

# MAY2013-02-02 - Checklist (Registration) Data Dictionary

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## Document Summary

| Property          | Value                                                     |
|-------------------|-----------------------------------------------------------|
| Document Title    | MAY2013-02-02 - Checklist (Registration): Data Dictionary |
| Date Created      | 09/19/2025                                                |
| Sections          | 2                                                         |
| Entries           | 37                                                        |
| Document Filename | dictionary_chklist_reg.rtf                                |

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## MAY2013-02-02 - Checklist (Registration): Data Dictionary

### Section 1: Identifiers

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| Class         | Variable       | Label          | Description | Format Text |
|---------------|----------------|----------------|-------------|-------------|
| 01. Principal | <b>subject</b> | Participant ID |             | Char        |

## Section 2: Eligibility Checklist (Registration)

| Class         | Variable            | Label                                                                                            | Description | Format Text                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------|---------------------|--------------------------------------------------------------------------------------------------|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01. Principal | <b>alt</b>          | ALT/SGPT                                                                                         |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 01. Principal | <b>alt_unl</b>      | ALT/SGPT UNL                                                                                     |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 01. Principal | <b>Arm</b>          | Treatment Arm                                                                                    |             | "A"="A"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 01. Principal | <b>ast</b>          | AST/SGOT                                                                                         |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 01. Principal | <b>ast_unl</b>      | AST/SGOT UNL                                                                                     |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 01. Principal | <b>casedetailid</b> | Case Number                                                                                      |             | Numeric                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 01. Principal | <b>creat</b>        | Creatinine                                                                                       |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 01. Principal | <b>creatunl</b>     | Creatinine UNL                                                                                   |             | Char                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 01. Principal | <b>ctep_arm</b>     | TAC/TAD Code                                                                                     |             | "TAC-1 (Erlotinib 50 mg PO Q am x 7 days [empty stomach])"="TAC-1 (Erlotinib 50 mg PO Q am x 7 days [empty stomach])"<br>"TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg PO Qam x 7 days [empty Stomach])"="TAC-1B (Non-Surgical Cohort B: Erlotinib 50mg PO Qam x 7 days [empty Stomach])"<br>"TAC-2A (Surgical Cohort A: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"="TAC-2A (Surgical Cohort A: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"<br>"TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"="TAC-2B (Non-Surgical Cohort B: Erlotinib 25mg PO Qam x 7 days [empty Stomach])"<br>"TAC1 (Erlotinib 75 mg PO Q am x 7 days [empty stomach])"="TAC1 (Erlotinib 75 mg PO Q am x 7 days [empty stomach])" |
| 01. Principal | <b>date_mod</b>     | Date Modified                                                                                    |             | SAS Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 01. Principal | <b>dc_num</b>       | Protocol Number                                                                                  |             | "MAY2013-02-02"="MAY2013-02-02"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 01. Principal | <b>doselevl</b>     | Dose Level (+2, +1, 0, -1, -2)                                                                   |             | "+1"="100 mg/day"<br>"+2"="150 mg/day"<br>"-1"="50 mg/day"<br>"-2"="25 mg/day"<br>"0"="75 mg/day"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 01. Principal | <b>EnrollDT</b>     | Enrollment Date                                                                                  |             | SAS Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 01. Principal | <b>eresnum</b>      | ERES Number                                                                                      |             | "0000-106261"="0000-106261"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 01. Principal | <b>exclu001</b>     | Receiving Any Other Investigational Agents <=6 Months Prior To Registration                      |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 01. Principal | <b>exclu002</b>     | Surgical Cohort (Cohort A Only): Percutaneous Or Transjugular Biopsy Incomplete Or Not Performed |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

| Class         | Variable        | Label                                                                                                                                      | Description | Format Text                                                                                                                                                                                                                   |
|---------------|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01. Principal | <b>form</b>     | Form                                                                                                                                       |             | 1="Main - chklist"                                                                                                                                                                                                            |
| 01. Principal | <b>group</b>    | Group: 1=Dose Escalation/De-Escalation Cohort 2=Expansion Cohort                                                                           |             | "1=Dose Escalation/De-escalation Cohort"="1=Dose Escalation/De-escalation Cohort"<br>"1=Dose escalation/de-escalation cohort"="1=Dose escalation/De-escalation cohort"<br>"2=Dose expansion cohort"="2=Dose expansion cohort" |
| 01. Principal | <b>inclu001</b> | ECOG Performance Status 0 Or 1 (Appendix A)                                                                                                |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu002</b> | Participants Must Have Normal Organ And Marrow Function                                                                                    |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu003</b> | INR <=1.5                                                                                                                                  |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu004</b> | Platelets >=50 B/L (10 <sup>9</sup> /L)                                                                                                    |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu005</b> | Total Bilirubin <=3 X Institutional ULN                                                                                                    |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu006</b> | AST (SGOT) And ALT (SGPT) <=5 X Institutional ULN                                                                                          |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu007</b> | Creatinine <=1.5 X Institutional ULN                                                                                                       |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu008</b> | Non-Surgical Cohort Only: Positive Phospho-EGFR Assessment (>=100 Stained Pixels) From Tissue Obtained From Previous Clinical Liver Biopsy |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inclu009</b> | Pre-Intervention Biopsy Sample Collected                                                                                                   |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>inr</b>      | INR (Decimal Use Available With Entry, If Needed)                                                                                          |             | Char                                                                                                                                                                                                                          |
| 01. Principal | <b>pielig</b>   | Is The Participant Eligible For Inclusion On This Study?                                                                                   |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes"                                                                                                                                                                                           |
| 01. Principal | <b>plt</b>      | Platelets, The Absolute Peripheral Platelet Count (Units Not Specified)                                                                    |             | Char                                                                                                                                                                                                                          |
| 01. Principal | <b>ps</b>       | ECOG Performance Status 0 Or 1                                                                                                             |             | "0"="0"<br>"1"="1"                                                                                                                                                                                                            |

| Class         | Variable        | Label                                                                                      | Description | Format Text                         |
|---------------|-----------------|--------------------------------------------------------------------------------------------|-------------|-------------------------------------|
| 01. Principal | <b>reg01</b>    | Intervention Cannot Begin Prior To Registration And Must Begin <=14 Days From Registration |             | "n"="No"<br>"na"="N/A"<br>"y"="Yes" |
| 01. Principal | <b>studyid</b>  | Study ID                                                                                   |             | Numeric                             |
| 01. Principal | <b>tbiliunl</b> | Total Bilirubin UNL                                                                        |             | Char                                |
| 01. Principal | <b>tot_bili</b> | Total Bilirubin                                                                            |             | Char                                |
| 01. Principal | <b>version</b>  | Version Number                                                                             |             | Numeric                             |