[redacted]

Technical Trial Statistical Analysis Plan- CTR display plan

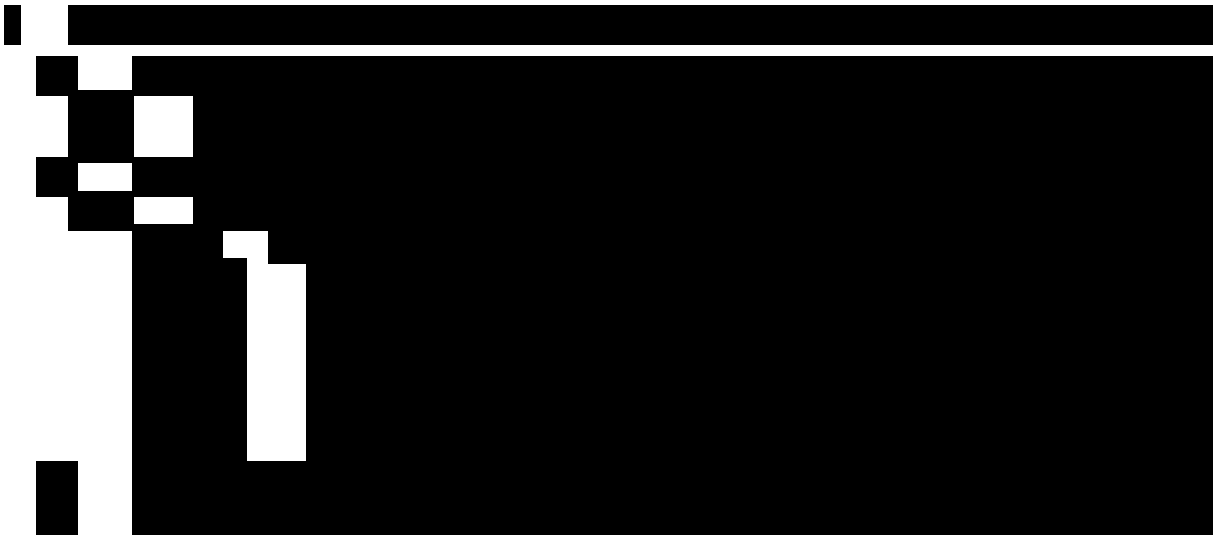
RealGiDo

RealGiDo: Real-world data on Gi(l)otrif® dose adjustment in first-line treatment, TKI-naïve, advanced non-small cell lung cancer patients with EGFR activating mutations

Project No:	5311000_NIS RealGiDo
Medication:	Gi(l)otrif®
Dokument ID:	TechnicalSAP_RealGiDo_Final_v1.1_2018-01-17.docx
Version:	Final 1.1
Date:	17.01.2018
Sponsor:	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Straße 173 D-55216 Ingelheim am Rhein
Author:	[redacted]
Protocol (Version, Date):	Final version 1.0, 01.03.2016

Tables of contents

Tables of contents 2
1 Methods for calculation of derived variables 3



The following tables, listings and figures are planned. The checked fields show the programmer where the parameter to be analysed may be found and will not appear in the report. In this context, the variable before the point displays the dataset and the variable after the point stands for the field name within the corresponding dataset. Take note, that the variable before the point must be always reported again as first term after the point, e.g. patient.birthyear stands for the field patient.patient_birthyear in the eCRF.

1 Methods for calculation of derived variables

Age at registration: Year of registration [patient.birthyear] – Year of birth [registration.registered_at]

Drug-related AE: All AE with relationship to Gi(l)otrif® [ae.gilotref_relation_1='yes']

Time on treatment: Date of last administration [endofobservation.date] - Date of first administration of Gi(l)otrif® [baseline.date]. For patients still on treatment, time on treatment will be censored at the date of data collection.

Time to progression (TTP): First date of progression [min(endofobservation.radio_date, endofobservation.clinic_date)] - Date of first administration of Gi(l)otrif® [baseline.date]. Patients not known to have a progression will be censored with the date of last contact. For patients still on treatment and without progression, time to progression will be censored at the date of data collection. For patients who stopped treatment and without progression or progression date missing, time to progression will be censored on the last contact date.

Missing / Incomlpete AE Onset Dates:

For each missing / incomplete AE onset date, an interval (INT_START, INT_END) is defined. The true unkniown analysis start date of the AE is assumed to be within this interval. If the AE onset date is completely missing INT_START will be Min(AE end date, Date of informed consent) and INT_END will be Min(AE end date, Date of last visit). If only the year of the AE onset date is non-missing INT_START will be Min(AE end date, 01 JAN of the reported year) and INT_END will be Min(AE end date, 31 DEC of the reported year). If only year and month of the AE onset date are non-missing INT_START will be Min(AE end date, 01 of the reported month) and INT_END will be Min(AE end date, Last date of the reported month). Completely missing AE end dae will not be considered in this derovation step. Partially missing AE end date (i.e., year and month are non-missing or only year is non-missing) will be temporarily assigned the largest possible date in the observed year or month and year in this derivation step. After this the imputed AE onset dates will be derived based on the intervals (INT_START, INT_END). If the date of first drug administration is within the interval [INT_START, INT_END] then the imputed AE onset date will be the date of drug administration. If the date of first drug administration is before INT_START then the imputed AE onset date will equal INT_START. If the date of first drug administration is after INT_END or missing then the imputed AE onset date equals INT_END.