by treatment group using descriptive statistics. Data will be aggregated and presented for overall days of antibiotic treatment (all routes of administration) and for number of days of IV antibiotic administration.

Subjects Receiving Antibiotics

The number and proportion of subjects who receive antibiotics due to SSI will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the proportions between treatment groups. This analysis will be performed on the ITT, mITT, and PP populations.

Time to Surgical Site Infection Post-Surgery

Time to surgical site infection for the D-PLEX treatment group will be compared to that of the SOC treatment group using a Gehan-Wilcoxon test. The comparison will also be depicted using Kaplan-Meier curves.

Non-confirmed SSI by Adjudication

The number and proportion of subjects who experience at least one SSI that was not confirmed upon adjudication will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the non-confirmed SSI proportions between treatment groups.

Any SSI (Confirmed and Non-confirmed)

The number and proportion of subjects who experience at least one SSI, regardless of whether it was confirmed upon adjudication, will be presented by treatment. A two-sided Fisher's Exact Test will be conducted to test for a significant difference in the SSI proportions between treatment groups.

All secondary efficacy data will be listed as shown in Appendix B.

5.0 Analysis of Pharmacokinetics

5.1 Description of Pharmacokinetic Variables

Doxycycline pharmacokinetic (PK) sampling will be collected from [redacted] subsets administered with different doses of D-PLEX (1, 2, or 3 vials) in at least [redacted] subjects (i.e., [redacted] subjects per subset, pending subset recruitment). For subjects where D-PLEX was re-applied due to re-intervention, PK sampling should be stopped, and the reason stated on their PK collections form.

Pharmacokinetic samples of 4mL blood will be collected, prepared, and shipped to a central laboratory at the following time points: pre-application of D-PLEX, after application of D-PLEX, 2-, 4-, 6-, 8-, 12-, 24-hours, 120 hours (Day 5), 336 hours (Day 14), and 720 hours (Day 30) following the application of D-PLEX. Additional samples may be taken at the 48- and 72-hour time points if the subject is still hospitalized following surgery.

The following PK parameters will be estimated for each subject:

PK Parameter	Definition
C_{max}	Maximum observed plasma concentration
t_{max}	Time of maximum observed plasma concentration; if it occurs at more than one time point, T_{max} is defined as the first time point with this value
AUC_{0-t}	Cumulative area under the plasma concentration time curve calculated from 0 to the last measured plasma concentration using the linear trapezoidal method
$AUC_{0-\infty}$	Area under the plasma concentration time curve extrapolated to infinity, calculated as $AUC_{0-T} + C_{LQC}/\lambda_Z$, where C_{LQC} is the measured concentration at time T_{LQC}
λ_Z	Apparent elimination rate constant, estimated by linear regression of the terminal linear portion of the log concentration versus time curve
$t_{1/2}$	Terminal elimination half-life, calculated as

	ln(2)/λz
Vz	Steady-state distribution volume based on the last observed concentration
MRT	Mean residence time from the time of dosing to the time of the last measurable concentration

5.2 Analysis of Pharmacokinetic Variables

Plasma sample Doxycycline concentrations will be summarized by dose group and time point using descriptive statistics.

The concentrations will be depicted for each subject by dose group using linear scale. Mean and median doxycycline concentrations will also be depicted by dose group, for each time point, in linear scale.

PK parameter values will be summarized by dose group using descriptive statistics (n, mean, standard deviation, CV%, geometric mean, and 90% confidence interval).

6.0 Analysis of Safety

The safety variables for this study are:

- Adverse events (AE)
- Vital Signs
- Physical Examination (at screening, day 30 and day 60)
- Laboratory Results
- Wound Healing assessment by blinded assessor

Adverse Events
Prior to analysis, all AEs will be coded using the MedDRA coding dictionary. Treatment-emergent AEs (TEAEs) are those AEs that start on the day of or after study treatment administration. The number and percentage of subjects with at least one TEAE will be summarized by system organ class (SOC) and by preferred term (PT) within SOC for each treatment group. Similar summary tables will be provided to display the number and percentage of subjects with at least one serious TEAE (SAE) and at least one study drug-related TEAE by SOC and

by PT within SOC. For the purposes of this study, a study drug-related TEAE is any TEAE with a relationship to study drug of possibly related or related.

In addition, tables will be constructed to summarize TEAEs by relation to study drug and by severity.

A summary table with the count and percentage of subjects exhibiting an AE due to delay of wound healing will be created by treatment and overall.

All AEs will be listed, regardless of whether they were treatment emergent. AEs having an end date prior to signing the informed consent for this study will not be displayed in the AE data listings.

Vital Signs
Summary statistics (mean, median, sample size, standard deviation, minimum, and maximum) will be computed on the raw and change from baseline values for each vital sign parameter by time point, for each treatment. The Day 0 prior to treatment time point will serve as baseline. If there are multiple vital signs taken at any time point, then the latest set of vital signs will be used for the analysis. All vital sign data will be listed.

Physical Exam
The number and proportion of subjects with abnormal physical examination findings will be summarized by body system. A physical exam (PE) shift table will be constructed for each treatment group to identify the changes in body system findings from pre-treatment to each post-treatment time point where PE is performed (Days 30 and 60).

Laboratory Results
Summary statistics (mean, median, sample size, standard deviation, minimum, and maximum) will be computed on the raw and change from baseline values for each laboratory parameter by time point, for each treatment. The screening time point will serve as baseline. Shift tables will be constructed to show the changes in laboratory findings from pre-treatment to each post-treatment time point.

Wound Healing Assessment
The number and proportion of subjects who achieved a wound healing (Y/N) will be calculated by treatment and visit. Additionally, the count and proportions of the assessment response will be displayed by treatment and visit.

7.0 Other Relevant Data Analyses/Summaries

7.1 Subject Disposition

A table will be constructed with counts of screen failures and enrolled subjects. Of those enrolled, counts and percentages of the number of subjects withdrawing

from the study before study completion and the number completing the study will be displayed. For those subjects that withdraw before completion of the study, counts and percentages of the reasons for withdrawal will be tabulated. The table will include summary counts and percentages by treatment. A data listing of all subject completion and withdrawal data will also be constructed.

7.2 Bacteriological Testing

A table will be constructed with the number and proportion of subjects with abnormal results reported from the bacteriological test will be summarized by treatment.

Additionally, the number and percent of bacteria resistant to antibiotics other than Doxycycline will be summarized by treatment and overall.

Bacterial growth will be analyzed for subjects who experience SSI with the count and percentage of microorganisms presented by treatment and overall. A data listing of all microorganisms identified will also be constructed.

7.3 Medical History

Prior to analysis, all medical history terms will be coded using the MedDRA coding dictionary. The number and percentage of subjects with at least one medical history term will be summarized by system organ class (SOC) and by preferred term (PT) within SOC for each treatment group. A complete medical history of past and present illnesses and surgeries will be listed.

7.4 Concomitant Medication

All concomitant medications will be coded with the WHO Drug Dictionary. A table will be constructed with counts and percentages of subjects by ATC level 4 and preferred term. Additional analysis will be performed for antibiotics that were taken prior to and after surgery. A table will be constructed with counts and percentages of subjects by ATC level 4 and preferred term.

7.5 Wound Characteristics and Surgery Type

A table will be constructed with the number and proportion of subjects to analyze wound characteristics and surgery type. The length of surgical incision, type of surgery, and surgery with or without stoma will be summarized by treatment and overall. An additional analysis of the subset of subjects who experience SSI will also be summarized by treatment group and overall.

8.0 List of Analysis Tables, Figures and Listings

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
1	Subject Disposition	X	X
2	Demographics and Baseline Data Summary Statistics–Continuous Variables (Safety Population)	X	X
3	Demographics and Baseline Data Summary Statistics–Categorical Variables (Safety Population)	X	X
4	Number and Proportion of Subjects who Experience SSI or Mortality within 30 Days (ITT Population)	X	X
5	Number and Proportion of Subjects who Experience SSI or Mortality within 30 Days (mITT Population)	X	
6	Number and Proportion of Subjects who Experience SSI or Mortality within 30 Days (PP Population)	X	
7	Number and Proportion of Subjects who Experience SSI or Mortality within 30 Days by Type of Surgery (ITT Population)	X	X
8	Number and Proportion of Subjects who Experience SSI or Mortality within 30 Days by Type of Surgery (mITT Population)	X	
9	Number and Proportion of Subjects who Experience SSI or Mortality within 30 Days by Type of Surgery (PP Population)	X	
10	Number of Hospitalization Days Post-Surgery Due to SSI Summary Statistics (ITT Population)	X	X
11	Number of Hospitalization Days Post-Surgery Due to SSI Summary Statistics (mITT Population)	X	
12	Number of Hospitalization Days Post-Surgery Due to SSI Summary Statistics (PP Population)	X	
13	Total ASEPSIS Score Summary Statistics by Treatment and Visit (ITT Population)	X	X
14	Total ASEPSIS Score Summary Statistics by Treatment and Visit (mITT Population)	X	
15	Total ASEPSIS Score Summary Statistics by Treatment and Visit (PP Population)	X	
16	Total ASEPSIS Score Summary Statistics by Treatment (ITT Population)	X	X
17	Total ASEPSIS Score Summary Statistics by Treatment (mITT Population)	X	
18	Total ASEPSIS Score Summary Statistics by Treatment (PP Population)	X	
19	Cumulative ASEPSIS Score Summary Statistics by Treatment (ITT Population)	X	X
20	Cumulative ASEPSIS Score Summary Statistics by Treatment (mITT Population)	X	
21	Cumulative ASEPSIS Score Summary Statistics by Treatment (PP Population)	X	
22	Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment and Visit (ITT Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
23	Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment and Visit (mITT Population)	X	
24	Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment and Visit (PP Population)	X	
25	Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment (ITT Population)	X	X
26	Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment (mITT Population)	X	
27	Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment (PP Population)	X	
28	Cumulative ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment (ITT Population)	X	X
29	Cumulative ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment (mITT Population)	X	
30	Cumulative ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment (PP Population)	X	
31	Number of Surgical Interventions Due to SSI Summary Statistics by Treatment (ITT Population)	X	X
32	Number of Surgical Interventions Due to SSI Summary Statistics by Treatment (mITT Population)	X	
33	Number of Surgical Interventions Due to SSI Summary Statistics by Treatment (PP Population)	X	
34	Number and Proportion of Subjects who Experience Death within 30 Days Post-Surgery by Treatment (ITT Population)	X	X
35	Number and Proportion of Subjects who Experience Death within 30 Days Post-Surgery by Treatment (mITT Population)	X	
36	Number and Proportion of Subjects who Experience Death within 30 Days Post-Surgery by Treatment (PP Population)	X	
37	Number and Proportion of Subjects Who Experience SSI within 30 Days by Treatment (ITT Population)	X	X
38	Number and Proportion of Subjects Who Experience SSI within 30 Days by Treatment (mITT Population)	X	
39	Number and Proportion of Subjects Who Experience SSSI within 30 Days by Treatment (ITT Population)	X	X
40	Number and Proportion of Subjects Who Experience SSSI within 30 Days by Treatment (mITT Population)	X	
41	Number and Proportion of Subjects Who Experience DSSI within 30 Days by Treatment (ITT Population)	X	X
42	Number and Proportion of Subjects Who Experience DSSI within 30 Days by Treatment (mITT Population)	X	

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
43	Number and Proportion of Subjects who Experience Death within 60 Days Post-Surgery by Treatment (ITT Population)	X	X
44	Number and Proportion of Subjects who Experience Death within 60 Days Post-Surgery by Treatment (mITT Population)	X	
45	Summary of Bacterial Growth Susceptibility to Doxycycline by Treatment and Overall (ITT Population)	X	X
46	Summary of Bacterial Growth Susceptibility to Doxycycline by Treatment and Overall (mITT Population)	X	
47	Number of Overall Hospitalization Days within 60 Days Post-Surgery Summary Statistics by Treatment (ITT Population)	X	X
48	Number of Overall Hospitalization Days within 60 Days Post-Surgery Summary Statistics by Treatment (mITT Population)	X	
49	Number and Proportion of Subjects Hospitalized Due to SSI within 30 Days Post-Surgery (ITT Population)	X	X
50	Number and Proportion of Subjects Hospitalized Due to SSI within 30 Days Post-Surgery (mITT Population)	X	
51	Number and Proportion of Subjects Hospitalized Due to SSI within 30 Days Post-Surgery (PP Population)	X	
52	Number and Proportion of Subjects Hospitalized Due to SSI within 60 Days Post-Surgery (ITT Population)	X	
53	Number and Proportion of Subjects Hospitalized Due to SSI within 60 Days Post-Surgery (mITT Population)	X	
54	Number and Proportion of Subjects Hospitalized Due to SSI within 60 Days Post-Surgery (PP Population)	X	
55	Number and Proportion of Subject Re-admission Due to SSI by Treatment (ITT Population)	X	X
56	Number and Proportion of Subject Re-admission Due to SSI by Treatment (mITT Population)	X	
57	Number of Antibiotic Treatment Days Due to SSI Summary Statistics by Administration Route within 60 Days Post-Surgery (ITT Population)	X	X
58	Number of Antibiotic Treatment Days Due to SSI Summary Statistics by Administration Route within 60 Days Post-Surgery (mITT Population)	X	
59	Number and Proportion of Subjects who Received Antibiotics Due to SSI (ITT Population)	X	X
60	Number and Proportion of Subjects who Received Antibiotics Due to SSI (mITT Population)	X	
61	Number and Proportion of Subjects who Received Antibiotics Due to SSI (PP Population)	X	
62	Analysis of Time to Adjudicated SSI Post-Surgery (ITT Population)	X	X
63	Analysis of Time to Adjudicated SSI Post-Surgery (mITT Population)	X	
64	Number and Proportion of Subjects with Non-confirmed SSI by Adjudication by Treatment (ITT Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
65	Number and Proportion of Subjects with Non-confirmed SSI by Adjudication by Treatment (mITT Population)	X	
66	Number and Proportion of Subjects Who Experience Any SSI (Confirmed and Non-confirmed) within 30 Days by Treatment (ITT Population)	X	X
67	Number and Proportion of Subjects Who Experience Any SSI (Confirmed and Non-confirmed) within 30 Days by Treatment (mITT Population)	X	
68	Summary Statistics of Doxycycline Concentration Levels by Dose and Time (PK Population)	X	X
69	Summary Statistics of Estimated PK Parameters by Dose (PK Population)	X	X
70	Number and Percent of Subjects with Treatment Emergent Adverse Events (Safety Population)	X	X
71	Summary of Treatment Emergent Adverse Events (Safety Population)	X	X
72	Number and Percent of Subjects with Serious Treatment Emergent Adverse Events (Safety Population)	X	X
73	Number and Percent of Subjects with Study Drug-Related Treatment Emergent Adverse Events (Safety Population)	X	X
74	Number and Percent of Subjects with Treatment Emergent Adverse Events by Relationship to Study Drug (Safety Population)	X	X
75	Number and Percent of Subjects with Treatment Emergent Adverse Events by Severity (Safety Population)	X	X
76	Number and Percent of Subjects with Delay of Wound Healing by Treatment (Safety Population)	X	X
77	Vital Sign Parameters Summary Statistics (Safety Population)	X	X
78	Physical Exam Results by Body System (Safety Population)	X	X
79	Physical Exam Results Shift Table by Body System and Visit (Safety Population)	X	X
80	Laboratory Parameters Summary Statistics (Safety Population)	X	X
81	Laboratory Results Shift Table by Parameter and Visit (Safety Population)	X	X
82	Wound Healing Assessment by Treatment and Overall (Safety Population)	X	X
83	Number and Proportion of Abnormal Bacteriological Test Results by Treatment (Safety Population)	X	X
84	Number and Percent of Bacteria Resistant to Other Antibiotics by Treatment (Safety Population)	X	X
85	Number and Percent of Bacterial Growth in Subjects who Experience SSI by Treatment (Safety Population)	X	X
86	Number and Proportion of Subjects with Medical History Events (Safety Population)	X	X
87	Number and Proportion of Subjects with Comorbid Medical History Events (Safety Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
88	Number and Percent of Subjects Taking Concomitant Medications by ATC Level 4 and Preferred Term (Safety Population)	X	X
89	Number and Percent of Subjects Taking Antibiotics Prior to Surgery by ATC Level 4 and Preferred Term (Safety Population)	X	X
90	Number and Percent of Subjects Taking Antibiotics After Surgery by ATC Level 4 and Preferred Term (Safety Population)	X	X
91	Summary of Wound Characteristics and Surgery Type (Safety Population)	X	X
92	Summary of Wound Characteristics and Surgery Type for Subjects who Experience SSI (Safety Population)	X	X
93	Study Drug Administration Summary Statistics (Safety Population)	X	X
94	Number and Proportion of Subjects Given each Study Drug Dose (Safety Population)	X	X

Listing No.	Data Listing Title	Included in Final Listings	Shown in Appendix B
DL1	Subject Disposition Data Listing	X	X
DL2	Protocol Deviations Data Listing	X	X
DL3	Demographics Data Listing	X	X
DL4	Subjects Excluded from mITT Population Data Listing	X	X
DL5	Subjects Excluded from ITT Population Data Listing	X	
DL6	Subjects Excluded from PP Population Data Listing	X	
DL7	Subjects Excluded from Safety Population Data Listing	X	
DL8	Substance Abuse Data Listing	X	X
DL9	Medical History Data Listing	X	X
DL10	Comorbid Medical History Data Listing		
DL11	Concomitant Medications Data Listing	X	X
DL12	Adverse Events Data Listing	X	X
DL13	Physical Exam Data Listing	X	X
DL14	Vital Signs Data Listing	X	X
DL15	Hematology Laboratory Results Data Listing	X	X
DL16	Serum Biochemistry Laboratory Results Data Listing	X	X
DL17	Urinalysis Laboratory Results Data Listing	X	X
DL18	Surgery Data Listing	X	X
DL19	Re-Admissions Due to SSI Data Listing	X	X
DL20	Study Drug Administration Data Listing	X	X
DL21	Surgical Site Infection Data Listing	X	X
DL22	SSI by Adjudication Data Listing	X	X
DL23	Would Healing Assessment Data Listing	X	X
DL24	ASEPSIS Score Data Listing	X	X
DL25	Hospitalization Data Listing	X	X

Listing No.	Data Listing Title	Included in Final Listings	Shown in Appendix B
DL26	Bacterial Test Data Listing	X	X
DL27	Bacterial Growth Data Listing	X	X
DL28	Doxycycline Concentrations Data Listing	X	X
DL29	Pharmacokinetics Parameters Data Listing	X	X
DL30	Randomization Data Listing	X	X
DL31	ECG Data Listing	X	X
DL32	Rectal Swab Data Listing	X	X

Figure No.	Data Listing Title	Included in Final Listings	Shown in Appendix B
FIG1	Subject Doxycycline Concentration levels for the 1 Vial Dose Group – Linear Scale (PK Population)	X	X
FIG2	Subject Doxycycline Concentration levels for the 2 Vial Dose Group – Linear Scale (PK Population)	X	
FIG3	Subject Doxycycline Concentration levels for the 3 Vial Dose Group – Linear Scale (PK Population)	X	
FIG4	Mean Doxycycline Concentration Levels by Dose Group – Linear Scale (PK Population)	X	X
FIG5	Median Doxycycline Concentration Levels by Dose Group – Linear Scale (PK Population)	X	
FIG6	Graphical Representation of Time to SSI Post-Surgery (ITT Population)	X	X
FIG7	Graphical Representation of Time to SSI Post-Surgery (mITT Population)	X	

9.0 References

Not applicable.

Appendix A – Tables, Figures and Listing Specifications

Orientation

Tables, figures, and listings will be displayed in landscape.

Margins

Margins will be 1 inch on all sides. Table, figure, and listing boundaries will not extend into the margins.

Font

Courier New, 8 point.

Headers

The table number will be on the second line of the title area. The title area will contain the Sponsor name, the study number, and the name of the table. The title area will contain the page number (Page x of y) on the far right, one line above the name of the table.

Footers

- The first line will be a solid line.
- Next will be any footnotes regarding information displayed in the table.
- Below these footnotes will be displayed “STATKING Clinical Services (month day, year)” on the far left.
- The last line will display the name of the SAS program that generated the table and (if applicable) the source data reference.

Table Disclaimer

The format of the mock tables shown in the appendix of this Statistical Analysis Plan (SAP) will be the format of the deliverable tables to the extent that Word document constructed tables can match production tables produced by SAS. This formatting includes the content and format of the header and footer areas of the tables. The Sponsor agrees to the format of the tables as shown in the appendix.

Further programming charges will be applicable for changes in the format of tables (including title statements, notes, data dependent footnotes, etc.) made after the approval of the SAP.

Missing Values

All missing values will be displayed on the output tables/listings as blanks.

Computation Values for Study Dates

The date format to be used is dd-mmm-yyyy. Missing parts of dates are not shown (e.g., for a missing day value, the value displayed is in mmm-yyyy format).

Appendix B – Table Shells

Table 1. Subject Disposition
PolyPid Ltd. – Study No. D-PLEX 310

	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]
Screen Failures			xx
Enrolled	xx	xx	xx
Completed	xx (xxx)	xx (xxx)	xx (xxx)
Discontinued	xx (xxx)	xx (xxx)	xx (xxx)
Reason for Discontinuation			
Adverse Event	xx (xxx)	xx (xxx)	xx (xxx)
Lost to Follow-up	xx (xxx)	xx (xxx)	xx (xxx)
Death	xx (xxx)	xx (xxx)	xx (xxx)
Consent Withdrawn	xx (xxx)	xx (xxx)	xx (xxx)
Other	xx (xxx)	xx (xxx)	xx (xxx)

[a] The denominator for all percentages in the table is the number of enrolled subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 2. Demographics and Baseline Data Summary Statistics – Continuous Variables
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Variable	Treatment Group	Mean	Std Dev	n	Min	Max	Median
Age (years)	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Height (cm)	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Weight (kg)	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
BMI	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Page x of y

Table 3. Demographics and Baseline Data Summary Statistics – Categorical Variables
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Demographics Variable	Category	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]
Sex	Male	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Female	xxx (xxx)	xxx (xxx)	xxx (xxx)
Race	American Indian	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Asian	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Black	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Hawaiian	xxx (xxx)	xxx (xxx)	xxx (xxx)
	White	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Other	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all percentages in the table is the number of safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 4. Number and Proportion of Subjects Who Experience SSI or Mortality within 30 Days
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	Treatment Group	Count (Proportion) (N=xxx)[a]	95% Confidence Interval[b]	P-value[c]
Subjects who experience ≥ 1 SSI within 30 days	D-PLEX	xxx (xxx)	(xxx, xxx)	xxxxx
	CONTROL	xxx (xxx)	(xxx, xxx)	

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[b] Confidence interval calculated using exact binomial methods.
[c] P-value based on a two-sided Fisher's Exact Test of difference in treatment group proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Page x of y

Table 7. Number and Proportion of Subjects Who Experience SSI or Mortality within 30 Days by Type of Surgery
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	Treatment Group	Surgery Type	Count (Proportion) (N=xxx)[a]	95% Confidence Interval[b]	P-value[c]
Subjects who experience ≥ 1 SSI within 30 days	D-PLEX (N=xxx)	Open Laparotomy	xxx (xxx)	(xxx, xxx)	xxxxx
		Laparoscopy	xxx (xxx)	(xxx, xxx)	xxxxx
		Overall	xxx (xxx)	(xxx, xxx)	xxxxx
	CONTROL (N=xxx)	Open Laparotomy	xxx (xxx)	(xxx, xxx)	
		Laparoscopy	xxx (xxx)	(xxx, xxx)	
		Overall	xxx (xxx)	(xxx, xxx)	
	Overall	Open Laparotomy	xxx (xxx)	(xxx, xxx)	
		Laparoscopy	xxx (xxx)	(xxx, xxx)	

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group/surgery type subgroup, and overall.
[b] Confidence interval calculated using exact binomial methods.
[c] P-value based on a two-sided Fisher's Exact Test of difference in treatment group proportions for each surgery type and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 10. Number of Hospitalization Days Post-Surgery Due to SSI Summary Statistics
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Hospitalization Event	Surgery Type	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	Initial	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Additional	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	Initial	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Additional	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 13. Total ASEPSIS Score Summary Statistics by Treatment and Visit
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Visit	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	xxx	
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences at each corresponding time point.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 16. Total ASEPSIS Score Summary Statistics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 19. Cumulative ASEPSIS Score Summary Statistics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 22. Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment and Visit
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Visit	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	xxx	
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	
	xxx	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences at each corresponding time point.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 25. Total ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery Summary Statistics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 28. Cumulative ASEPSIS Score for Subjects who Experience SSI within 30 Days Post-Surgery
Summary Statistics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 31. Number of Surgical Interventions Due to SSI Summary Statistics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 34. Number and Proportion of Subjects who Experience Death within 30 Days Post-Surgery by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Fatal Event[a]	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	P-value[c]
xxxxxxxxxxxxxxxxxxxxx	xxx (xxx)	xxx (xxx)	
xxxxxxxxxxxxxxxxxxxxx	xxx (xxx)	xxx (xxx)	
Overall	xxx (xxx)	xxx (xxx)	xxx

[a] Fatal event corresponds to the Serious Adverse Event which was the primary cause of death and/or was directly responsible for subject's death.
[b] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[c] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 37. Number and Proportion of Subjects who Experience SSI Within 30 days by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	Visit	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	P-value[b]
Number of Subjects with ≥ 1 SSI	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	Overall	xxx (xxx)	xxx (xxx)	xxx

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 39. Number and Proportion of Subjects who Experience SSSI[a] Within 30 days by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	P-value[c]
Number of Subjects with ≥ 1 SSSI[a]	xxx (xxx)	xxx (xxx)	xxx

[a] SSSI = Superficial Incisional Surgical Site Infection is an infection that involves only skin and subcutaneous tissue of the incision and does not includes diagnosis/treatment of cellulitis, a stitch abscess alone or a localized stab wound or pin site infection.
[b] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[c] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 41. Number and Proportion of Subjects who Experience DSSI[a] Within 30 days by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	P-value[c]
Number of Subjects with ≥ 1 DSSI[a]	xxx (xxx)	xxx (xxx)	xxx

[a] DSSI = Deep Incisional Surgical Site Infection is an infection that involves deep tissues, such as fascia and muscle layers; this also includes infection involving both superficial and deep incision sites.
[b] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[c] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 43. Number and Proportion of Subjects who Experience Death within 60 Days Post-Surgery by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Fatal Event[a]	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	P-value[c]
xxxxxxxxxxxxxxxxxxxxx	xxx (xxx)	xxx (xxx)	
xxxxxxxxxxxxxxxxxxxxx	xxx (xxx)	xxx (xxx)	
Overall	xxx (xxx)	xxx (xxx)	xxx

[a] Fatal event corresponds to the Serious Adverse Event which was the primary cause of death and/or was directly responsible for subject's death.
[b] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[c] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 45. Summary of Bacterial Growth Susceptibility to Doxycycline by Treatment and Overall
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Parameter	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]	P-value[b]
Bacterial Growth				
Yes	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx
No	xxx (xxx)	xxx (xxx)	xxx (xxx)	
Isolate XX				
Overall	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx
Sensitive	xxx (xxx)	xxx (xxx)	xxx (xxx)	
Intermediate	xxx (xxx)	xxx (xxx)	xxx (xxx)	
Resistant	xxx (xxx)	xxx (xxx)	xxx (xxx)	
No Sensitivity Test	xxx (xxx)	xxx (xxx)	xxx (xxx)	
Isolate XX				
Overall	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx
Sensitive	xxx (xxx)	xxx (xxx)	xxx (xxx)	
Intermediate	xxx (xxx)	xxx (xxx)	xxx (xxx)	
Resistant	xxx (xxx)	xxx (xxx)	xxx (xxx)	
No Sensitivity Test	xxx (xxx)	xxx (xxx)	xxx (xxx)	

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group and overall.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 47. Number of Overall Hospitalization Days within 60 Days Post-Surgery Summary Statistics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 49. Number and Proportion of Subjects Hospitalized Due to SSI within 30 Days Post-Surgery
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	P-value[b]
Number of Subjects Hospitalized Due to SSI	xxx (xxx)	xxx (xxx)	xxxx

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations and within 60 days post-surgery.

Table 55. Number and Proportion of Subject Re-admission Due to SSI by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	P-value[b]
Number of Subject Re-admissions	xxx (xxx)	xxx (xxx)	xxx

[a] Denominator for proportions is the number of ITT subjects in the respective treatment group.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 57. Number of Antibiotic Treatment Days Due to SSI Summary Statistics by Administration Route within 60 Days Post-Surgery
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Route of Administration	Treatment	Mean	Std Dev	n	Min	Max	Median	P-value[a]
xxxxxxxxxxxxxxxxxxxxxx	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	
xxxxxxxxxxxxxxxxxxxxxx	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	
All Routes	D-PLEX	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	CONTROL	xxx	xxx	xxx	xxx	xxx	xxx	

[a] P-value based on the Wilcoxon Rank Sum Test for treatment differences.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 59. Number and Proportion of Subjects who Received Antibiotics Due to SSI
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	P-value[b]
Number of Subjects who Received Antibiotics Due to SSI	xxx (xxx)	xxx (xxx)	xxxx

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT and PP Populations.

Table 62. Analysis of Time to Adjudicated SSI Post-Surgery
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

	D-PLEX (N=xxx)	CONTROL (N=xxx)
25 Quartile (95% CI)	xxx (xxx, xxx)	xxx (xxx, xxx)
50 Quartile (95% CI)	xxx (xxx, xxx)	xxx (xxx, xxx)
75 Quartile (95% CI)	xxx (xxx, xxx)	xxx (xxx, xxx)
Mean (SE)	xxx	xxx
Number Assessed	xxx	xxx
Number Censored	xxx	xxx
Number With Event	xxx	xxx
Test Statistic[a]	xxx	
P-value[a]	xxx	

[a] Test Statistic and P-value of the Gehan-Wilcoxon Test comparing the time to SSI post-surgery of the D-PLEX group to that of the CONTROL group.
All estimates and CIs derived from Kaplan-Meier survival curve.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 64. Number and Proportion of Subjects with Non-confirmed SSI by Adjudication by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	Visit	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	P-value[b]
Number of Subjects with ≥ 1 Non-confirmed SSI	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	Overall	xxx (xxx)	xxx (xxx)	xxx

[a] Denominator for proportions is the number of ITT subjects in the respective treatment group.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions by visit.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 66. Number and Proportion of Subjects Who Experience Any SSI (Confirmed and Non-confirmed) within 30 Days by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
ITT Population (N=xxx)

Variable	Visit	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	P-value[b]
Number of Subjects with ≥ 1 SSI (Confirmed and Non-confirmed)	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	xxxxx	xxx (xxx)	xxx (xxx)	xxx
	Overall	xxx (xxx)	xxx (xxx)	xxx

[a] The denominator for all proportions in the table is the number of ITT population subjects in the corresponding treatment group.
[b] P-value based on a two-sided Fisher's Exact Test of difference in treatment proportions by visit.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for mITT Population.

Table 68. Summary Statistics of Doxycycline Concentration Levels by Dose and Time
PolyPid Ltd. – Study No. D-PLEX 310
PK Population (N=xxx)

No. of Vials	Time (hrs)	n	Mean	Std Dev	Median	Minimum	Maximum
1	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx
2	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx
3	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 69. Summary Statistics of Estimated PK Parameters by Dose
PolyPid Ltd. – Study No. D-PLEX 310
PK Population (N=xxx)

Part 1 of 3: 1 Vial

Subject No.	C_{max} (ng/mL)	t_{max} (hrs)	AUC (0-t) (hrs*ng/mL)	AUC (0-∞) (hrs*ng/mL)	λ_z (/hrs)	$t_{1/2}$ (hrs)	V_z	MRT (hrs)
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
n	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Std Dev	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CV%	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Geometric Mean	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Lower 90% CI	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Upper 90% CI	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 69. Summary Statistics of Estimated PK Parameters by Dose
PolyPid Ltd. – Study No. D-PLEX 310
PK Population (N=xxx)

Part 2 of 3: 2 Vials

Subject No.	C_{max} (ng/mL)	t_{max} (hrs)	AUC (0-t) (hrs*ng/mL)	AUC (0-∞) (hrs*ng/mL)	λ_z (/hrs)	$t_{1/2}$ (hrs)	V_z	MRT (hrs)
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
n	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Std Dev	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CV%	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Geometric Mean	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Lower 90% CI	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Upper 90% CI	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 69. Summary Statistics of Estimated PK Parameters by Dose
PolyPid Ltd. – Study No. D-PLEX 310
PK Population (N=xxx)

Part 3 of 3: 3 Vials

Subject No.	C_{max} (ng/mL)	t_{max} (hrs)	AUC (0-t) (hrs*ng/mL)	AUC (0-∞) (hrs*ng/mL)	λ_z (/hrs)	$t_{1/2}$ (hrs)	V_z	MRT (hrs)
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xxxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
n	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Mean	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Std Dev	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
CV%	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Geometric Mean	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Lower 90% CI	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Upper 90% CI	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 70. Number and Percent of Subjects with Treatment Emergent Adverse Events
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Adverse Event Category[a]:	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Treatment Emergent Adverse Events (TEAEs)	xxx	xxx	xxx
Subjects with ≥ 1 TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 71. Summary of Treatment Emergent Adverse Events
PolyPid Ltd. – Study No. D-PlEX 310
Safety Population (N=xxxx)

	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]
Subjects with at Least One Treatment Emergent Adverse Event (TEAE)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Maximum TEAE Severity Grade			
Mild	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Moderate	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Severe	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Highest Relationship of TEAE to Study Drug			
Not Related	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Unlikely Related	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Possibly Related	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Related	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Subjects with at Least One Expected TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Subjects with at Least One Unexpected TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Subjects with at Least One Serious TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 72. Number and Percent of Subjects with Serious Treatment Emergent Adverse Events
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Adverse Event Category[a]:	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Serious Treatment Emergent Adverse Events (TEAEs)	xxx	xxx	xxx
Subjects with at Least One Serious TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 73. Number and Percent of Subjects with Study Drug-Related Treatment Emergent Adverse Events
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Adverse Event Category[a,b]:	D-PLEX (N=xxx)[c]	CONTROL (N=xxx)[c]	Overall (N=xxx)[c]
Total Number of Study Drug-Related Treatment Emergent Adverse Events (TEAEs)	xxx	xxx	xxx
Subjects with at Least One Serious TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] A study-drug related TEAE is any TEAE with a study drug relationship of Possibly Related or Related.
[c] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 74. Number and Percent of Subjects with Treatment Emergent Adverse Events
by Relationship to Study Drug
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

	D-PLEX (N=xxx)[b]				CONTROL (N=xxx)[b]			
Adverse Event Category[a]:	Not Related	Unlikely	Possibly	Related	Not Related	Unlikely	Possibly	Related
Total Number of Treatment Emergent Adverse Events (TEAEs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Subjects with at Least One TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 75. Number and Percent of Subjects with Treatment Emergent Adverse Events by Severity
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

	D-PLEX (N=xxx)[b]			CONTROL (N=xxx)[b]		
Adverse Event Category[a]:	Mild	Moderate	Severe	Mild	Moderate	Severe
Total Number of Treatment Emergent Adverse Events (TEAEs)	xxx	xxx	xxx	xxx	xxx	xxx
Subjects with at Least One TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 76. Number and Percent of Subjects with Delay of Wound Healing by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Adverse Event Category[a]:	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Adverse Events Due to Delay of Wound Healing	xxx	xxx	xxx
Subjects with at Least One AE Due to Delay of Wound Healing	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 77. Vital Sign Parameters Summary Statistics
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Vital Sign Parameter (units)	Visit	Data Type[a]	Mean	Std Dev	n	Min	Max	Median
D-PLEX	xxxxxxxxxx (xxx)	xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxxxxxxxxx (xxx)	xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = observed data recorded in database; CFB = change from baseline.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 78. Physical Exam Results by Body System
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx

Treatment	Body System	Visit	Normal[a]	Abnormal[a]
D-PLEX	xxxxxxxxxxxxxxxxx	xxxxxx	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)
CONTROL	xxxxxxxxxxxxxxxxx	xxxxxx	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 79. Physical Exam Results Shift Table by Body System and Visit
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Body System	Visit	Normal/ Normal[a]	Normal/ Abnormal[a]	Abnormal/ Normal[a]	Abnormal/ Abnormal[a]
D-PLEX	xxxxxxxxxxxxxxxx	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxxxxxxxxxxxx	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
CONTROL	xxxxxxxxxxxxxxxx	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxxxxxxxxxxxx	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 80. Laboratory Parameters Summary Statistics
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Laboratory Parameter (units)	Visit	Data Type[a]	Mean	Std Dev	n	Min	Max	Median
D-PLEX	xxxxxxxxxxxxx (xxx)	xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
CONTROL	xxxxxxxxxxxxx (xxx)	xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = observed data recorded in database; CFB = change from baseline.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 81. Laboratory Results Shift Table by Parameter and Visit
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Laboratory Parameter (units)	Treatment	Visit	Baseline/Time Point: High/ High[a]	High/ Normal[a]	High/ Low[a]	Normal/ High[a]	Normal/ Normal[a]	Normal/ Low[a]	Low/ High[a]	Low/ Normal[a]	Low/ Low[a]
xxxxxxxxxx (xxx)	D-PLEX	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	CONTROL	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
xxxxxxxxxx (xxx)	D-PLEX	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	CONTROL	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 82. Wound Healing Assessment by Treatment and Overall
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Visit		Response	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]
xxxxxx	Wound Healing?	Yes	xxx (xxx)	xxx (xxx)	xxx (xxx)
		No	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 83. Number and Proportion of Abnormal Bacteriological Test Results by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Visit	Normal[a]	Abnormal[a]
D-PLEX	xxxxxx	xxx (xxx)	xxx (xxx)
	xxxxxx	xxx (xxx)	xxx (xxx)
	xxxxxx	xxx (xxx)	xxx (xxx)
CONTROL	xxxxxx	xxx (xxx)	xxx (xxx)
	xxxxxx	xxx (xxx)	xxx (xxx)
	xxxxxx	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 84. Number and Percent of Bacteria Resistant to Other Antibiotics by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]
Total Number of Bacteria Resistant to Other Antibiotics	xxx	xxx	xxx
Resistant to:			
1 Antibiotic	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
2 Antibiotics	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
3 Antibiotics	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
>3 Antibiotics	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 85. Number and Percent of Bacteria Growth in Subjects who Experience SSI by Treatment
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

	D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall (N=xxx)[a]
Total Number of Bacterial Growth in Subjects with SSI	xxx	xxx	xxx
No Growth	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
1 Microorganism	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
2 Microorganisms	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
3 Microorganisms	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
>3 Microorganisms	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 86. Number and Proportion of Subjects with Medical History Events
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Medical History Category[a]:	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Medical History Events	xxx	xxx	xxx
Subjects with at Least One Medical History Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Medical history events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 87. Number and Proportion of Subjects with Comorbid Medical History Events
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Medical History Category[a]:	D-PLEX (N=xxx)[b]	CONTROL (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Comorbid Medical History Events	xxx	xxx	xxx
Subjects with at Least One Comorbid Medical History Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Medical history events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 88. Number and Percent of Subjects Taking Concomitant Medications by ATC Level 4 and Preferred Term
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Concomitant Medication Category[a,b]	D-PLEX (N=xxx)[c]	CONTROL (N=xxx)[c]	Overall (N=xxx)[c]
ATC Level 4 Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term 1	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term 2	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
ATC Level 4 Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term 1	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term 2	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)

[a] Concomitant medications coded with WHO Coding Dictionary xxxxxxxxxxxxx.
[b] Concomitant medication category will include anatomical therapeutic chemical (ATC) level 4 term followed by preferred term.
[c] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 89. Number and Percent of Subjects Taking Antibiotics Prior to Surgery by ATC Level 4 and Preferred Term
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Antibiotic Category[a,b]	D-PLEX (N=xxx)[c]	CONTROL (N=xxx)[c]	Overall (N=xxx)[c]
ATC Level 4 Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
ATC Level 4 Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)

[a] Concomitant medications coded with WHO Coding Dictionary xxxxxxxxxxxx.
[b] Concomitant medication category will include anatomical therapeutic chemical (ATC) level 4 term followed by preferred term.
[c] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 90. Number and Percent of Subjects Taking Antibiotics After Surgery by ATC Level 4 and Preferred Term
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Antibiotic Category[a,b]	D-PLEX (N=xxx)[c]	CONTROL (N=xxx)[c]	Overall (N=xxx)[c]
ATC Level 4 Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
ATC Level 4 Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)
WHO Preferred Term	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)

[a] Concomitant medications coded with WHO Coding Dictionary xxxxxxxxxxxx.
[b] Concomitant medication category will include anatomical therapeutic chemical (ATC) level 4 term followed by preferred term.
[c] The denominator for all percentages in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 91. Summary of Wound Characteristics and Surgery Type
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Variable		D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall
Length of Surgical Index Incision	5-10cm	xxx (xxx)	xxx (xxx)	xxx (xxx)
	11-20cm	xxx (xxx)	xxx (xxx)	xxx (xxx)
	>21cm	xxx (xxx)	xxx (xxx)	xxx (xxx)
Method of Surgery	Laparoscopy	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Laparotomy	xxx (xxx)	xxx (xxx)	xxx (xxx)
Surgery included colostomy/ileostomy?	Yes	xxx (xxx)	xxx (xxx)	xxx (xxx)
	NO	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 92. Summary of Wound Characteristics and Surgery Type for Subjects who Experience SSI
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Variable		D-PLEX (N=xxx)[a]	CONTROL (N=xxx)[a]	Overall
Length of Surgical Index Incision	5-10cm	xxx (xxx)	xxx (xxx)	xxx (xxx)
	11-20cm	xxx (xxx)	xxx (xxx)	xxx (xxx)
	>21cm	xxx (xxx)	xxx (xxx)	xxx (xxx)
Method of Surgery	Laparoscopy	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Laparotomy	xxx (xxx)	xxx (xxx)	xxx (xxx)
Surgery included colostomy/ileostomy?	Yes	xxx (xxx)	xxx (xxx)	xxx (xxx)
	NO	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions in the table is the number of Safety population subjects in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 93. Study Drug Administration Summary Statistics
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Variable	Mean	Std Dev	n	Min	Max	Median
D-PLEX	Number of Vials Administered	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 94. Number and Proportion of Subjects Given each Study Drug Dose
PolyPid Ltd. – Study No. D-PLEX 310
Treated Subjects[a] (N=xxx)

Treatment	Variable	1 Vial[b]	2 Vials[b]	3 Vials[b]
D-PLEX	Number of Subjects Given Study Drug Dose	xxxx (xxxx%)	xxxx (xxxx%)	xxxx (xxxx%)

[a] Subjects who received the D-PLEX study drug.
[b] The denominator for all proportions in the table is the total number of subjects who received D-PLEX.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 1. Subject Disposition Data Listing
PolyPid Ltd. – Study No. D-PLEX 310

Subject No.	Treatment	Disposition Status	Disposition Date	Date of Last Visit/ Withdrawal Date	If Withdrawn, Reason for Discontinuation
xxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 2. Protocol Deviations Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Date of Deviation	Deviation Description	Deviation Major or Minor
xxxxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 3. Demographics Data Listing
PolyPid Ltd. – Study No. D-PlEX 310
ITT Population (N=xxx)

Treatment	Subject No.	Informed Consent Date	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI	Gender	Ethnicity	Race
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 4. Subjects Excluded from mITT Population Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
All Subjects (N=xxx)

Treatment	Subject No.	Reason for Exclusion
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data listing will be repeated for the ITT, PP and Safety Populations.

Data Listing 8. Substance Abuse Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Chronic Drug Abuse? (Y/N)	Consumes Alcohol? (Y/N)	Currently Smokes? (Y/N)	Previously Smoked? (Y/N)
xxxxxx	xxxx	xxxxxxxxxxx	xxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxxxxx	xxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxxxxx	xxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxxxxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 9. Medical History Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Start Date	End Date	Ongoing? (Y/N)
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	xxx

[a] Medical history terms coded with MedDRA Coding Dictionary Version xxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 10. Comorbid Medical History Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Start Date	Ongoing? (Y/N)
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxx

[a] Medical history terms coded with MedDRA Coding Dictionary Version xxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 11. Concomitant Medications Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	WHO Preferred Term[a]/ Verbatim Drug Name/ Indication/ ATC Level 4 Term	Dose (units)	Frequency	Start Date	Stop Date	Route	Ongoing?
xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx (xxx)	xxxxxxxx	xxxxxxx	xxxxxxx	xxxxx	xxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx (xxx)	xxxxxxxx	xxxxxxx	xxxxxxx	xxxxx	xxxxx

[a] Concomitant medication coded with WHO Coding Dictionary xxxxxxxxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 12. Adverse Events Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Part 1 of 2

Treatment	Subject No.	Start Date/ End Date	Treatment Start Date	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Severity	Special Interest?	Relationship	Serious?/ Reason Serious?
xxxxxx	xxxxxxxxx	xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx/ xxxxxxxx
xxxxxx	xxxxxxxxx	xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx/ xxxxxxxx

[a] Adverse events coded with MedDRA Coding Dictionary Version xxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 12. Adverse Events Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Part 2 of 2

Treatment	Subject No.	Start Date/ End Date	Treatment Start Date	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Medication Given?	Expected? (Y/N)	Action Taken	Outcome
xxxxxx	xxxxxxxx	xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxx	xxxxxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxx/ xxxxxxxxxx	xxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxx	xxxxxxxx

[a] Adverse events coded with MedDRA Coding Dictionary Version xxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Data Listing 13. Physical Exam Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	Date Conducted	Body System	Result	Abnormality
xxxxxx	xxxx	xxxxxxx	xxxxxxx	xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 14. Vital Signs Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	Date	Time	Temp. (°C)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)	Heart Rate (bpm)
xxxxxx	xxxx	xxxxxxx	xxxxxxx	xxxxx	xxx	xxx	xxx	xxx
				xxxxx	xxx	xxx	xxx	xxx
				xxxxx	xxx	xxx	xxx	xxx
xxxxxx	xxxx	xxxxxxx	xxxxxxx	xxxxx	xxx	xxx	xxx	xxx
				xxxxx	xxx	xxx	xxx	xxx
				xxxxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 15. Hematology Laboratory Results Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	Date of Visit	Lab Test (units)	Result	Normal Range Low	Normal Range High	Normal/High/Low[a]
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxx

[a] Indicates whether the results of the lab test indicated were within the normal range, lower than the normal range or higher than the normal range.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 16. Serum Biochemistry Laboratory Results Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	Date of Visit	Lab Test (units)	Result	Normal Range		Normal/High/Low[a]
						Low	High	
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxxx

[a] Indicates whether the results of the lab test indicated were within the normal range, lower than the normal range or higher than the normal range.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 17. Urinalysis Laboratory Results Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	Date of Visit	Lab Test (units)	Result
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 18. Surgery Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Start Time	End Time	Length of Incision	Type of Surgery	Anastomosis Performed	Surgery Included Colostomy/Ileostomy? (Y/N)	Additional Procedure? (Y/N)	Problems During Surgery? (Y/N)
xxxxxx	xxxx	xxxxxxxx	xxxxxx	xxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxx	xxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 19. Re-Admissions due to SSI Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Hospitalization Date	Discharge Date	Department	Reason for Re-Admission	If due to SAE, describe event
xxxxxx	xxxx	xxxxxxxx	xxxxxx	xxxxxxxx	xxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxx	xxxxxxxx	xxxxxxx	xxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 20. Study Drug Administration Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Time of Application	No. of Vials	Vial Serial No.	Batch No.	Expiration Date	Problems with Preparation?
xxxxxx	xxxx	xxxxxxxx	xxxxxxx	xxx	xxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 21. Surgical Site Infection Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Treatment Date	Date of Infection	Time to Infection[a]	Deep Incisional SSI? (Y/N)	Superficial Incisional SSI? (Y/N)
xxxxxx	xxxx	xxxx	xxxxxxxx	xxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxx	xxxxxxxx	xxxxx	xxxx	xxxx

[a] Time to Infection = Date of Infection – Treatment Date + 1.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 22. SSI by Adjudication Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Date of Adjudication	Adjudication Committee Decision
xxxxxx	xxxx	xxxxxxxx	xxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxx

Data Listing 23. Wound Healing Assessment Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visual Wound Healing Assessment Performed? (Y/N)	Wound Discharge? (Y/N)	If Yes, Type of Discharge	Bacteriological Test Taken? (Y/N)	Test Taken Prior to Antibiotic Treatment? (Y/N)
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxx	xxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxx	xxxxxxxx	xxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 24. ASEPSIS Score Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	ASEPSIS Parameter[a,b,c]	Score
xxxxxx	xxxx	xxxxxxxx	Serous Exudate	xxxxxx
			Erythema	xxxxxx
			Purulent Exudate	xxxxxx
			Separation of Deep Tissue	xxxxxx
			Drainage of Pus	xxxxxx
			Isolation of Pathogenic Bacteria	xxxxxx
			Stay as Inpatient	xxxxxx
			Total	xxxxxx
xxxxxx	xxxx	xxxxxxxx	Serous Exudate	xxxxxx
			Erythema	xxxxxx
			Purulent Exudate	xxxxxx
			Separation of Deep Tissue	xxxxxx
			Drainage of Pus	xxxxxx
			Isolation of Pathogenic Bacteria	xxxxxx
			Stay as Inpatient	xxxxxx
			Total	xxxxxx

[a] For scoring of Serous Exudate and Erythema: 0= 0% of wound affected; 1 = less than 20% of wound affected; 2= 20-39% of wound affected; 3= 40-59% of wound affected; 4= 60-79% of wound affected; 5= greater than 80% of wound affected.
[b] For scoring of Purulent Exudate and Separation of Deep Tissue: 0= 0% of wound affected; 2 = less than 20% of wound affected; 4= 20-39% of wound affected; 6= 40-59% of wound affected; 8= 60-79% of wound affected; 10= greater than 80% of wound affected.
[c] For scoring of Drainage of Pus, 5= Yes; 0= No. For scoring Isolation of Pathogenic Bacteria, 10= Yes, 0= No. For scoring Stay as Inpatient, 5= Yes, 0=No.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sasw

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Data Listing 25. Hospitalization Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Hospitalization Date	Discharge Date	Department	Time to Release[a]	Reason for Admission?	Cause?
xxxxxx	xxxx	xxxx	xxxx	xxxxxxxx	xxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxx	xxxx	xxxxxxxx	xxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxx

[a] Time to Release = Discharge Date – Hospitalization Date
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 26. Bacterial Test Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Test Date	Specimen Source	Isolate Observed	Bacterial Growth? (Y/N)	Sensitivity to Doxycycline?	Related to AE?	If related to AE, Describe AE
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx	xxxx	xxx	xxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 27. Bacterial Growth Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Test Date	Specimen Source	Bacterial Growth?(Y/N)	Microorganism Identified
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx	xxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx	xxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 28. Doxycycline Concentrations Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Treated Subjects[a] (N=xxx)

Dose Group	Subject No.	Time Point	Sample Collected? (Y/N)	Sample Date/Time	Back-up Sample Collected? (Y/N)	Concentration (ng/mL)
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx	xxx	xxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx	xxx	xxxxxxx

[a] Subjects who received the D-PLEX study drug.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 29. Pharmacokinetics Parameters Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Treated Subjects[a] (N=xxx)

Dose Group	Subject No.	C_{max} (ng/mL)	t_{max} (hrs)	AUC (0-t) (hrs*ng/mL)	AUC (0-∞) (hrs*ng/mL)	λ_z (/hrs)	$t_{1/2}$ (hrs)	V_z	MRT (hrs)
xxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxxxx	xxxxxxx	xxxxxx	xxxxxxx	xxxxx	xxxxxx
xxxxx	xxxx	xxxxxxxx	xxxxx	xxxxxxxx	xxxxxx	xxxxxx	xxxxxxx	xxxxx	xxxxx

[a] Subjects who received the D-PLEX study drug.
STATKING Clinical Services (month day, year)
Source Program: xxxxxx.sas

Data Listing 30. Randomization Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Method of Surgery	Included Colostomy? (Y/N)	Randomization Date/Time	Subject Group	Randomization Arm
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxxx/xxxxx	xxxxxxx	xxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxx	xxxxx/xxxxx	xxxxxxx	xxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 31. ECG Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Date of ECG	Normal/Abnormal?	Clinically Significant?	Description
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxx	xxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxx	xxxxxxxxxxxxxxx

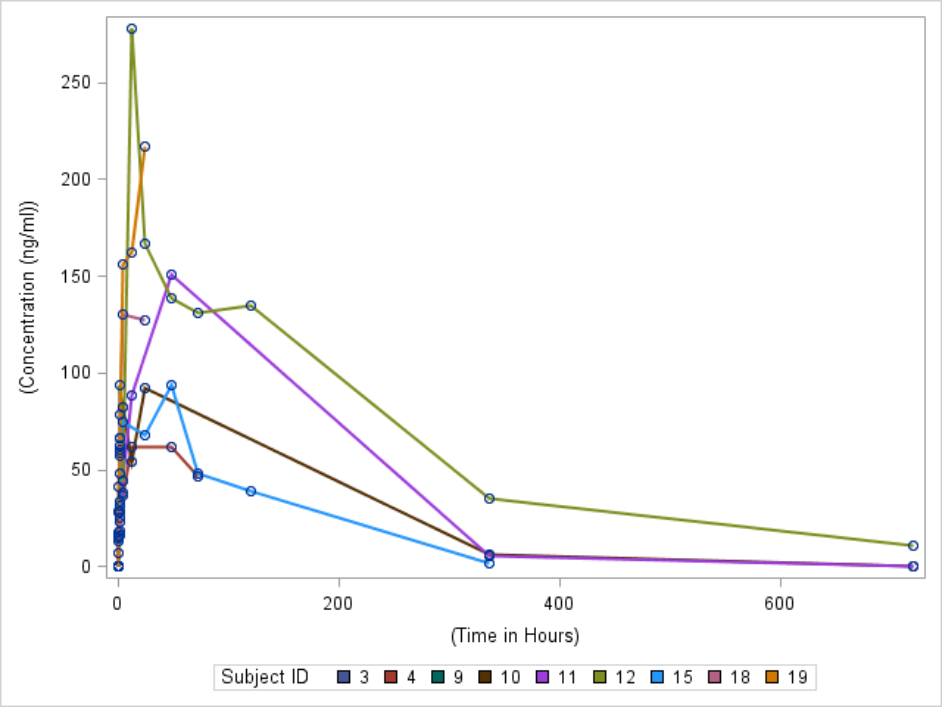
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 32. Rectal Swab Data Listing
PolyPid Ltd. – Study No. D-PLEX 310
Safety Population (N=xxx)

Treatment	Subject No.	Visit	Rectal Swab Done?	Specify Reason	Describe Bacteriologic Findings
xxxxxx	xxxx	xxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Figure 1. Subject Doxycycline Concentration levels for the 1 Vial Dose Group – Linear Scale
PolyPid Ltd. – Study No. D-PLEX 310
PK Population (N=xxx)



STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Figure format will be repeated for the 2 Vial and 3 Vial Dose Groups.

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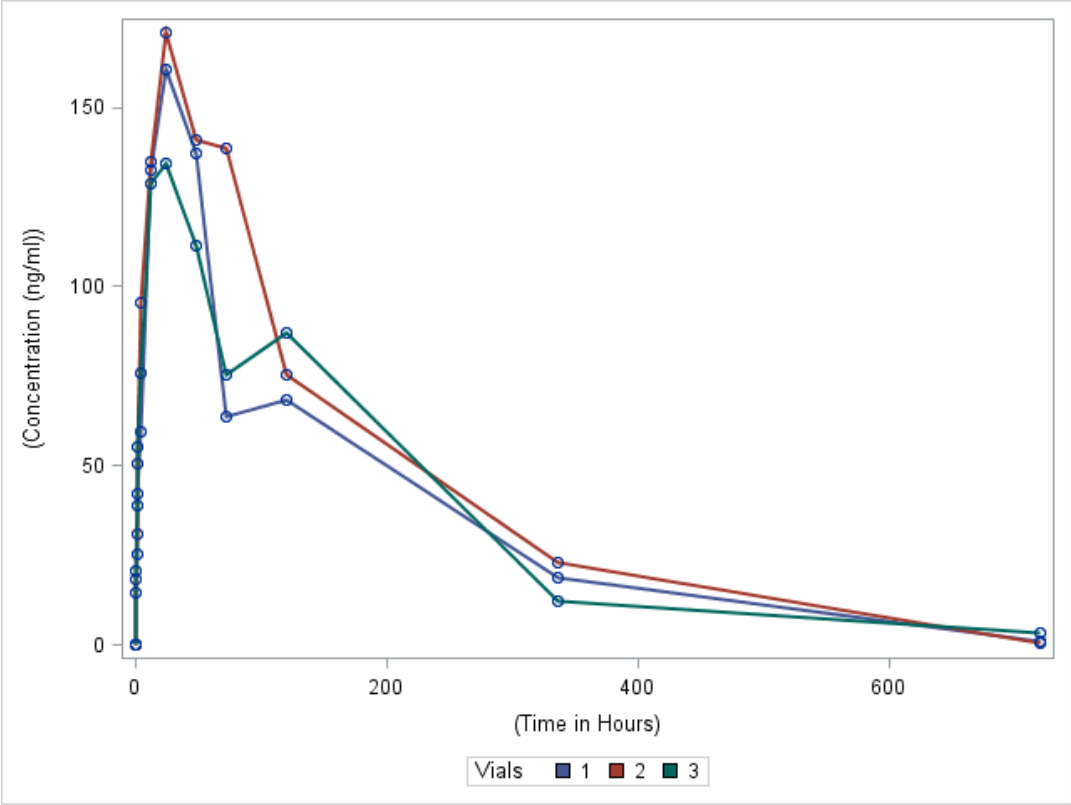
Figure 4. Mean Doxycycline Concentration Levels by Dose Group – Linear Scale
PolyPid Ltd. – Study No. D-PLEX 310
PK Population (N=xxx)

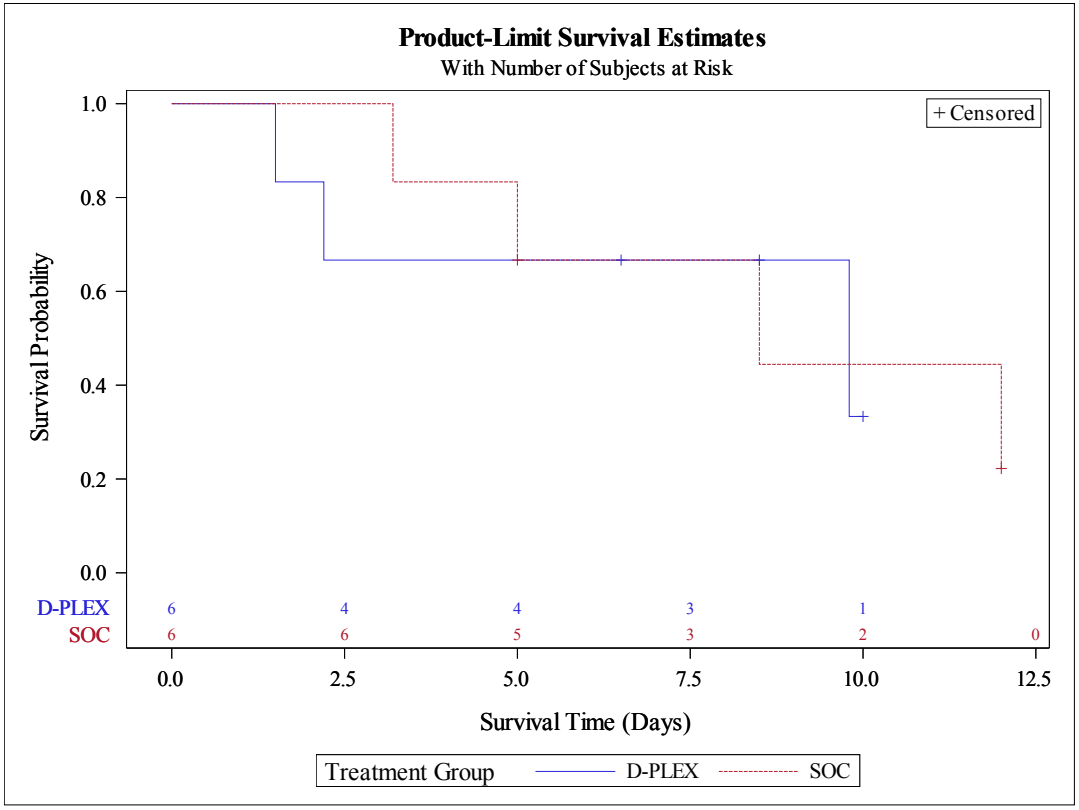


STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Figure format will be repeated for median levels.

Page x of y

Figure 6. Graphical Representation of Time to SSI Post-Surgery
PolyPid Ltd. - Study No. D-PLEX 310
ITT Population (N=xxx)



STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Figure format will be repeated for the mITT Population.