Software for
Business Intelligence

BizInt Smart Charts

Patents & IP Sequences | Clinical Trials | Drug Pipelines

Updating Drug Pipeline and Clinical Trial Reports

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Update reports and identify changes

ClinicalTrials.Gov: Updated MCC

	Trial Title	Row Status	Drugs	Sponsor(s)	Brief Summary	Overall Status	Primary Outcome	Enrollment	Last Changed Date
23	A Phase 1 Open-Label, Dose-Escalation, Safety and Tolerability Study of INCAGN02385 in Participants With Select Advanced Malignancies	Added	INCAGN02385	Incyte Biosciences International Sàrl	The purpose of this study is to determine the safety, tolerability, and preliminary efficacy of INCAGN02385 in participants with advanced malignancies.	Recruiting	Number of treatment-emergent adverse events (TEAEs) - TEAE defined as adverse events reported for the first time or worsening of a pre-existing event after first dose of study drug.	55 (Anticipated)	2018-08-27
24	A Phase 1, Open-label, Multicenter, Dose-escalation Study of CK-301 Administered Intravenously as a Single Agent to Subjects With Advanced Cancers	Updated	CK-301	Checkpoint Therapeutics, Inc. Novotech (Australia) Pty Limited	CK-301 is a fully human monoclonal antibody of IgG1 subtype that directly binds to Programmed Death-Ligand 1 (PD-L1) and blocks its interactions with the Programmed Death-1 (PD-1) and B7.1 receptors. The primary objectives of this study are to assess the safety, tolerability and efficacy of CK-301 when administered intravenously as a single agent to subjects with selected recurrent or metastatic [CONT.]	Recruiting	Dose Limiting Toxicity Number of subjects with Treatment-Emergent Adverse Events according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 4.03 (or most current version) Confirmed Objective Response Rate (ORR) as per Response Evaluation Criteria in Solid Tumors (RECIST Version 1.1)	500 (Anticipated)	2019-01-11
25	A Phase I Trial of the mTOR Inhibitor RAD001 in Combination With VEGF Receptor Tyrosine Kinase Inhibitor PTK787/ZK 222584 in Patients With Advanced Solid Tumors	Updated	everolimus vatalanib	Mayo Clinic National Cancer Institute (NCI)	RATIONALE: Everolimus and vatalanib may stop the growth of tumor cells by blocking some of the enzymes needed for cell growth and by blocking blood flow to the tumor. Giving everolimus together with vatalanib may kill more tumor cells. PURPOSE: This phase I trial is studying the side effects and best dose of everolimus and vatalanib in treating patients with advanced solid tumors.	Completed	Maximum tolerated dose of everolimus and vatalanib (Cohort I) (Closed to enrollment as of 12/6/06) Toxicity associated with everolimus and vatalanib (Cohort I) (Closed to enrollment as of 12/6/06) Therapeutic	96 (Anticipated)	2018-01-12

In this webinar

- How Update works

- The Row Status column

- Update in Reference Rows

Updating reports

- File | Update
- All charts need to be open before updating.
- The "key" chart is your baseline – your existing report, against which new data is compared
- Rows are compared when both the database and the accession number are the same.
- Columns do not need to be the same in the charts – the "key" chart is the template.

Updating reports

- File | Update

- Rows from the baseline are copied, in order, to the new chart

- New records added at bottom of the new chart

- Rows that have new data remain in their position from the baseline chart

Keep Your Smart Charts Files!

- In order to update, you need to have the BizInt Smart Charts CHT file

- Reports exported to Word or Excel cannot be updated, but you can generate a new export once you update the report

Example: Update a Clinical Trials Report

Updating reports

- Added charts in an update can be a set of new records (as in an alert, or date limited search)
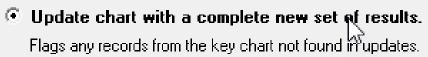- This only reports Added and Updated rows.

Select the operation you would like to perform:

⊙ **Update chart with partial results**
   Useful for alerts and other date limited searches.

○ **Update chart with a complete new set of results.**
   Flags any records from the key chart not found in updates.

○ **Update combined chart with new results from one database.**
   Changes update status for one database only.

Updating reports

- Added charts can also be a complete set of data (as in exporting a workbook after new records added)

- In this case, you could use the "Update with complete set of results" option, which will report any rows which were no longer in the set.

Select the operation you would like to perform:

○ **Update chart with partial results**
Useful for alerts and other date limited searches.

● **Update chart with a complete new set of results.**
Flags any records from the key chart not found in updates.

○ **Update combined chart with new results from one database.**
Changes update status for one database only.
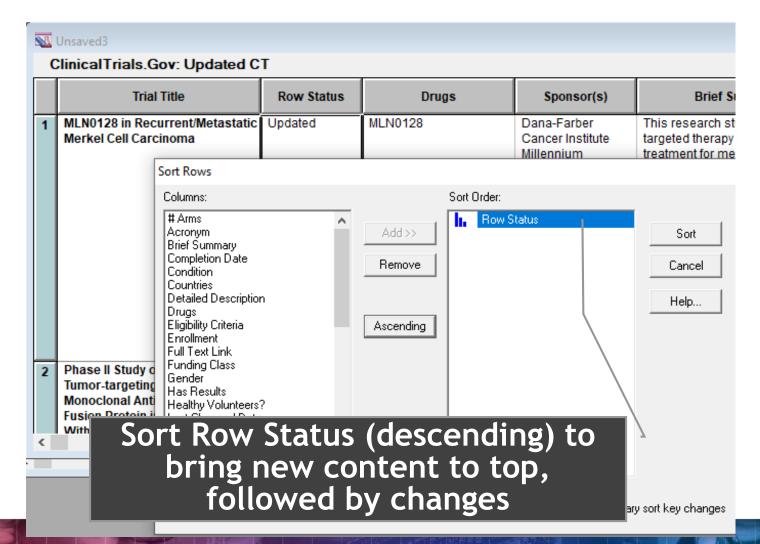
Updating reports with multiple new sets

- Combine all new charts into one and update key chart with this new chart

- -or-

- Update key chart by adding charts from all sources

- Change detection is for the last update, so you want to do the update in one step.

Updating reports (Row Status)

- "Added" means this **record** is new in this report

- "Updated" means the record was seen before but has new/changed information

- "Unchanged" means the record has not changed from the baseline

- Row Status reflects what happened to the record at that row.

Sorting updated reports

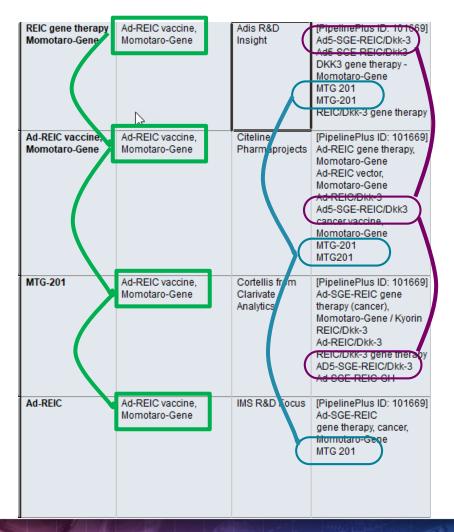Sort Row Status (descending) to bring new content to top, followed by changes

Example: Update a Combined Pipeline

Introducing Reference Rows

- One or more record in each group
- Records grouped based on "Common Drug Name" or "Common Trial ID"
- Selection for each field is based on rules
- Special rule for the Row Status columns

Tools | Identify Common Drug Name

Updated reports in Reference Rows

- Must identify common records in the updated chart before proceeding
- You can use the "Regenerate" button in the Reference Rows wizard

Row Status in Reference Rows

- "Added" means this **group** of related records (drug, trial) is new in this report

- "Updated" means the baseline had group before, but has new/changed information, possibly from added records

- "Unchanged" means the group has not changed from the baseline

- Row Status reflects what happened to the group at that row.

Example: Reference Rows

To recap

- Combine charts before updating
- Charts must be open
- File | Update
- Choose the appropriate update type
- Row Status column shows changed records
- Identify Common before Reference Rows
- Reference Rows shows Row Status for changed groups (drugs / trials)

Thank you…
Questions???