

**EMPOWER**  
*life changing decisions.*



# Kaluza C Flow Cytometry Software

Be efficient. Be compliant

May 19, 2019

*Delivering INNOVATIVE and trusted scientific solutions across the globe*

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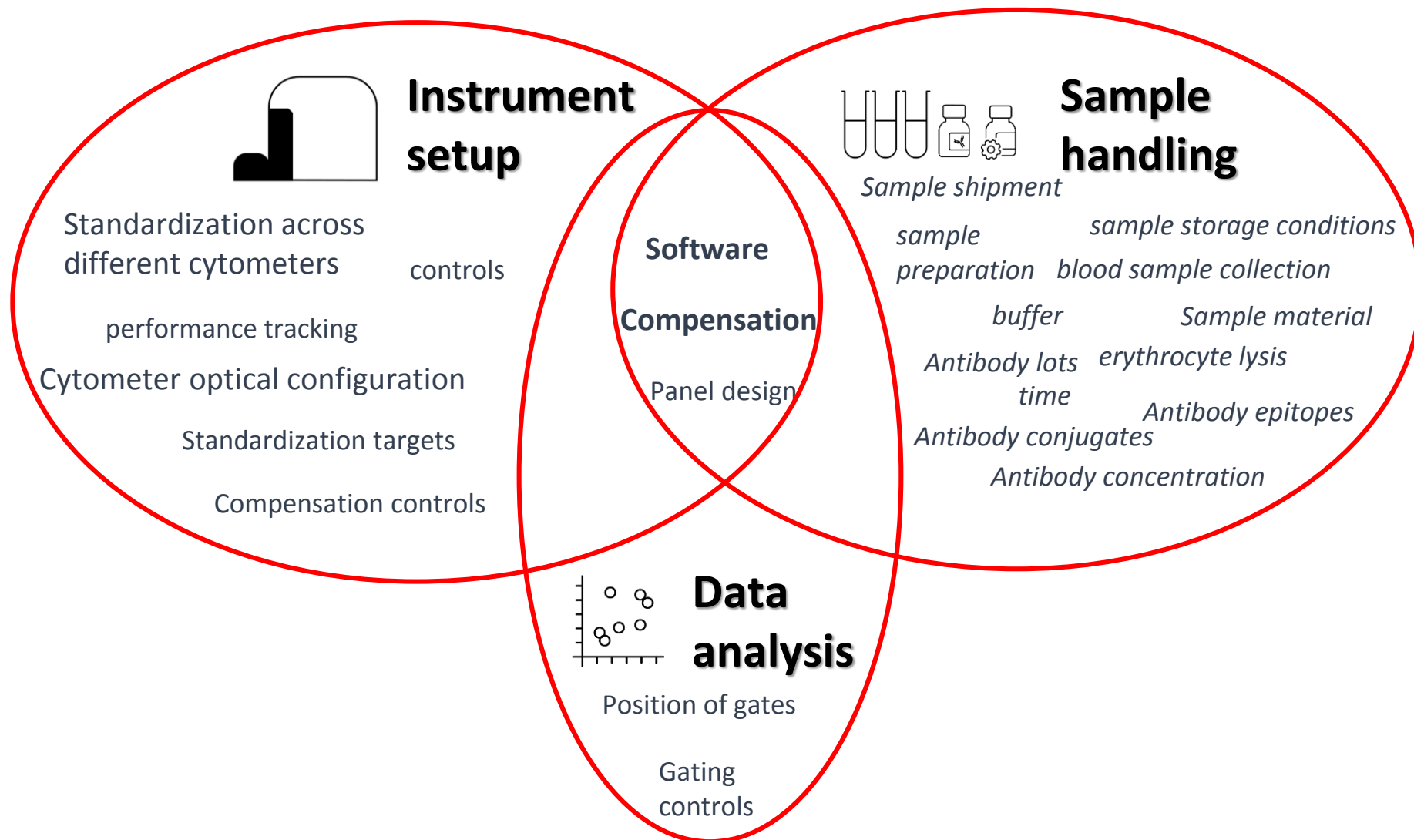
Kaluza C is listed with the U.S. FDA



FLOW-4094CP09.18

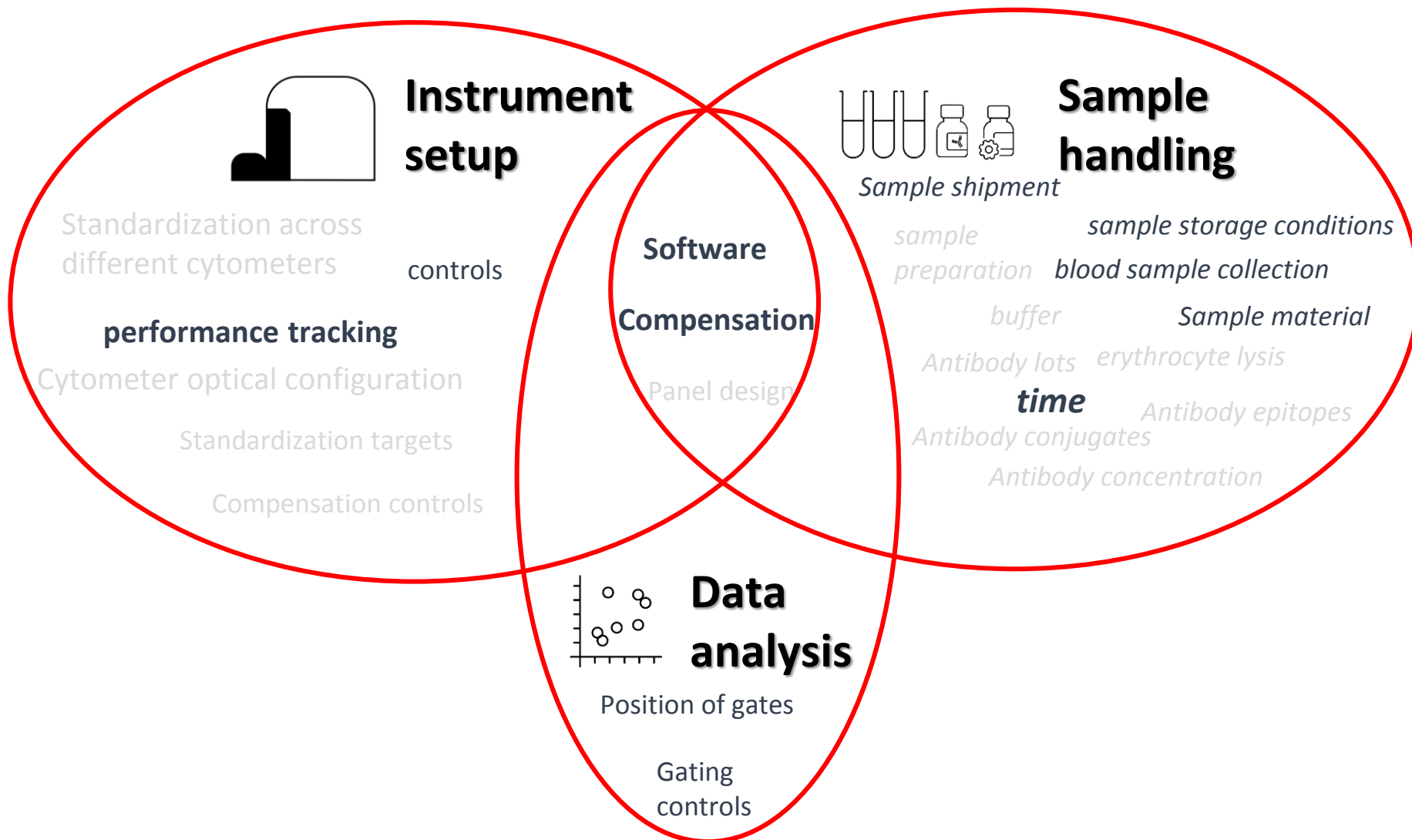


# Standardization in Flow Cytometry



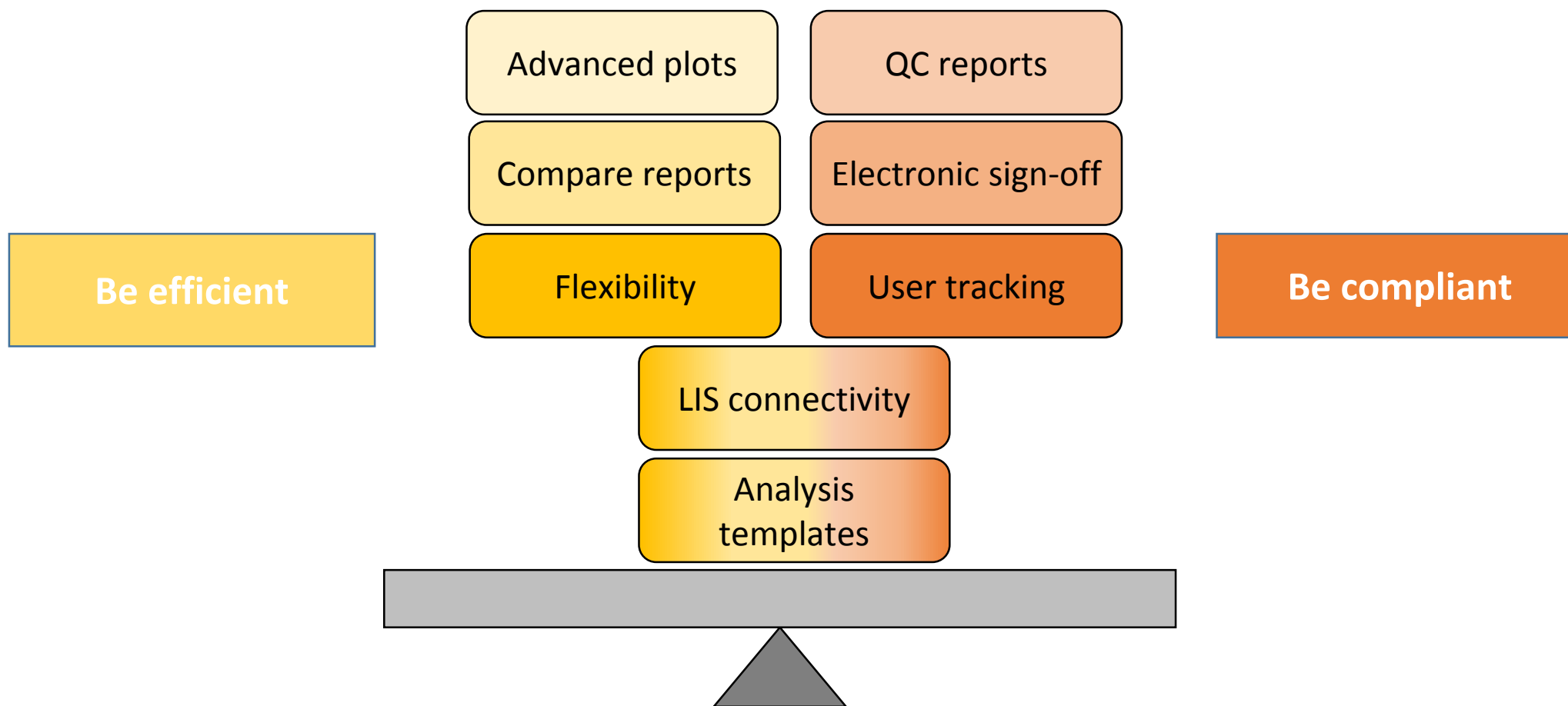


# Standardization in Flow Cytometry





# Clinical Flow Cytometry Data Analysis





Kaluza C



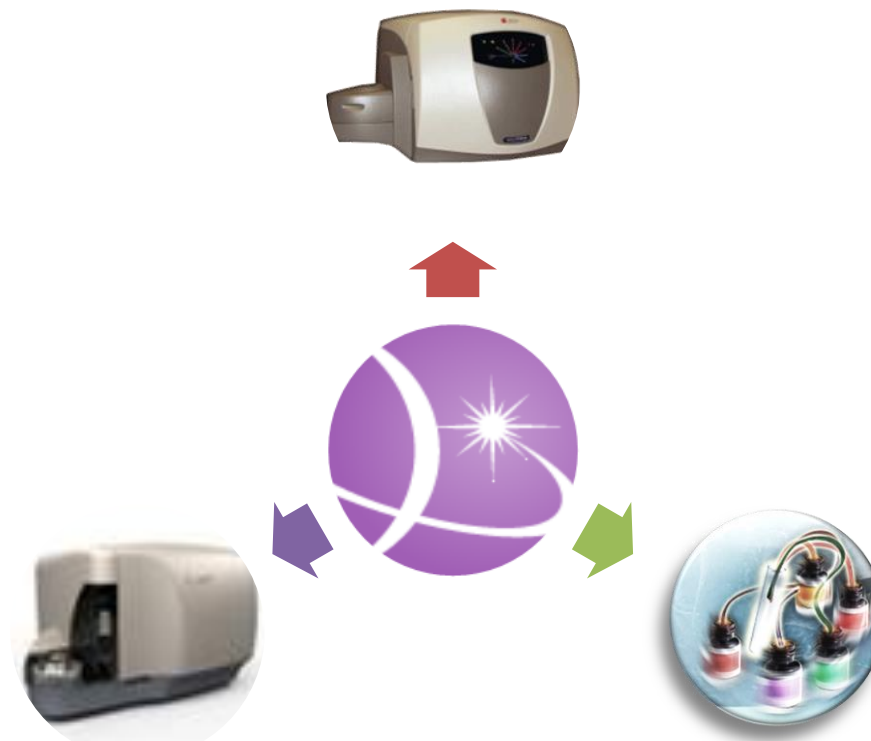
- The development of Kaluza C followed ISO 13485 – a quality management system for medical devices. The software has been listed with the U.S. **FDA**.
- **Platform agnostic**
- Provides **compliant** software environment for clinical analysis
- Designed to offer **simplicity & speed** for efficient data analysis
- Tools for analysis of **high complexity** data



## Standardize Your Workflow for All Data



- Not only data generated by Beckman Coulter flow cytometers, **ALL** standard FCS files (FCS2.0, 3.0, 3.1) and LMD files can be read and analyzed by Kaluza.
- Plots and gates embedded in LMD files can be loaded directly into Kaluza workspace.

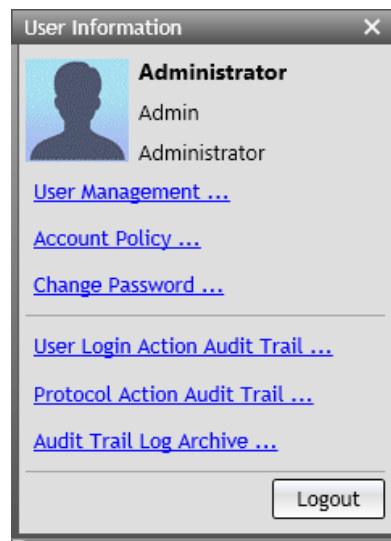




# User Management



- **User management**
  - User name and password are required to log in.
  - Different levels of operator authority can be set.
- **Log files for audit trail**
  - Track user logins and Protocol Actions for compliance with lab policy for data management and safety.



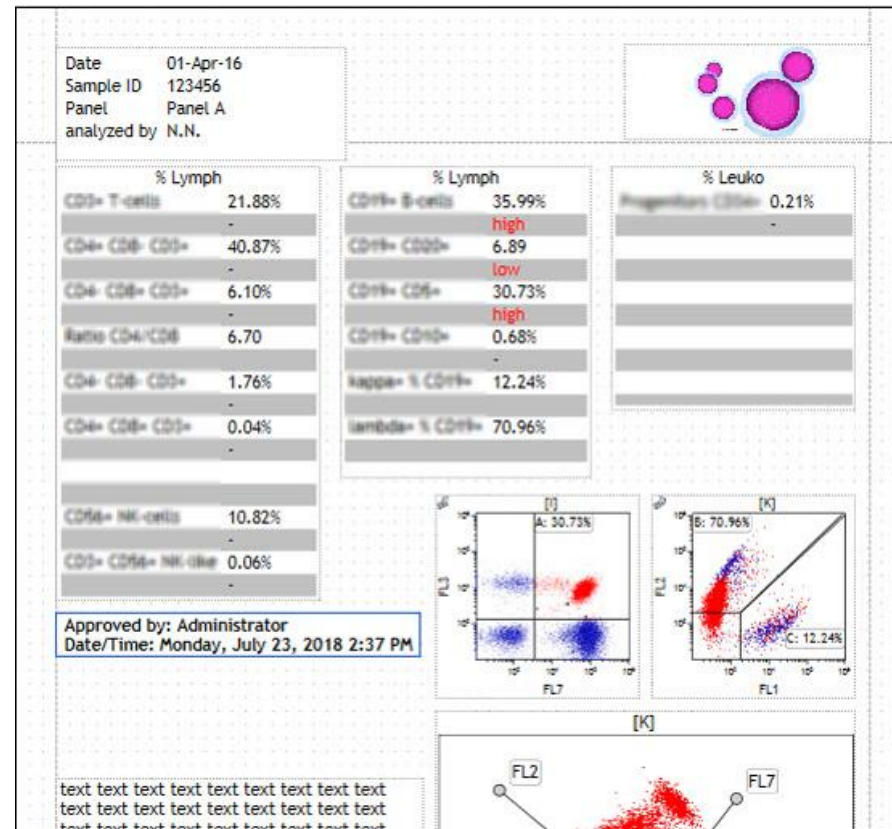
Protocol Action Audit Trail Report					
Report Generated Time: 2017-07-24 18:33:49					
<b>Query Criteria</b>					
User: All Users					
Time Range: 2017-06-24 00:00:00 - 2017-07-24 23:59:59					
Record:					
Timezone: (UTC-05:00) Eastern Time (US & Canada)					
<b>Query Result</b>					
#	Operation	Username	User Full Name	Timestamp	Record
1	Open document	Katherine Jones	Katherine Jones	2017-07-24 18:14:51	Open a document, file name: C:\Users\Desktop\Kaluza 2.0\Kaluza Data Files\AAKaluza v1.5 Training\6c3l.LMD.
2	Save document	Katherine Jones	Katherine Jones	2017-07-24 18:15:52	Save a document, file name: C:\Users\Desktop\6c3l_1.analysis.
3	Save document	Katherine Jones	Katherine Jones	2017-07-24 18:15:55	Save a document, file name: C:\Users\Desktop\6c3l_1.analysis.
4	Open document	Admin	Administrator	2017-07-24 18:16:30	Save a document, file name: C:\Users\Desktop\6c3l_1.analysis.
5	Save document	Admin	Administrator	2017-07-24 18:17:08	Save a document, file name: C:\Users\Desktop\6c3l_1.analysis.



## Electronic Sign off



- Electronically sign off on reports for accountability and work flow control
- select from different date/time formats and font styles



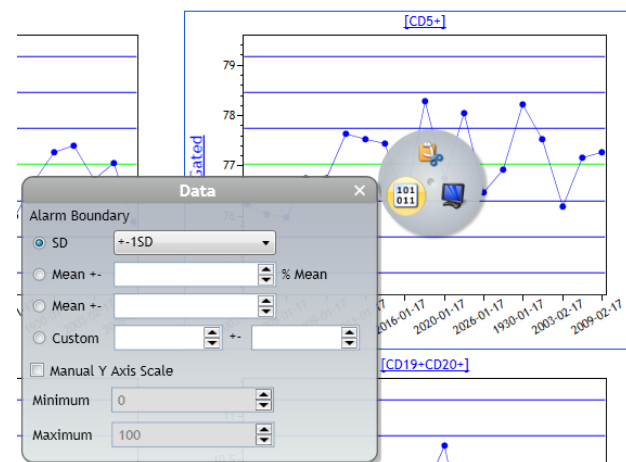
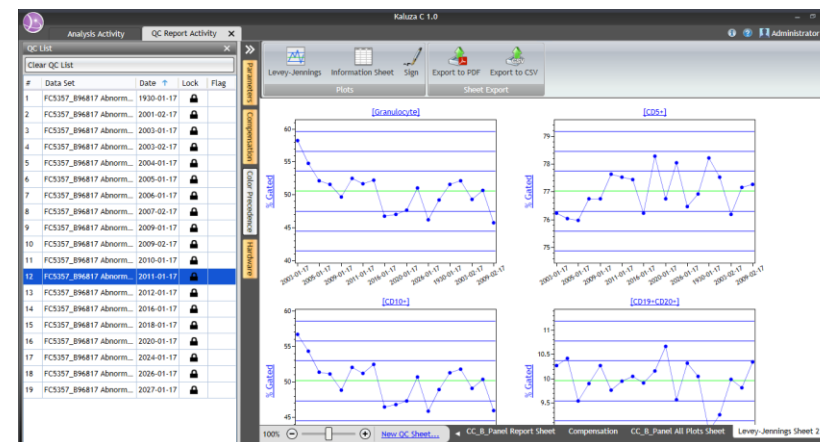




# QC Report



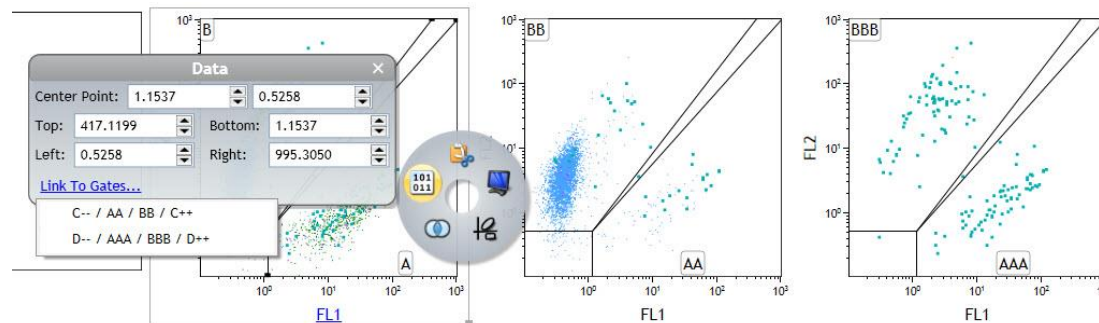
- User friendly creation of **instrument QC** and **Assay QC** reports to check the reliability of the instruments and the assays.
- Generate reports and Levey-Jennings charts with **user defined alarm boundaries**.
- Easy to save the data for future audits.



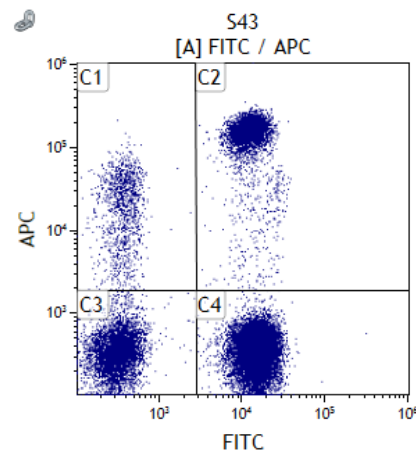
# Tools for Real Time Data Analysis



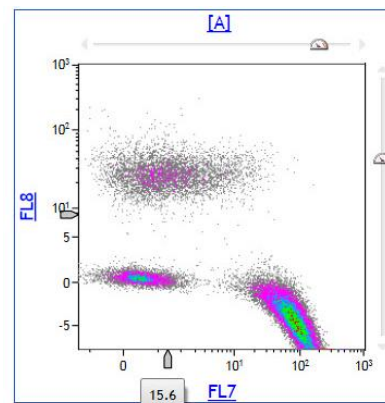
Right-click for  
context-sensitive  
**Radial menus**  
instead of  
cluttered  
workspaces



**Link quadrants** across  
plots and/or samples



**Link plots**  
between  
workspace and  
report sheets.  
New short-cut:  
Ctrl + L



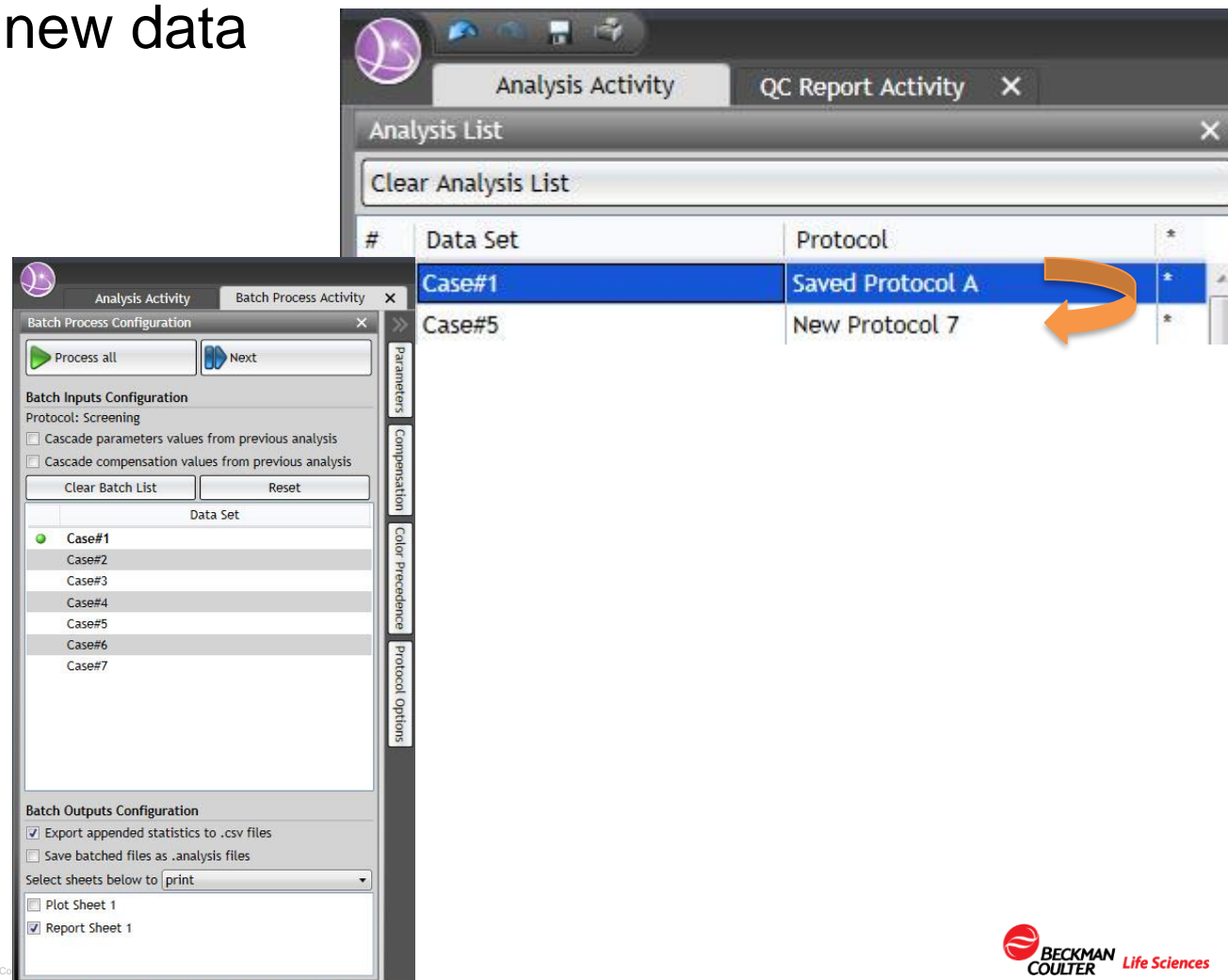
**Use slider** to  
visualize also  
negative  
fluorescences  
and to adjust  
compensation.



# Apply Analysis Protocols to New Data Sets



- Easily apply pre-defined Plot & Report Sheets & LIS export templates to new data files by **drag & drop**
- Automatically save and print analyses and export statistics using the Batch Process Activity





## Information Table



- Polished look and feel
- Present data that contains a Label and Value
- Display fcs keyword information
- Summarize Statistic results in tabular format
- Use formulas to calculate the result you need

Date 04-May-2018  
Sample ID 123456  
Panel Panel name  
analyzed by N.N.

% Lymph	
CD X+	35.99
	high
CD X+ CD Z+	6.89
	low
CD X+ CD Y+	30.73
	high

Date 04-May-2018  
Sample ID 123456  
Panel Panel name  
analyzed by N.N.

% Lymph	
CD X+	35.99
	high
CD X+ CD Z+	6.89
	low
CD X+ CD Y+	30.73
	high

Data

CD X+ =PCTGATED("CD X",2)  
<no formula defined> =IF((PCTGATED("CD X",2))>0.25,1,0)  
CD X+ CD Z+ =PCTGATED ("CD X",2)  
<no formula defined> =IF((PCTGATED("CD X",2))>0.25,1,0)  
CD X+ CD Y+ =PCTGATED ("CD X",2)  
<no formula defined> =IF((PCTGATED("CD X",2))>0.25,1,0)

Selected Value

Name:

Value: =IF((PCTGATED("CD X", 2))>0.25, 1, 0)

[Add Keywords](#) [Add Statistic](#)



## Information Sheets



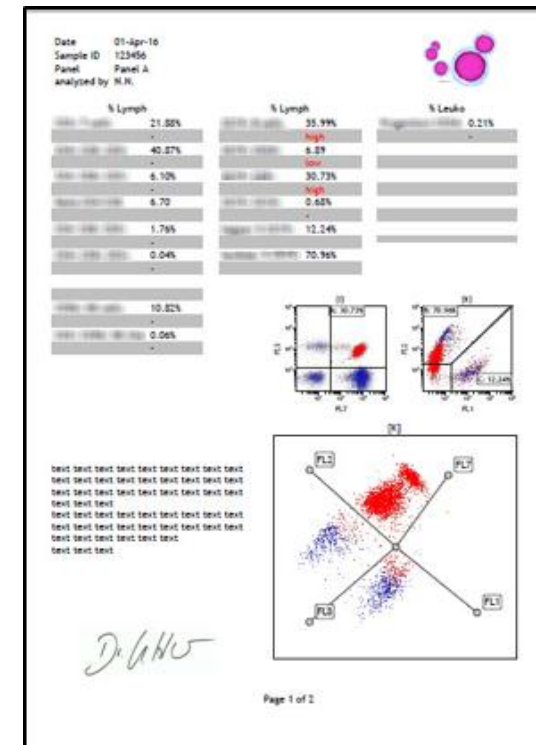
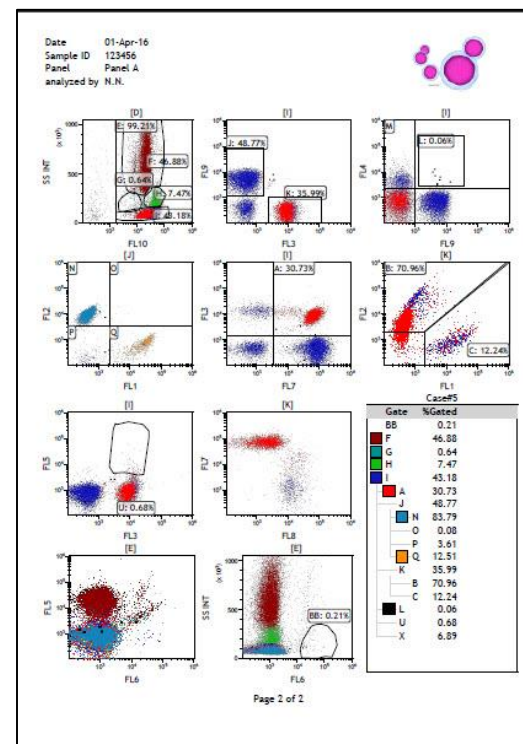
- Similar to a spreadsheet application, this table is easy to use and is highly adjustable to your needs
- Add as many columns as desired
- Full control over the width of the column
- Copy/paste information from spreadsheet applications

Name	Value	Internal Code
Name of the data file containing the data set	nim-DAPI First J45.01 control - solvent 2013-08-07 007.LMD	H1-A5A
Clock time at end of data acquisition	10:28:32	H1-C1H
FS INT Median	423.17	D1-K5N
TIME Standard Deviation	19.95	D1-K5J



# Flexible Report Sheet

- Easily link the plots from workspace to report sheets.
- Multiple report layouts per sample
- Easy to edit the format of the report sheet
- Master page can be saved as template.



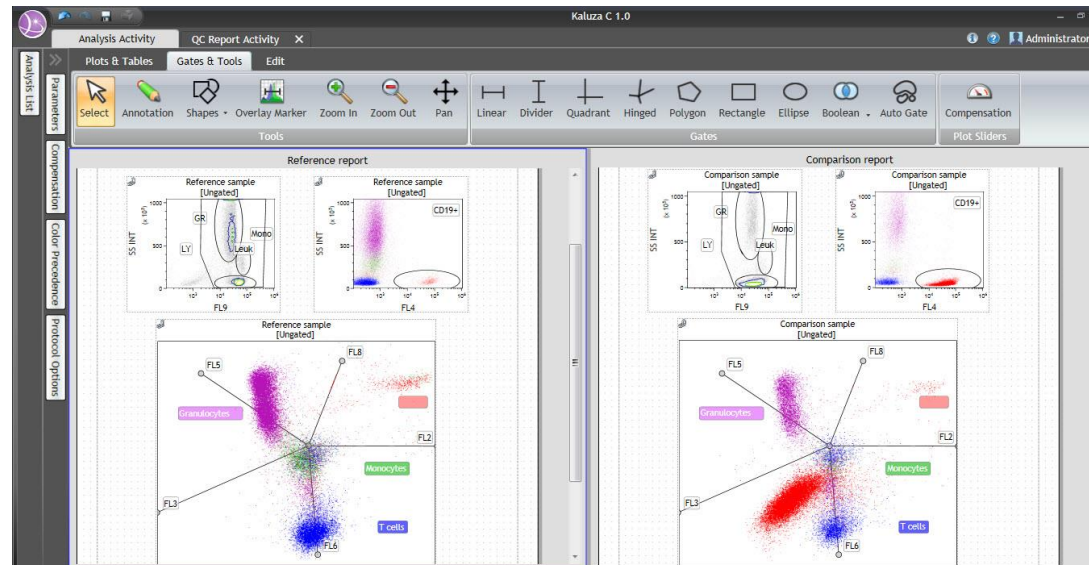




# Compare And Find The Abnormal Results



- The **report comparison** feature allows user to compare the reports side by side.
- Editable information table allows you to add formulas to do calculation and **label** the results which are out of reference range.



Name	Value	Reference Range
A %	74.51	60-80
B %	44.85	10-20



# Export Your Analysis Results to LIS



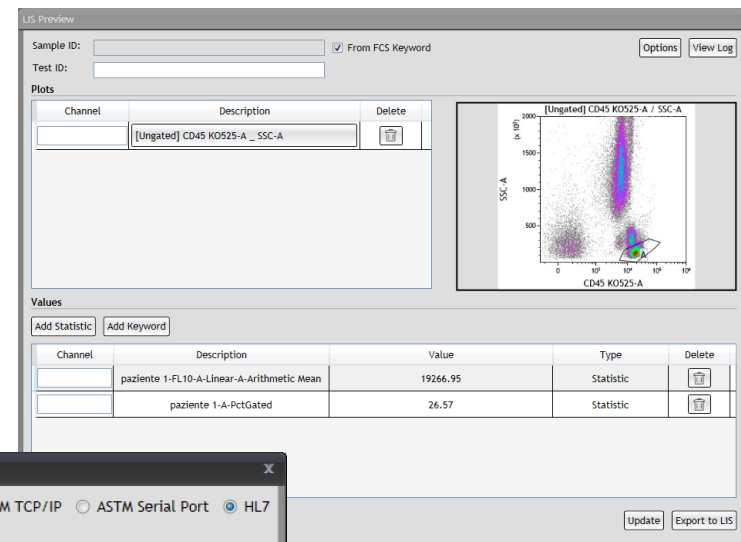
- Data can be transferred to **LIS** directly with three connection options

ASTM TCP/IP Interface

ASTM Serial Port Interface

HL7 Interface.

- Both statistics and plots can be exported.
- Export templates are part of the protocol and be reused easily.



The LIS Option Window is used to configure the LIS connection. It includes the following fields:

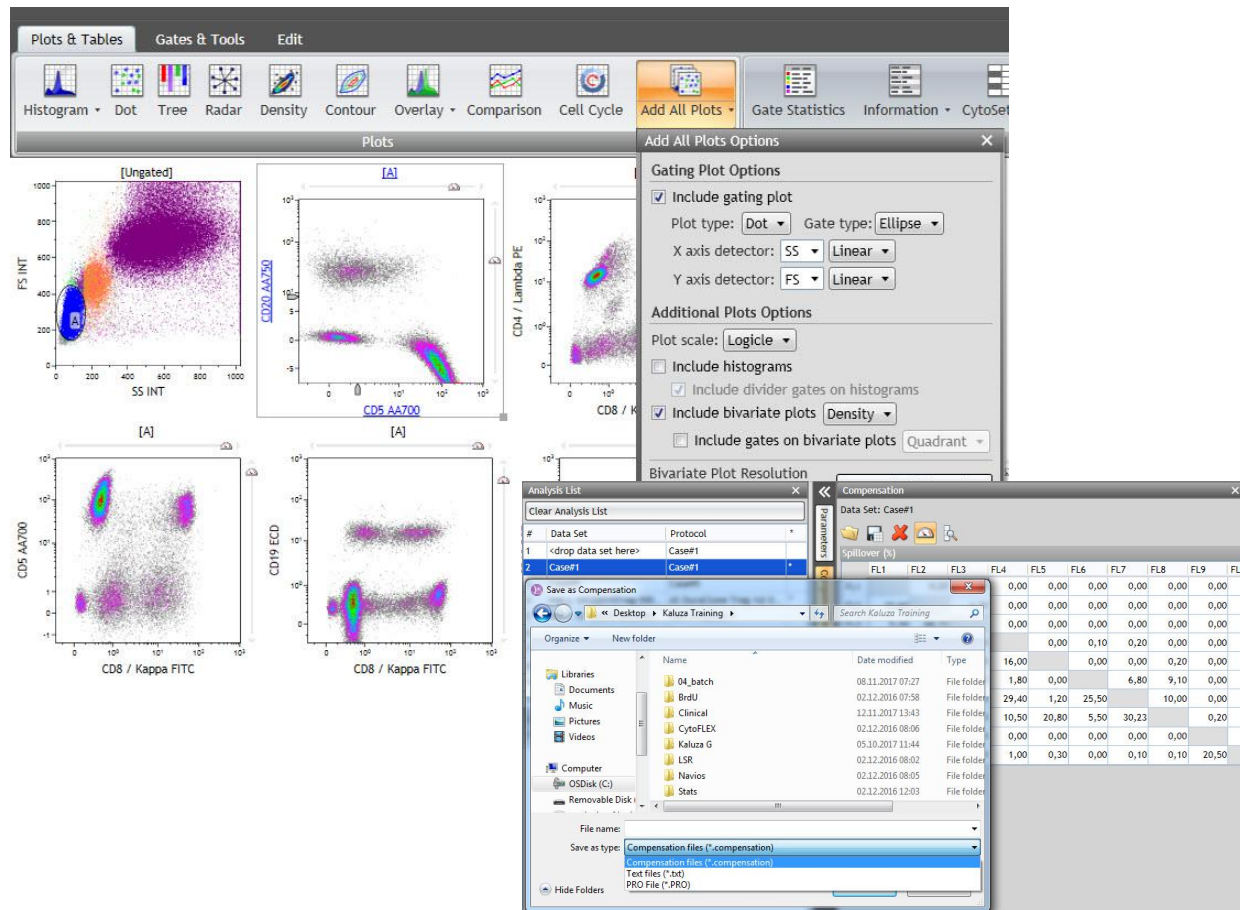
- LIS Connection:** Radio buttons for ASTM TCP/IP, ASTM Serial Port, and HL7 (selected).
- Timeout:** 15 Seconds.
- TCP/IP:**
  - LIS Server Address:** 127.0.0.1
  - LIS Server Port:** 8080

An "Apply" button is located at the bottom right.





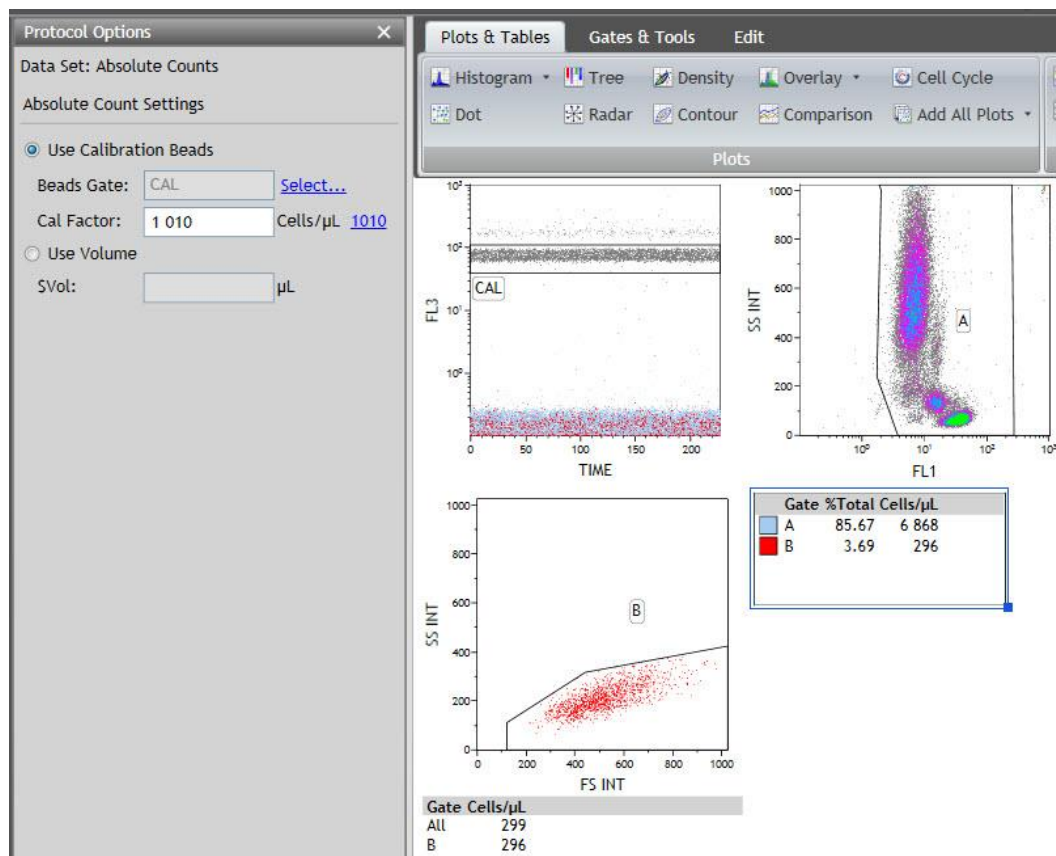
# Solutions for Compensation



- Use “**Add All Plots**” and logicle scaling to quickly evaluate the compensation of a multi color staining.
- Use **Compensation Sliders** to adjust.
- Export full compensation matrix as Kaluza Comp, text file or .PRO for use in Navios software
- Compensation composite with **automatic spillover calculation** is also available.



# Integrated Absolute Count Calculation



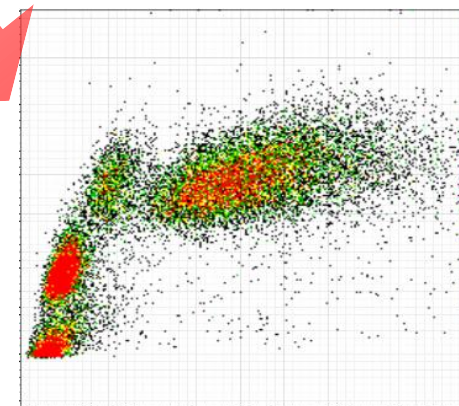
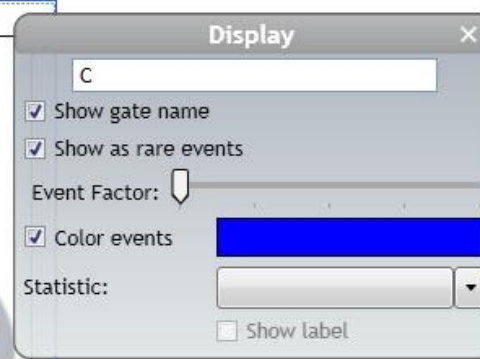
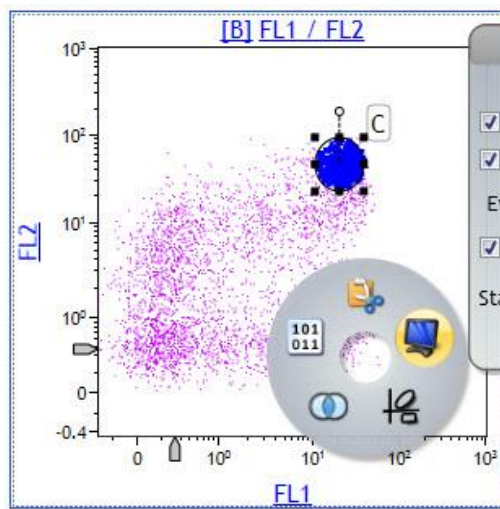
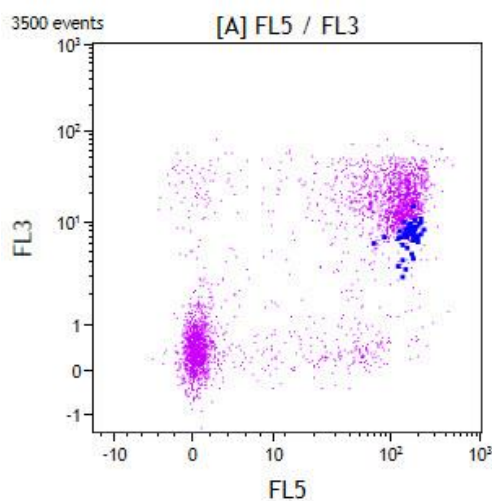
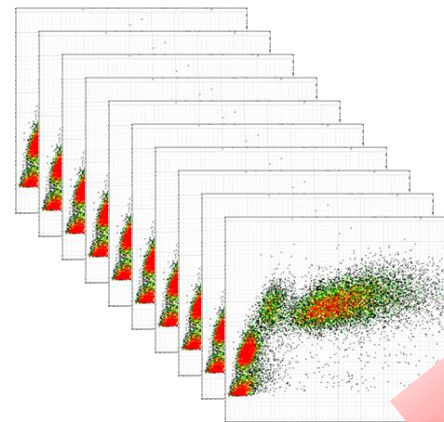
- Absolute cell counts can be calculated using Calibration Beads or Volume
- For Calibration Beads the CAL factor can be imported from the fcs Keyword or entered manually



# Designs for Rare Events Analysis

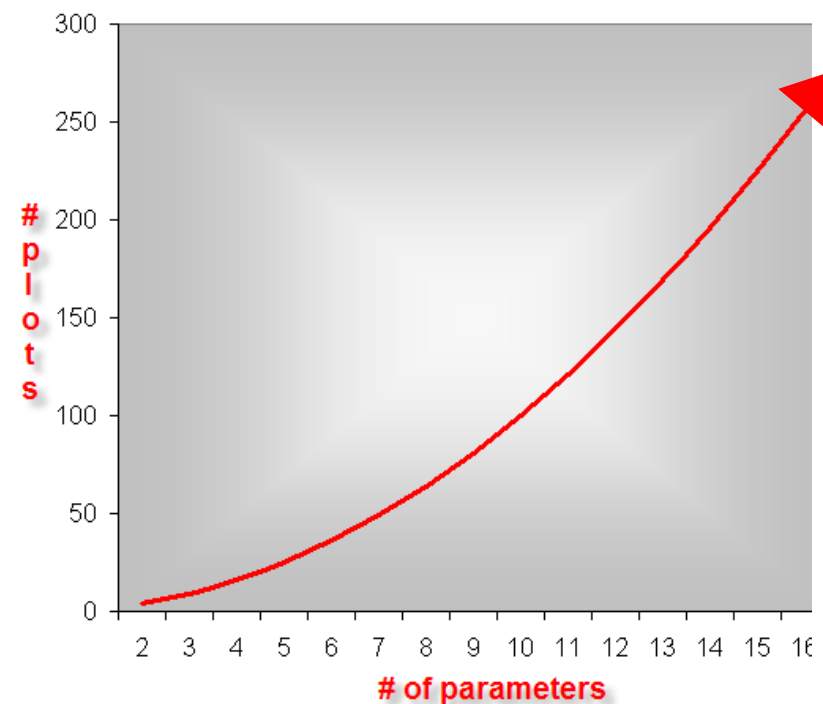
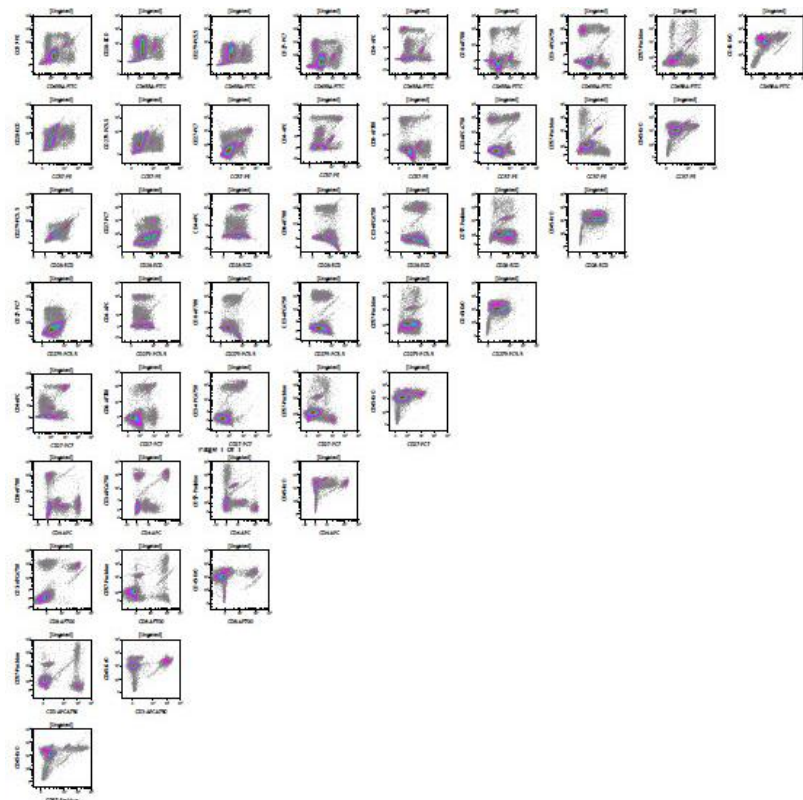


- Kaluza C makes visualization of **RARE EVENTS** easier by providing
  - Merging data functionality
  - Rare events display
  - Define number of events displayed





# Challenges in Multiparameter Data Display



Bivariate plotting becomes inadequate when exploring data in more than 4 or 5 dimensions

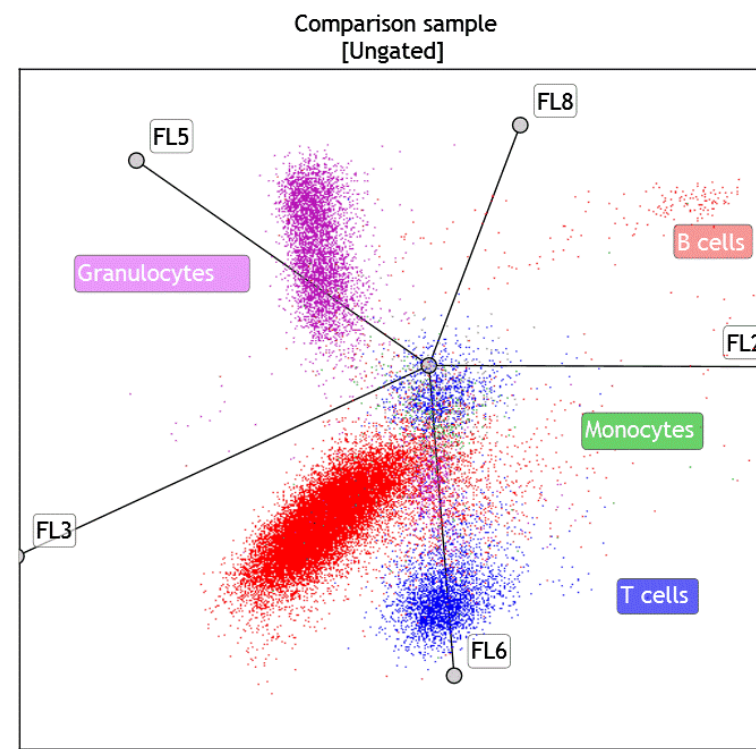




## Radar Plots



- The Radar plot maps multi-dimensional data onto a two-dimensional surface
- Events are displayed by adding axes
- When these axes are moved, relationships become apparent; axes can be moved manually
- You may choose to animate one of the axes, which prompts automatic movement in the defined direction and rate of speed.



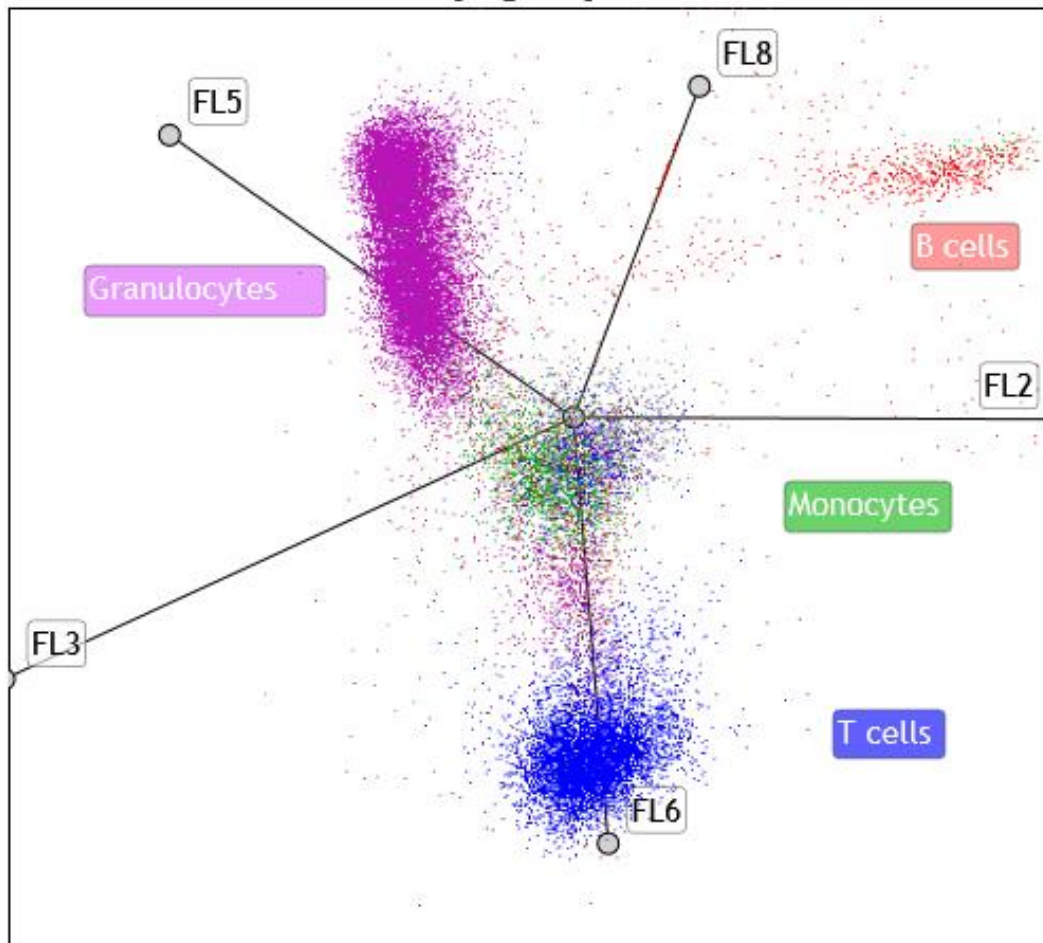
FLOW-4094CP09.18



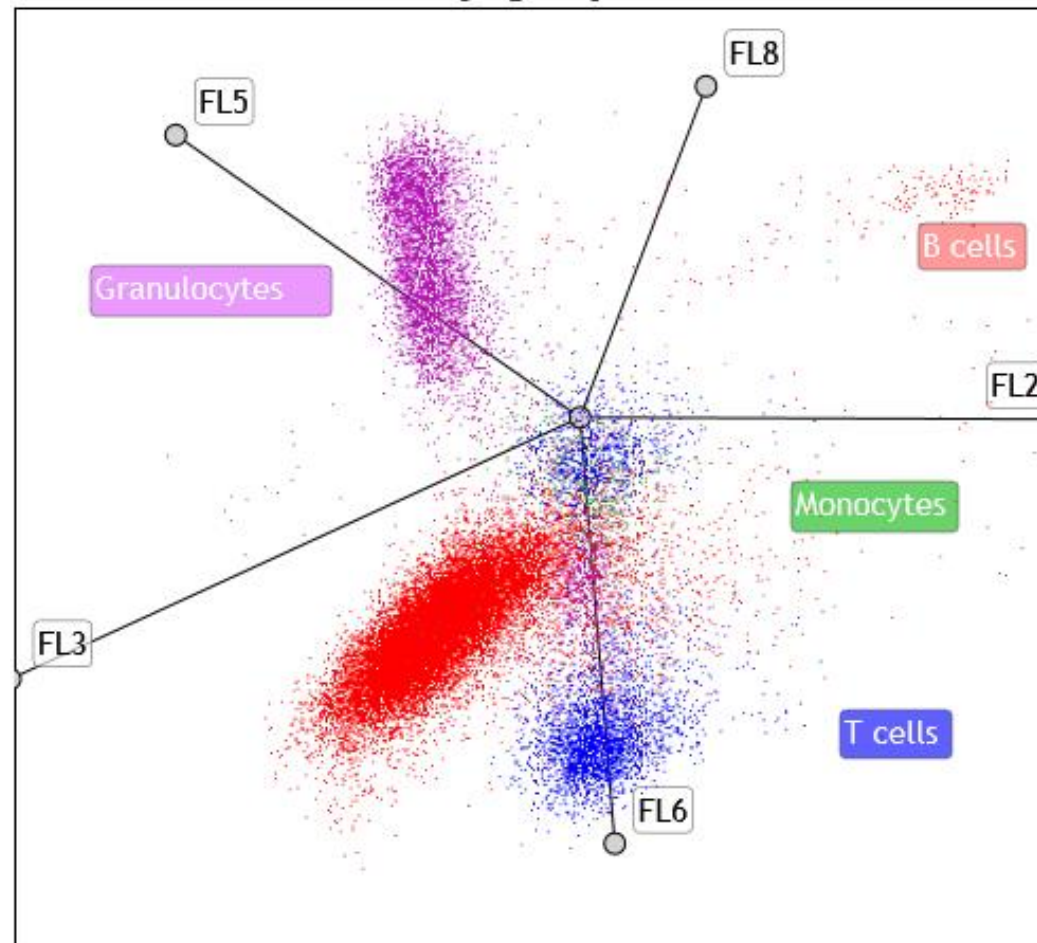
# Radar Plots Can Reveal Patterns in Multidimensional Space



Reference sample  
[Ungated]



Comparison sample  
[Ungated]

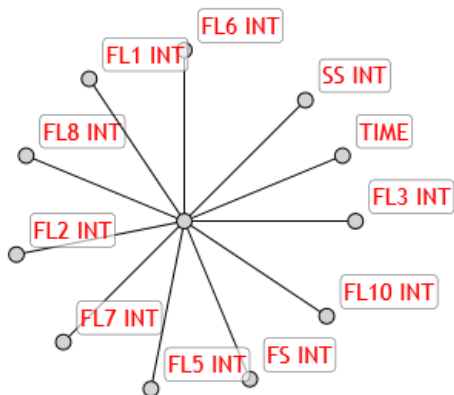




# Radar Plot Setup

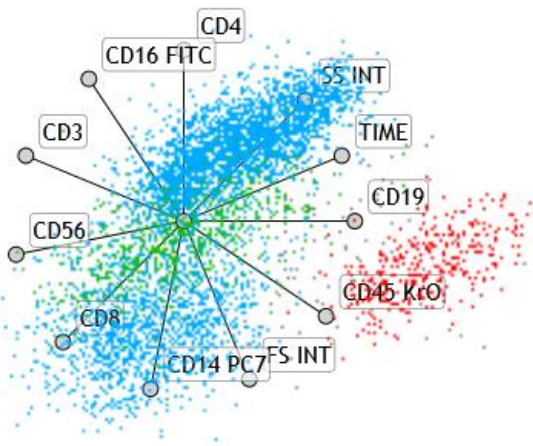


[Ungated]



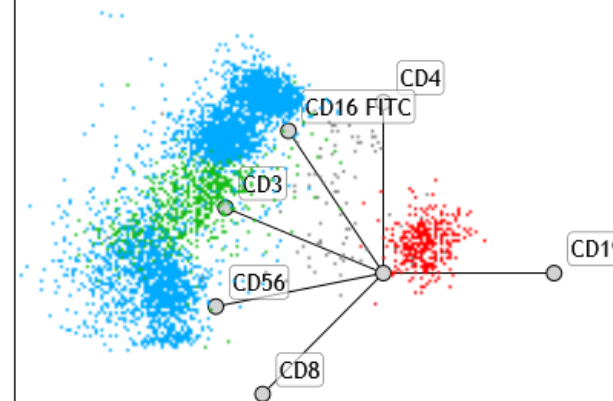
1) By default the axes will be evenly spread

[Lymph not Mono]



2) Define population you want to display

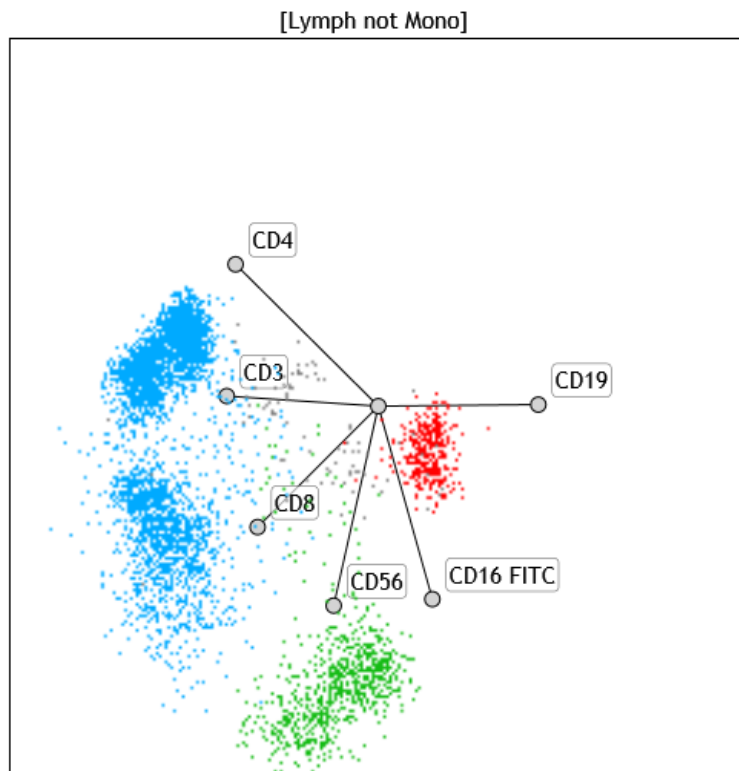
[Lymph not Mono]



3) Select Parameters to be displayed



# Radar Plot Optimization

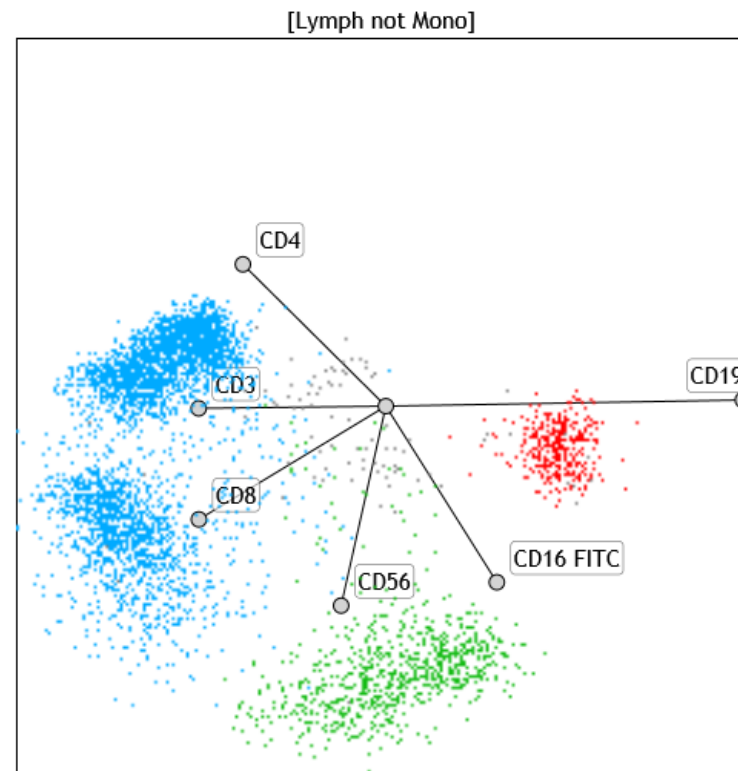


Options you can try to improve resolution of populations:

Position co-expressed markers close to each other

Juxtapose mutually exclusive markers

Adjust axis length to draw out populations







# Tree Plots

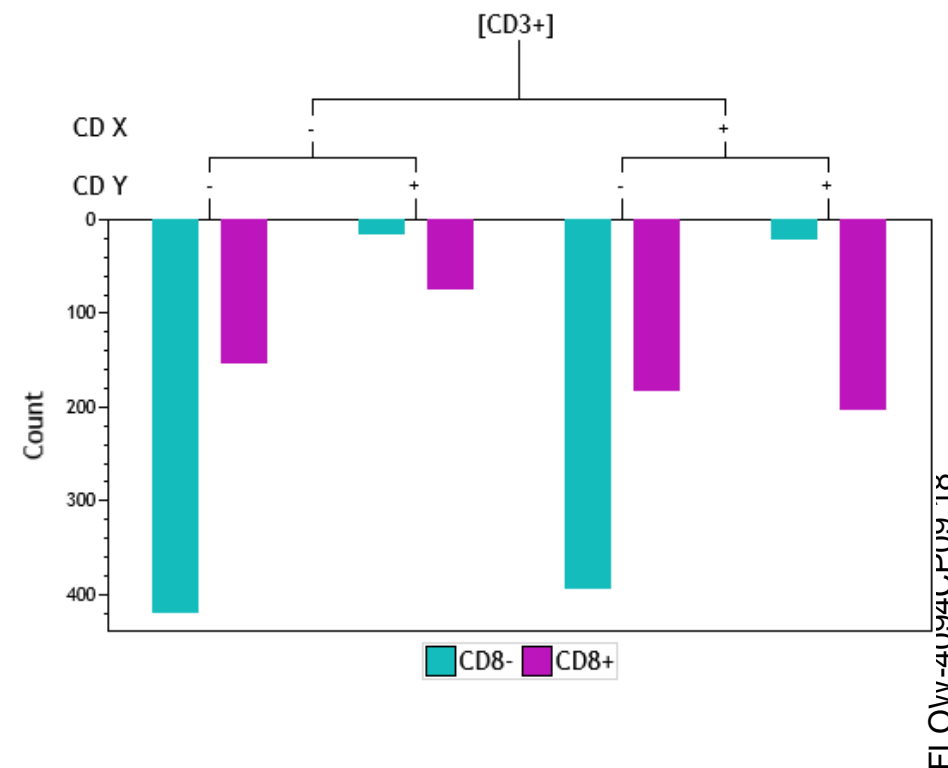


- Comprehensive data comparison tool:
- One Tree Plot can condense data from up to 28 bivariate plots

A Tree Plot includes:

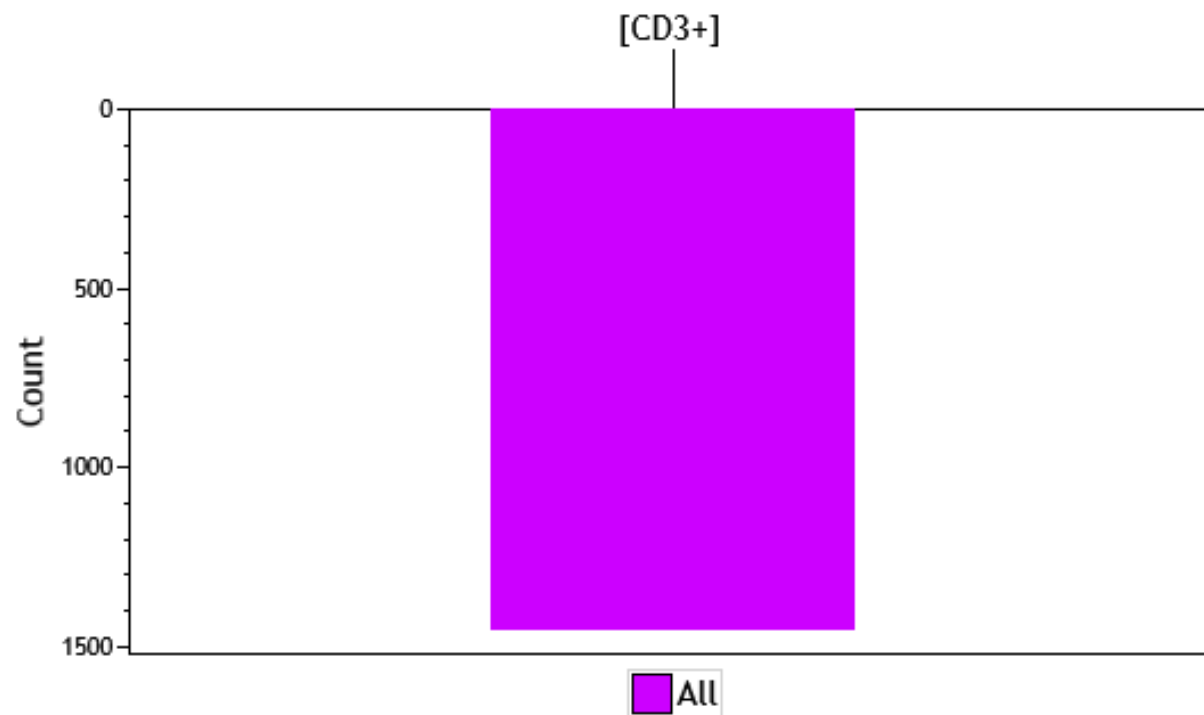
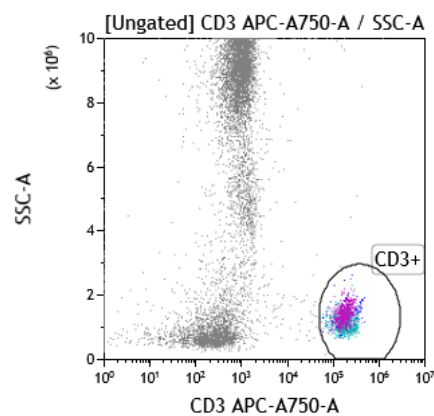
- **Branches**, which are used to categorize cell populations based on whether they have a negative or positive result for a specified phenotypic data type.  
Branches are located at the top of the plot.
- **Bars**, which are the event populations used to characterize every possible negative/positive branch combination. Bars can be viewed as either Count or % Gated.

**Bars are the central focus of the Tree Plot, as they are the pictorial representation of this phenotypic classification system.**



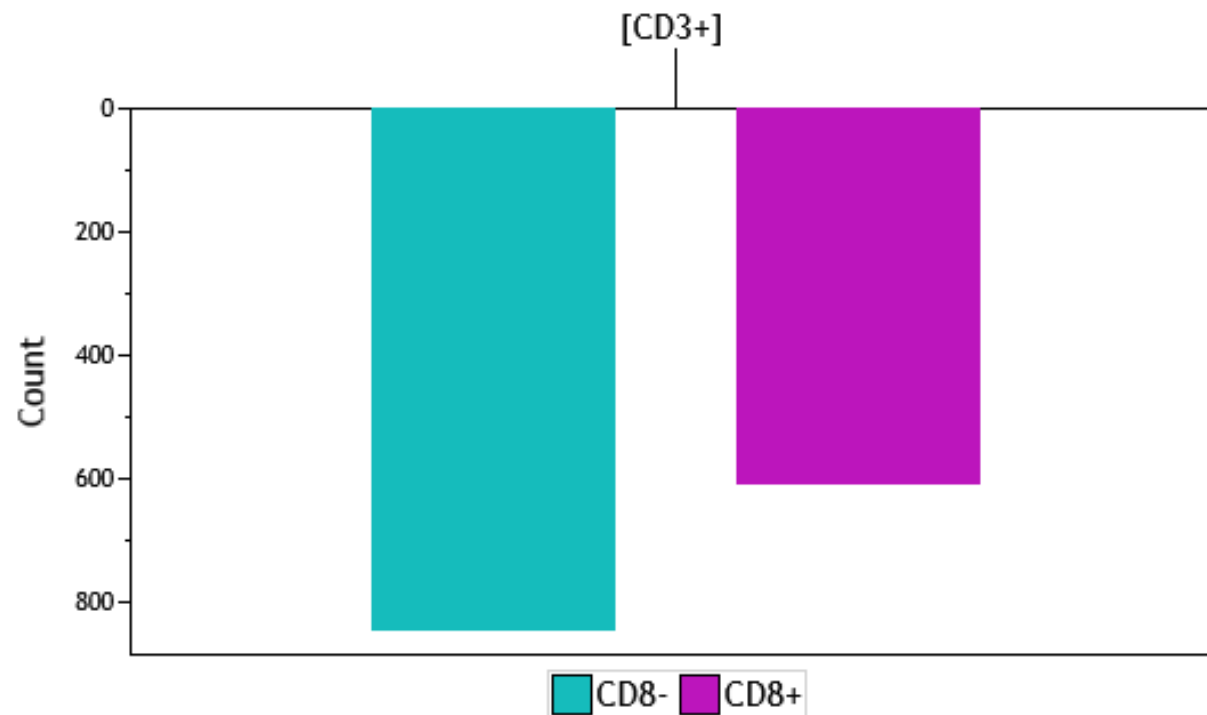
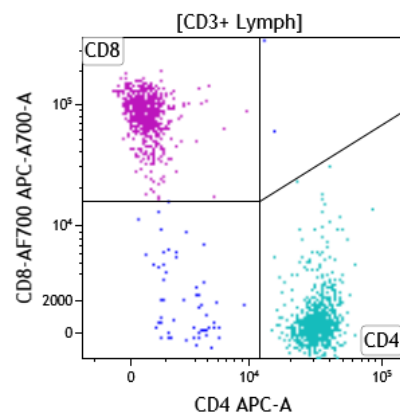
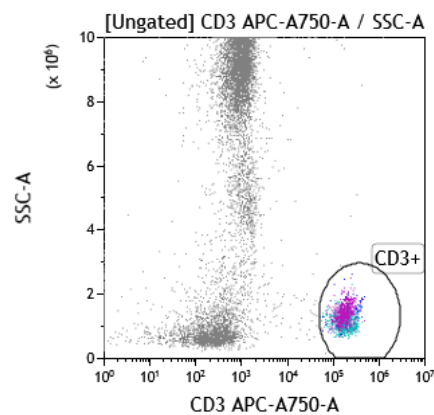


# Tree Plot Setup: Definition of Input Gate



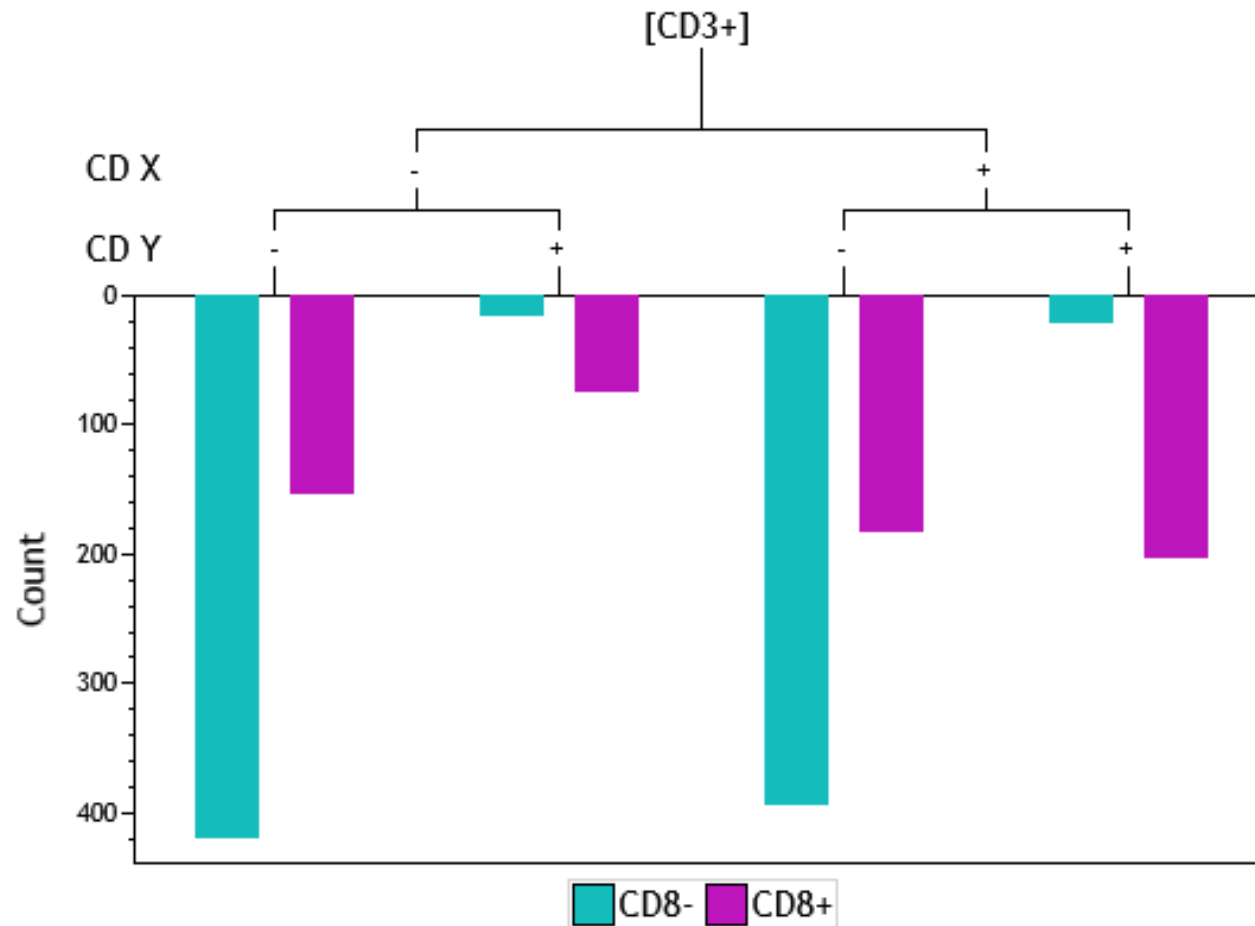
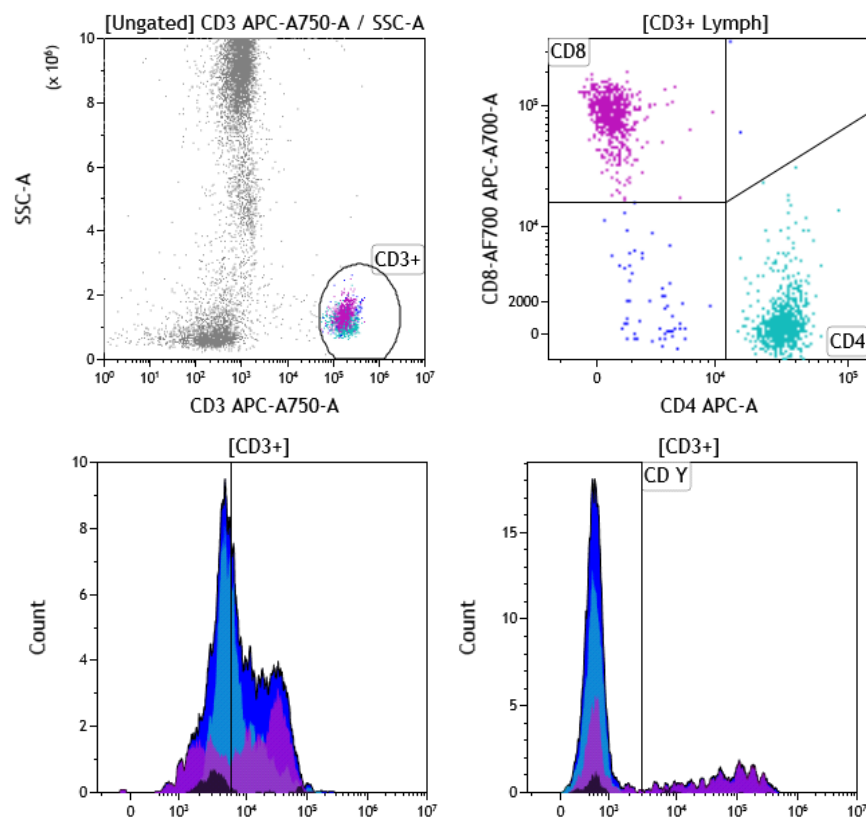


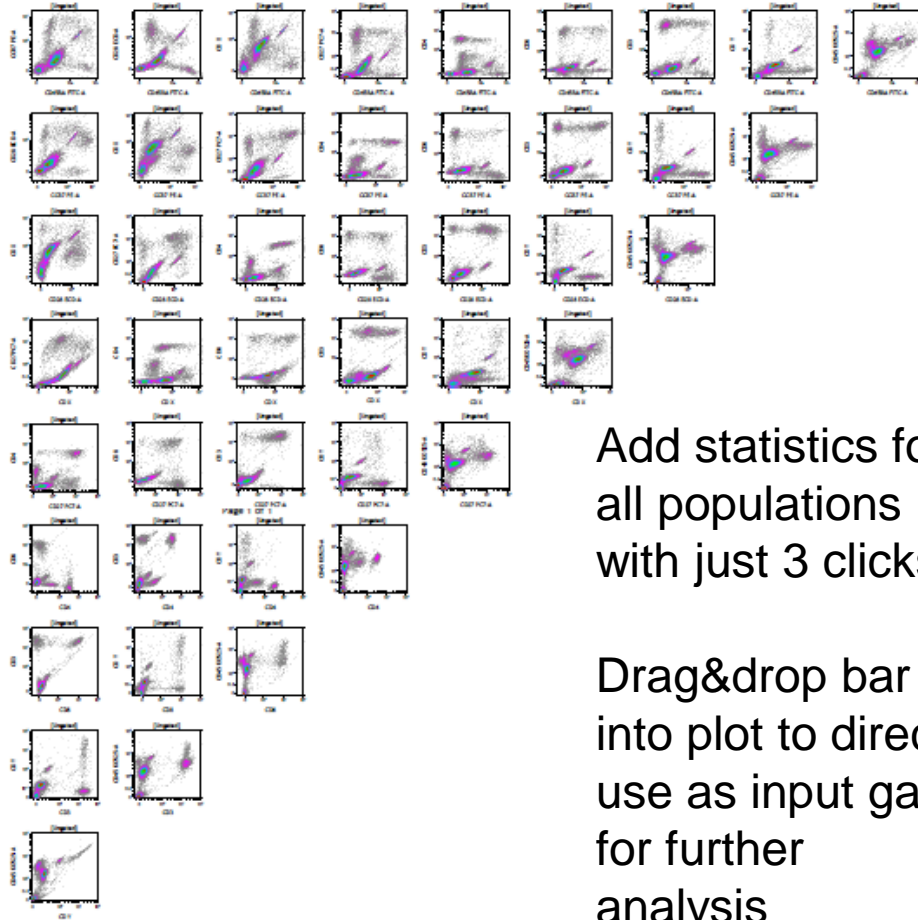
# Tree Plot Setup: Define Bars



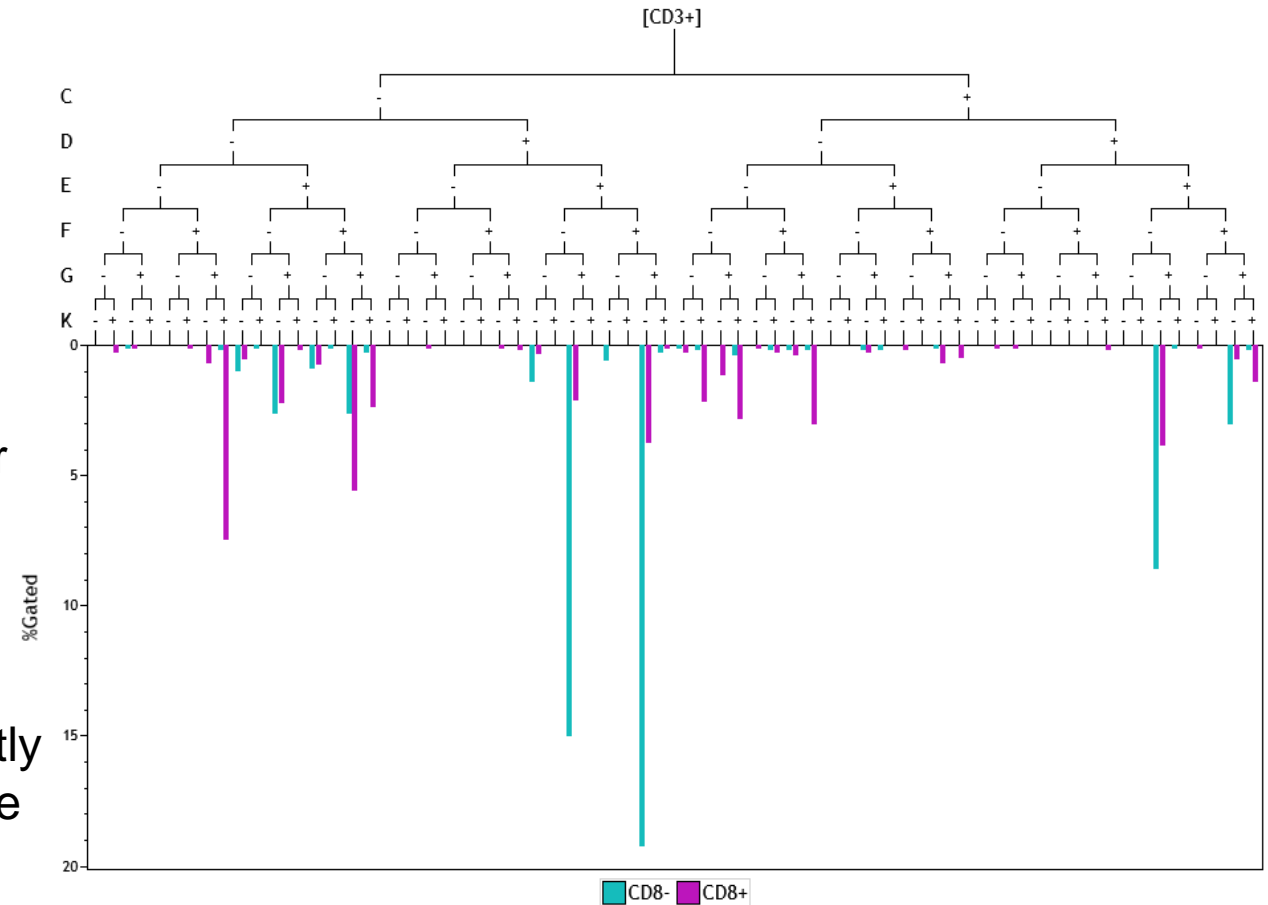


# Tree Plot Setup: Define Branches





Drag&drop bar  
into plot to directly  
use as input gate  
for further  
analysis





## Kaluza C



- Provides a **compliant** software environment for clinical analysis
- Designed to offer **simplicity & speed**
- Tools to support **clinical labs**:
  - LIS connectivity
  - QC module
  - compare reports
  - electronic sign off
- Tools for analysis of **high complexity** data:
  - Advanced plot types (eg. Radar)
  - Rare event display
  - Editable information table
  - IF conditionals

