



DV09

Data visualization in a risk based approach to support decision making

Joke De Wever

 Business & Decision
Life Sciences



4th-7th November
KAP Europa
Frankfurt, Germany

EU 2018

The Clinical Data
Science Conference



Agenda



Introduction



Queries dashboard



Development



Conclusion



Introduction



and



recommend a Risk Based Approach for Monitoring clinical trials

Using a dashboard on data queries

efficiency of data management and monitoring

Introduction



EDC



DB

Introduction

queries

Visits / screens

*Country
Site*



Type of query

Resolution time

Introduction

■ *Data visualization:*

- Identification of trends and outliers
- Provides facts and figures that support decision making

■ *Dashboard on data queries (Tableau®):*

- Improves the efficiency in data management and monitoring

■ *This presentation:*

- Development of queries dashboard
- Interpretation & potential benefits

Agenda



Introduction



Queries dashboard



Development



Conclusion



Quick Filters

Study

(All)

Country

(All)

Site

(All)



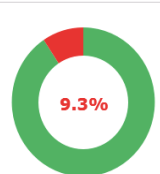
Open Queries

612

Total # of Queries

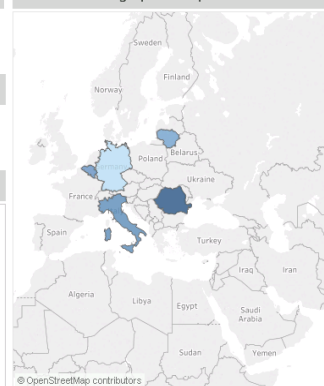
6,554

% of Queries by Status



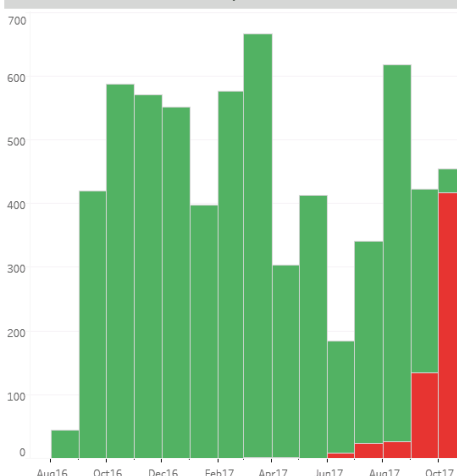
Query Status
CLOSED
OPEN

Geographical Repartition

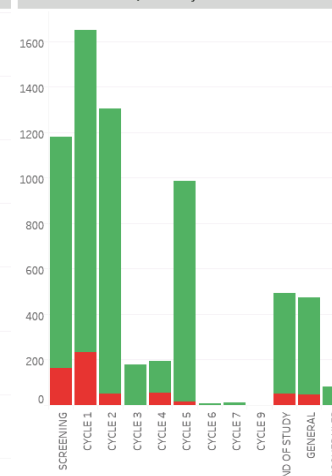


Number of Queries
330 2,283

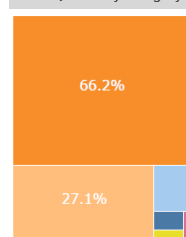
Number of Queries over time



Queries by Visits

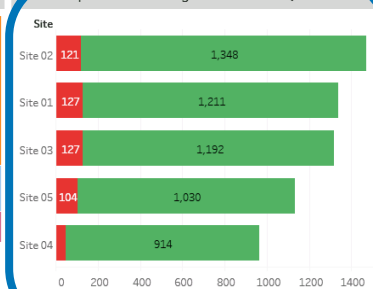


% of Queries by Category

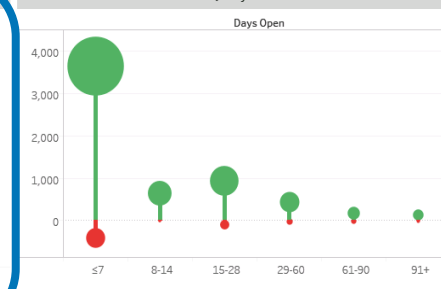


Query Category
CODING
MEDICAL REVIEW
MISSING DATA
OTHER
PROTOCOL DEVIATION
SAE RECONCILIATION

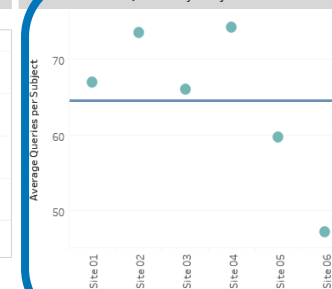
Top 5 Sites with Highest Total # of Queries



Time for Query Resolution

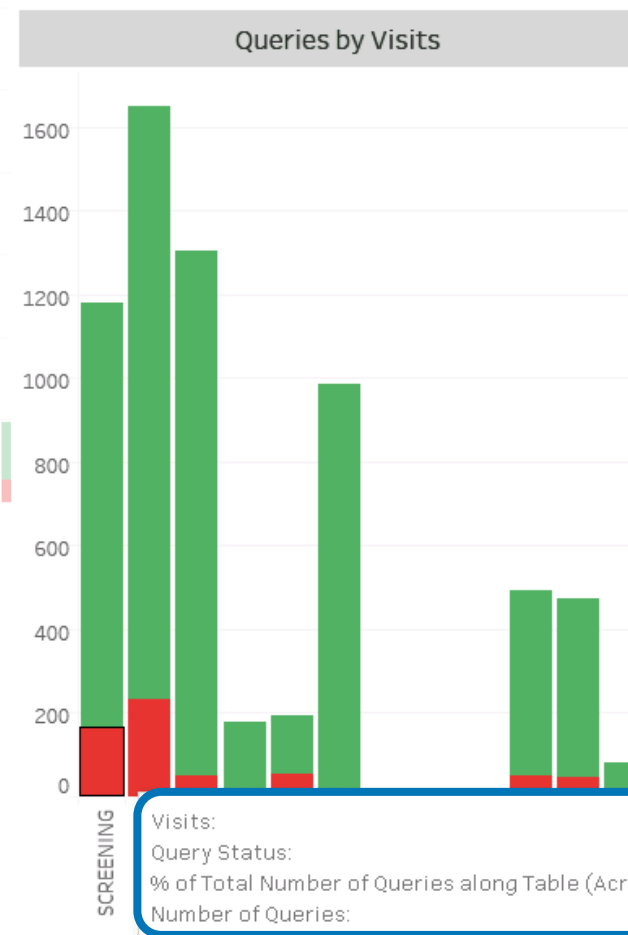
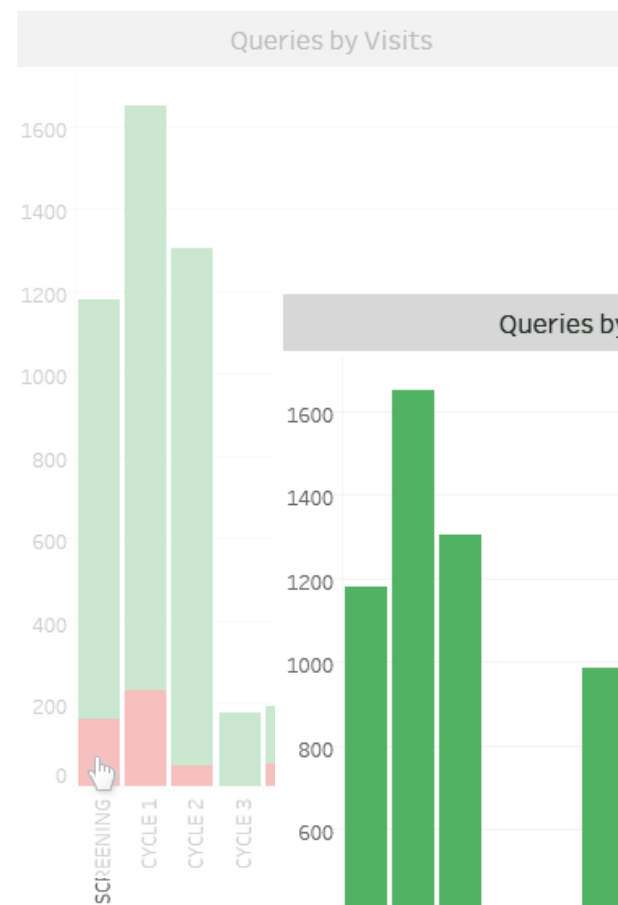
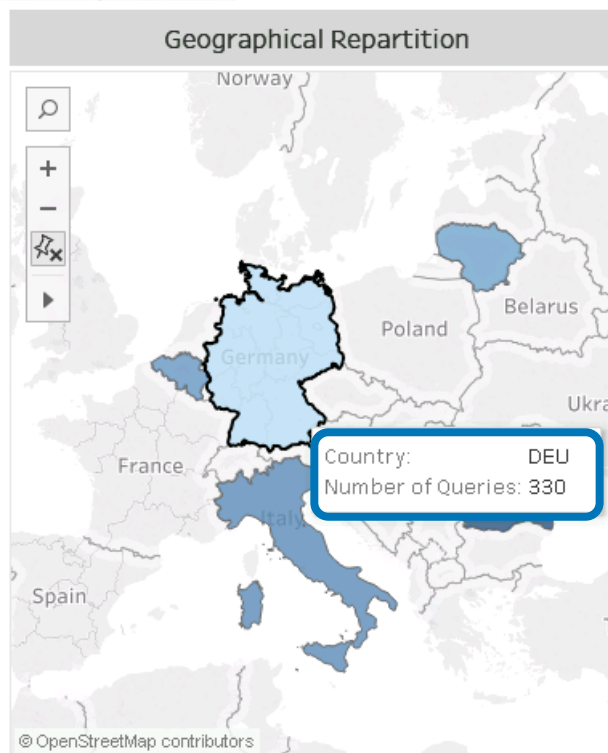
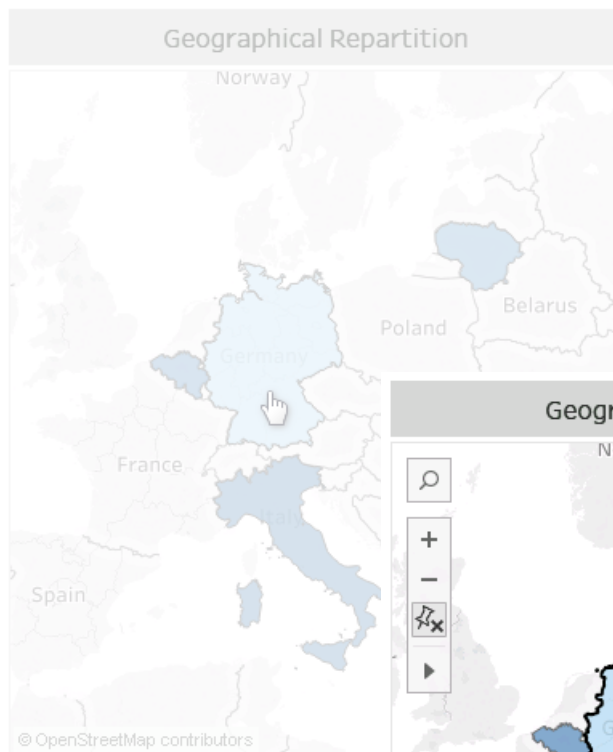


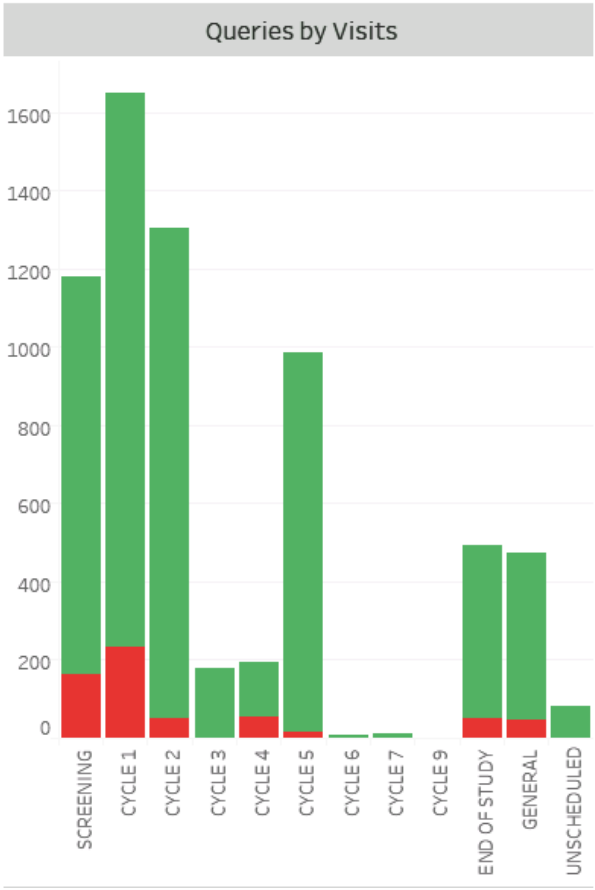
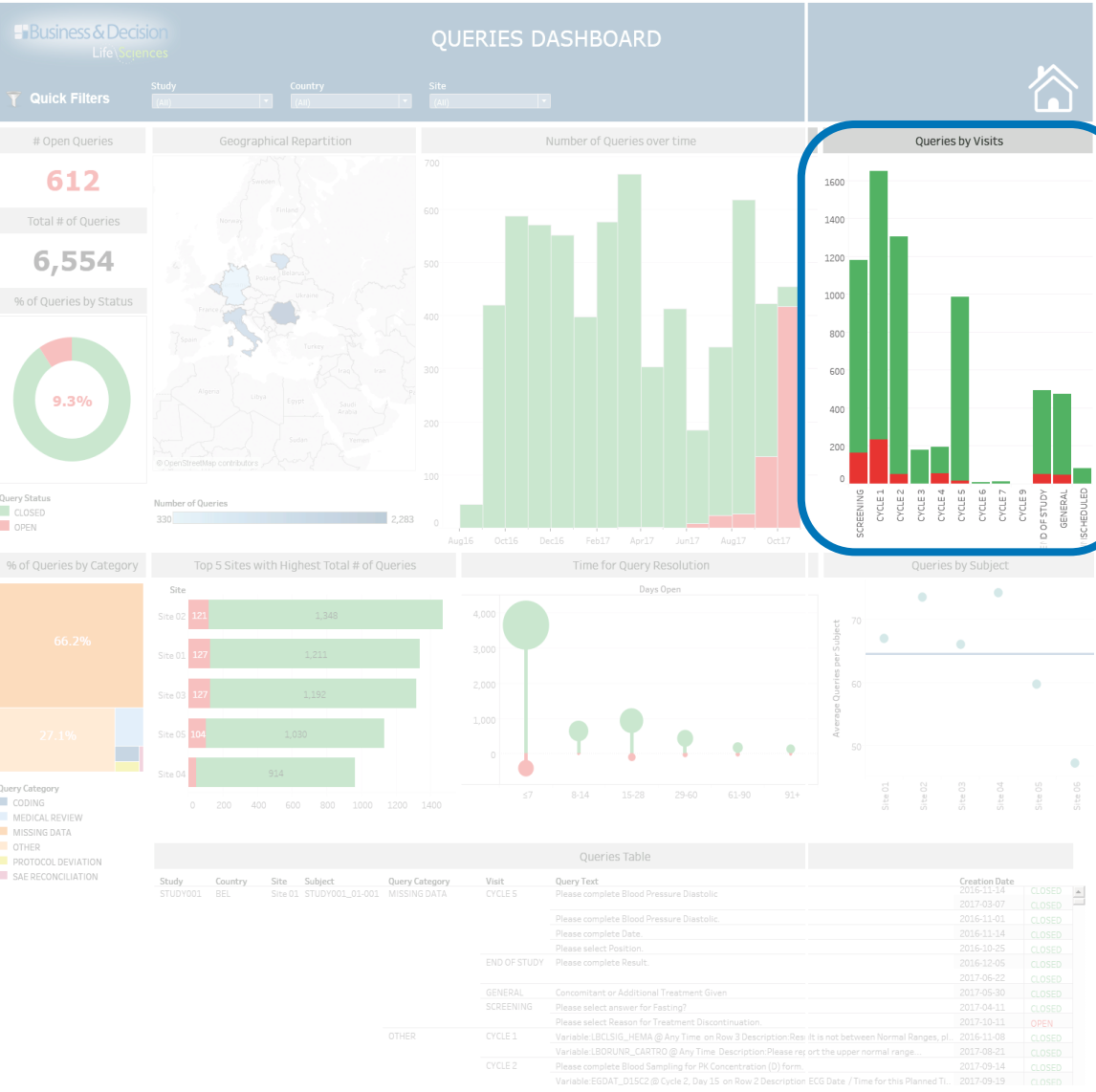
Queries by Subject

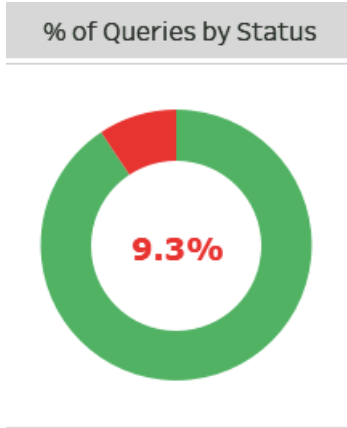


Queries Table

Study	Country	Site	Subject	Query Category	Visit	Query Text	Creation Date	Status
STUDY001	BEL	Site 01	STUDY001_01-001	MISSING DATA	CYCLE 5	Please complete Blood Pressure Diastolic.	2016-11-14	CLOSED
						Please complete Blood Pressure Diastolic.	2017-03-07	CLOSED
						Please complete Date.	2016-11-01	CLOSED
						Please select Position.	2016-11-14	CLOSED
						Please complete Result.	2016-10-25	CLOSED
				END OF STUDY			2016-12-05	CLOSED
							2017-06-22	CLOSED
				GENERAL		Concomitant or Additional Treatment Given	2017-05-30	CLOSED
				SCREENING		Please select answer for Fasting?	2017-04-11	CLOSED
						Please select Reason for Treatment Discontinuation.	2017-10-11	OPEN
				OTHER	CYCLE 1	Variable:LBCLSIG_HEMA @ Any Time on Row 3 Description:Result is not between Normal Ranges, pl...	2016-11-08	CLOSED
						Variable:LBORUNR_CARTRO @ Any Time Description:Please report the upper normal range...	2017-08-21	CLOSED
					CYCLE 2	Please complete Blood Sampling for PK Concentration (D) form.	2017-09-14	CLOSED
						Variable:EGDAT_D1SC2 @ Cycle 2, Day 15 on Row 2 Description:ECG Date / Time for this Planned Tr...	2017-09-19	CLOSED

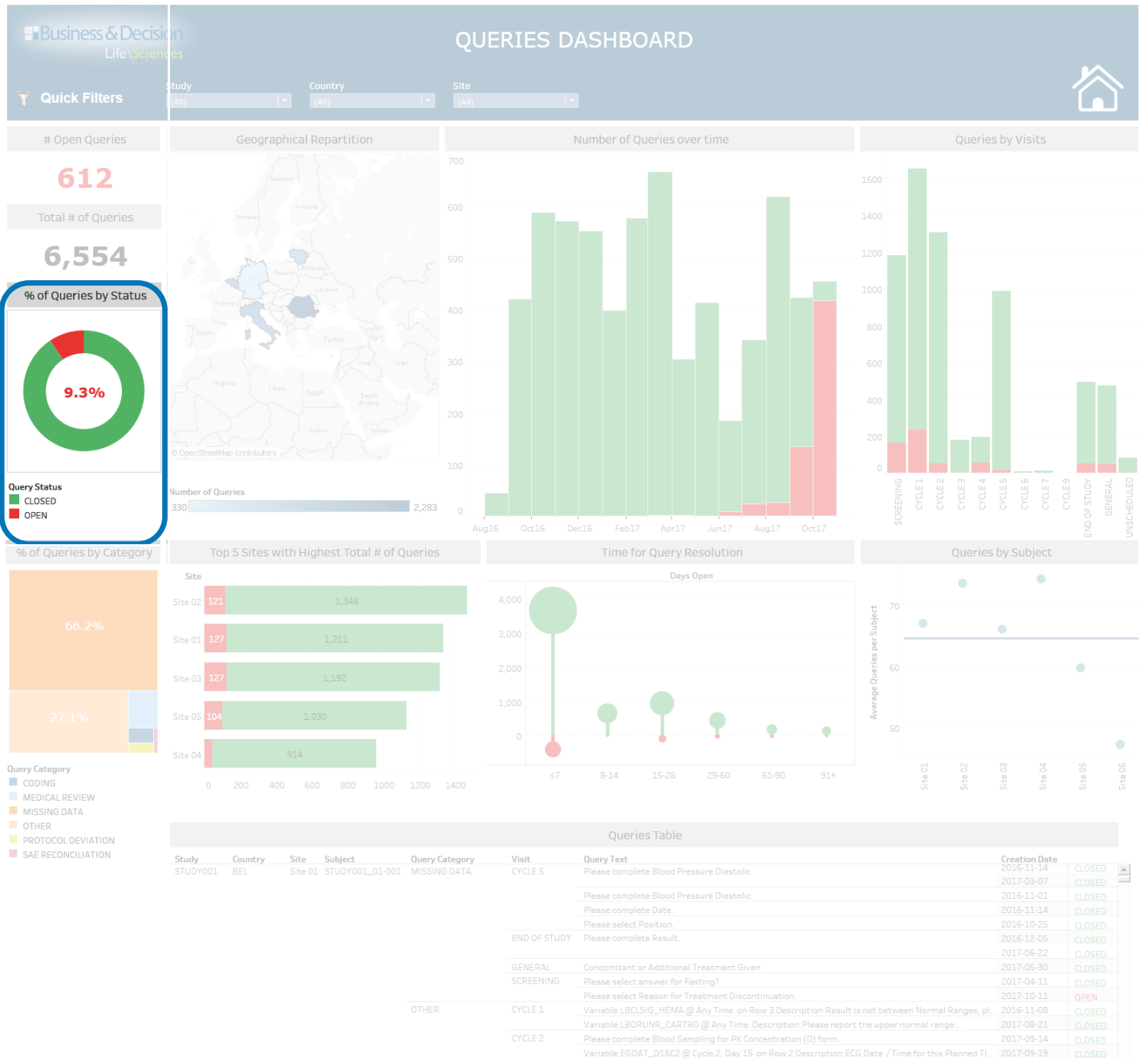


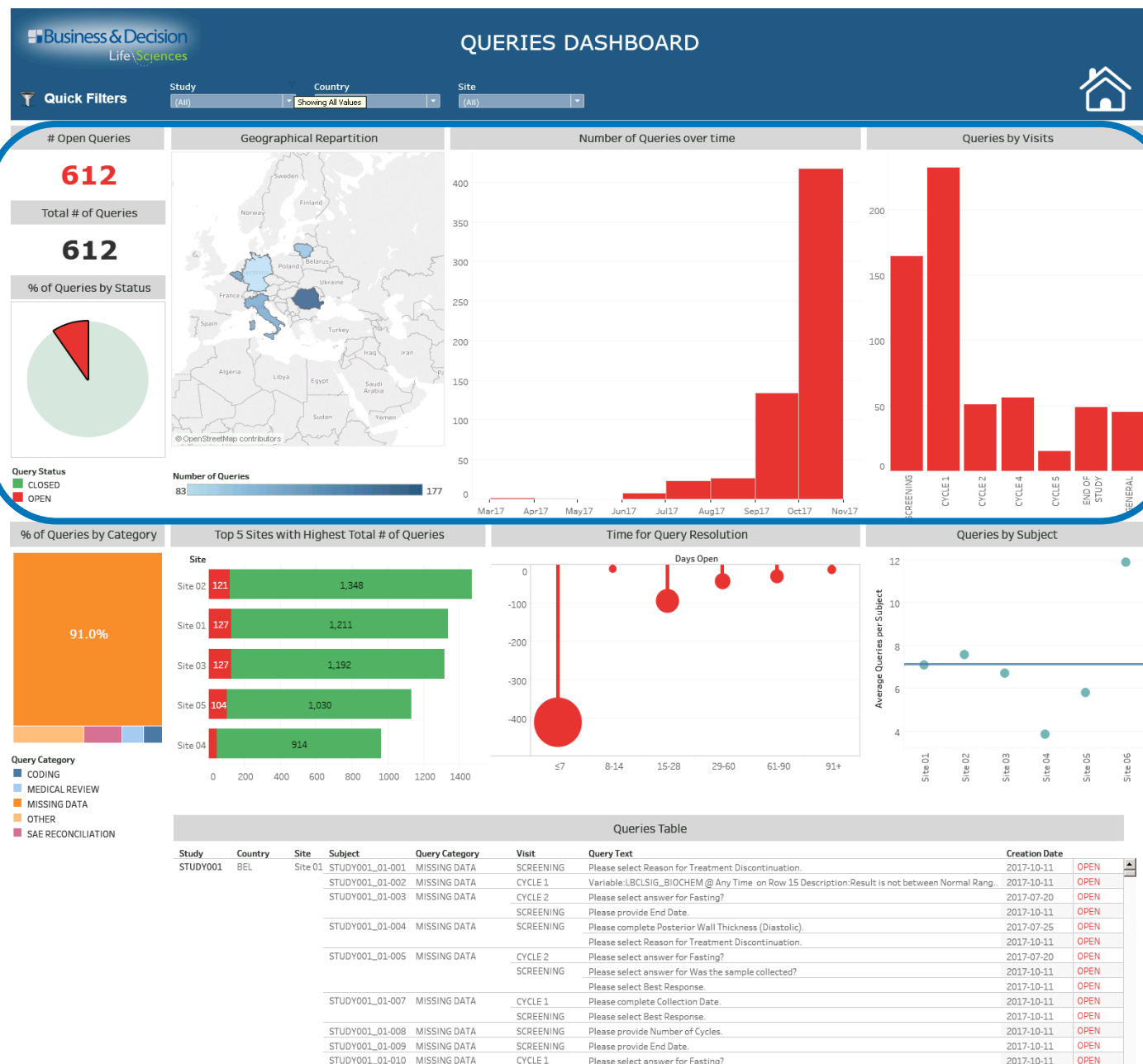


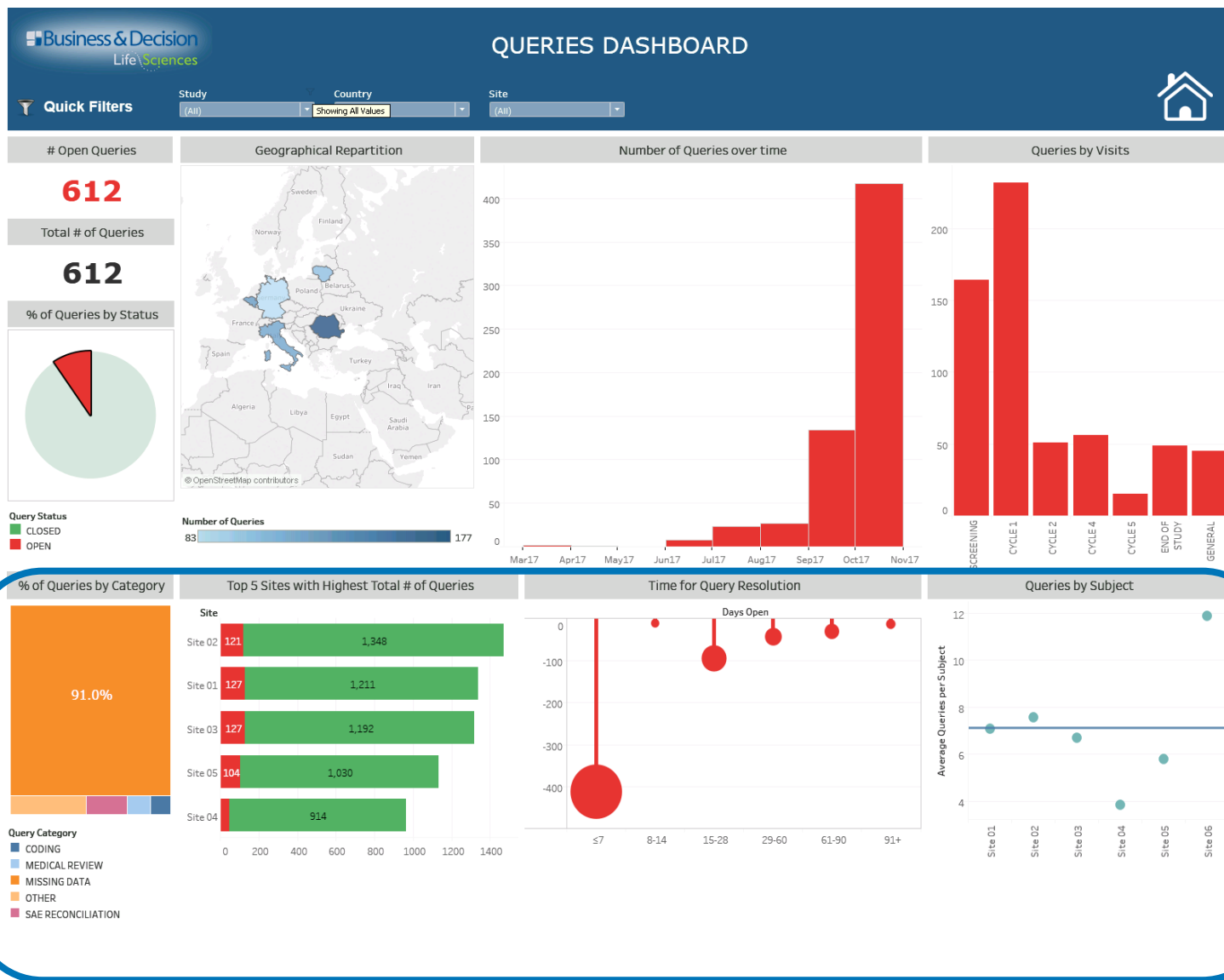


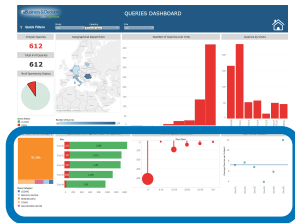
Query Status

- CLOSED
- OPEN

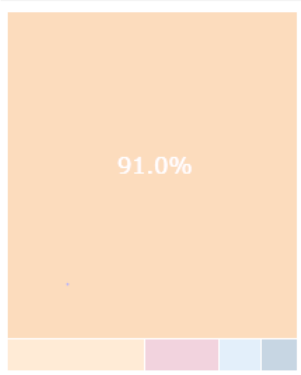






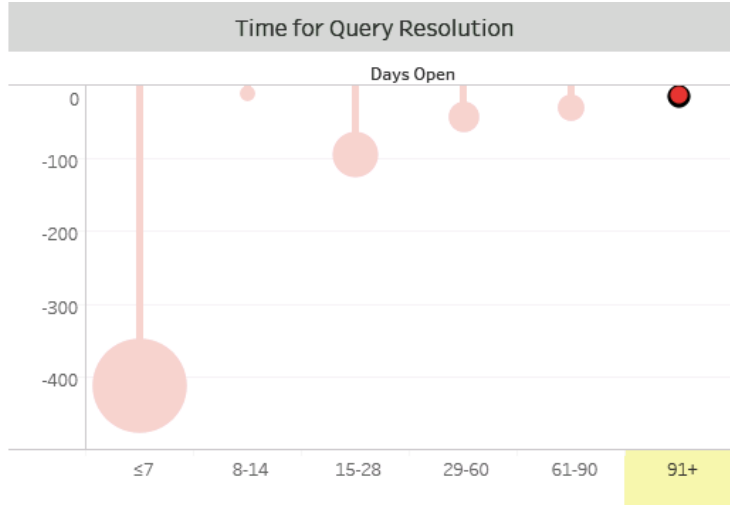
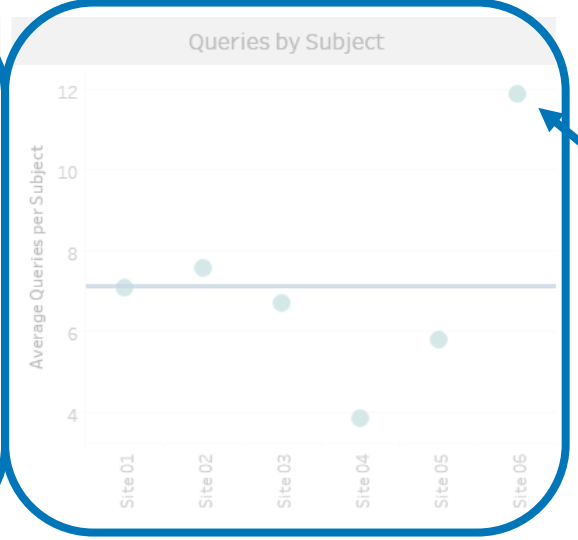
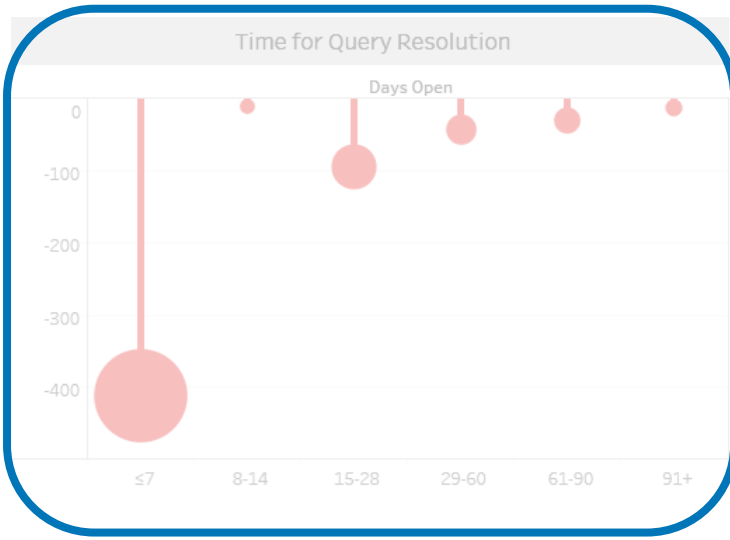
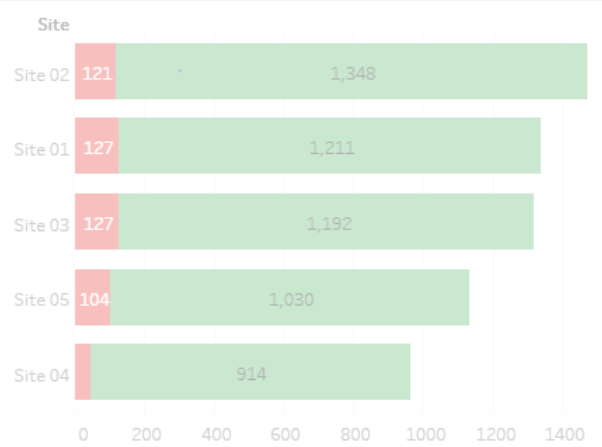


% of Queries by Category



- Query Category
- CODING
 - MEDICAL REVIEW
 - MISSING DATA
 - OTHER
 - SAE RECONCILIATION

Top 5 Sites with Highest Total # of Queries





Quick Filters

Study

(All)

Country

(All)

Site

(All)

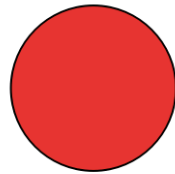
Open Queries

14

Total # of Queries

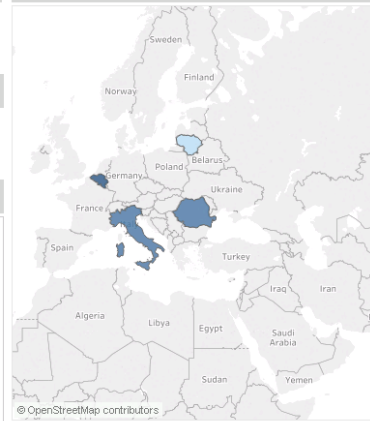
14

% of Queries by Status



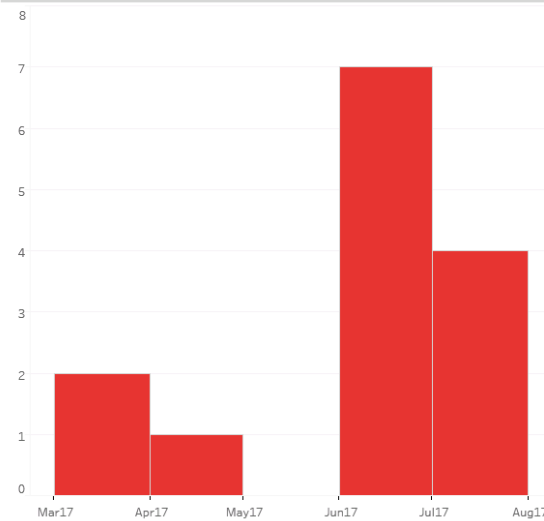
Query Status
OPEN

Geographical Repartition

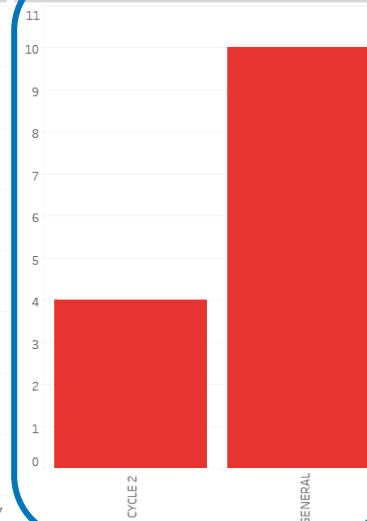


Number of Queries
1 5

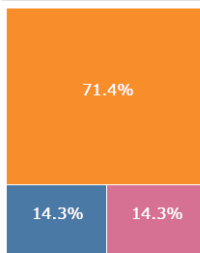
Number of Queries over time



Queries by Visits

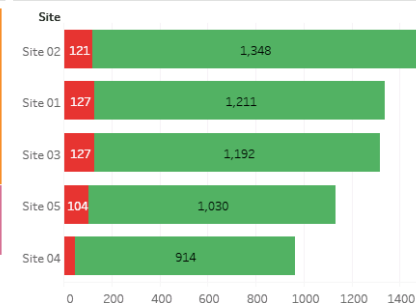


% of Queries by Category

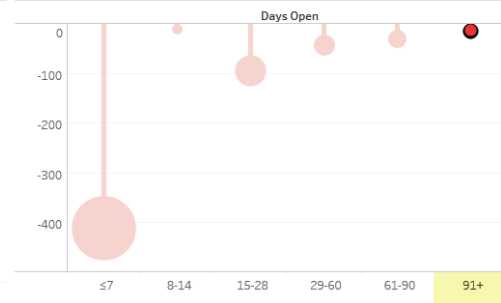


Query Category
CODING
MISSING DATA
SAE RECONCILIATION

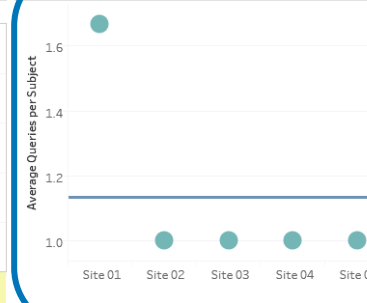
Top 5 Sites with Highest Total # of Queries



Time for Query Resolution



Queries by Subject



Queries Table

Study	Country	Site	Subject	Query Category	Visit	Query Text	Creation Date	Status
STUDY001	BEL	Site 01	STUDY001_01-010	MISSING DATA	GENERAL	Please select answer for Relationship to Study Treatment.	2017-06-07	OPEN
						Variable:CMDOSU_MED @ General on Row 8 Description:Please provide the Dose unit...	2017-06-16	OPEN
			STUDY001_01-017	MISSING DATA	CYCLE 2	Please complete Amount 1mg.	2017-07-12	OPEN
						Please complete Amount 5mg.	2017-07-12	OPEN
						Variable:CMDOSFRQ_MED @ General on Row 8 Description:Please provide the Frequency...	2017-06-16	OPEN
	ITA	Site 02	STUDY001_02-005	SAE RECONCILIATION	GENERAL	There is a discrepancy in the term reported between Safety database ("Left lobe new pneumonia") a...	2017-03-14	OPEN
						Please complete Amount 1mg.	2017-07-12	OPEN
			STUDY001_02-010	SAE RECONCILIATION	GENERAL	There is a discrepancy in the severity reported between Safety database ("Moderate") and EDC ("Se...	2017-03-14	OPEN
						To allow proper coding, could you please precise the active ingredients (salmon oil, Docosahexaenoic...	2017-04-03	OPEN

Agenda



Introduction



Queries dashboard



Development



Conclusion



Dashboard specifications

■ *Consider all aspects:*

- End user requirements
- Data structure
- Features and limitations of visualization software

■ *Recommendation:*

formal User Requirement Specifications (URS)

Data

■ *Data from the EDC query audit trail:*

Date of creation/closure

Query Status

Query Type

...

■ *Recommendation:*

keep all source variables → allows dashboard enrichment

Structure

■ ≠ EDC systems → ≠ query related variables

ID	Site	Patient	Visit	iCRF	Question	Type	QueryNote	Date Opened	Originator	Last Modified	Last Response	Assigned Users	Assigned Roles	Hidden	Current Status	Priority	Read Only
QUERY ID	QUERY NAME	SITE	SUBJECT ID	Visit	FORM	VARIABLE	ROW NUMBER	FIELD STATUS	STATUS	DATE CREATED	MESSAGE	DATE CLOSED	REASON FOR CLOSING	RESPONSES	DESIGNATION	QUERY TYPE	DAY OPEN

■ **Best practice: create a standard structure**

Sponsor-specific

SDTM-like

DOMAIN PREFIX	VARIABLE NAME	Label	FORMAT	DOMAIN PREFIX	VARIABLE NAME	CODING T	Additional programming comments
XQ	USUBJID	Unique Subject Identifier		QL			source field is blank; therefore populate with concatenation of XQ.STUDYID and QL.SUBJECT_ID e.g. study "STUDY001" and patient "1" becomes "STUDY001-000001"
XQ	XQGRPID	Group ID		QL	QUERY_NAME		
XQ	XQREFID	Reference ID		QL	QUERY_ID		
XQ	XQCAT	Category		QL	DESIGNATION		
XQ	XQOUT	Outcome		QL			SCAN(STATUS;";")
XQ	XQSTDT	Start Date/Time of Observation	ISO 8601	QL	DATE_CREATED		
XQ	XQENDT	End Date/Time of Observation	ISO 8601	QL			INTC(X'DAY', DATE_CREATED, DAY_OPEN)
XQ	XQDUR	Duration	ISO 8601	QL	DAY_OPEN		

■ **New system → map query related variables to standard structure**

Maintenance & data governance

■ *Define:*

- Roles & Responsibilities
- Change control

■ *Best approach: Dashboard library*

- Basis for more specific dashboard
- Amend mapping
- Customize lay-out

Agenda



Introduction



Queries dashboard



Development



Conclusion



Conclusion

■ *A queries dashboard:*

- Improves study & site management

■ *Recommendations:*

- Formal URS
- Standard data structure



ROI²
return on investment
through
return on information



Joke DE WEVER

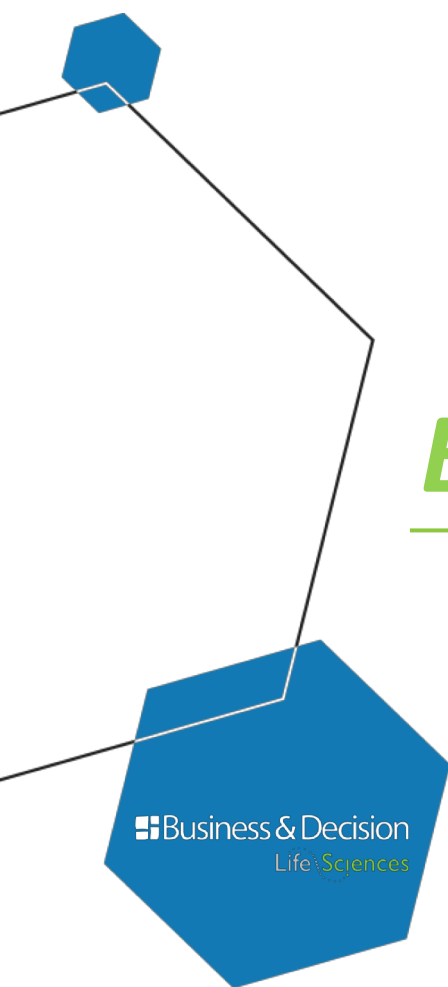
CRO Manager

joke.dewever@businessdecision.be

+32 2 774 11 00

References

- **INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE (R2) – Dated 9 November 2016 -**
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4_2016_1109.pdf
- **FDA Guidance for Industry - Oversight of Clinical Investigations – A Risk Based Approach to Monitoring -**
<https://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf>



Back-up slides

Why Tableau®?

- *Data Visualization is done by Life Science experts and technical experts*
- *Gartner Magic Quadrant for Business Intelligence and Analytics Platforms:*
 - leader for the 5th consecutive year
 - positioned as highest in ability to execute

Figure 1. Magic Quadrant for Analytics and Business Intelligence Platforms



Source: Gartner (February 2018)

Mapping



DOMAIN PREFIX	VARIABLE NAME	Label	FORMAT	DOMAIN PREFIX	VARIABLE NAME	CODELIST	Additional programming comments
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XQ	XQGRPID	Group ID		QL	QUERY_NAME		
XQ	XQREFID	Reference ID		QL	QUERY_ID		
XQ	XQCAT	Category		QL	DESIGNATION		
XQ	XQOUT	Outcome		QL			SCAN(STATUS;',1)
XQ	XQSTDTC	Start Date/Time of Observation	ISO 8601	QL	DATE_CREATED		
XQ	XQENDTC	End Date/Time of Observation	ISO 8601	QL			INTCX(DAY, DATE_CREATED, DAY_OPEN)
XQ	XQDUR	Duration	ISO 8601	QL	DAY_OPEN		

Quick Filters

Study

(All)

Country

(All)

Site

(All)



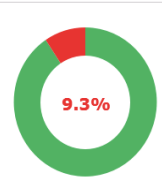
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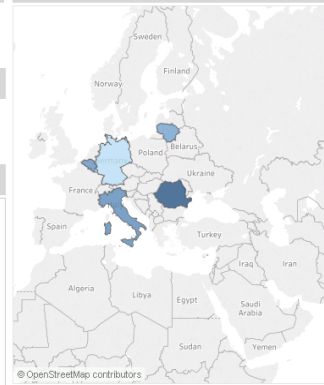
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% of Queries by Status



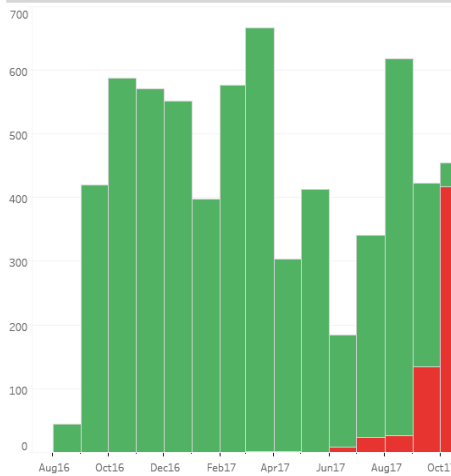
Query Status
CLOSED
OPEN

Geographical Repartition

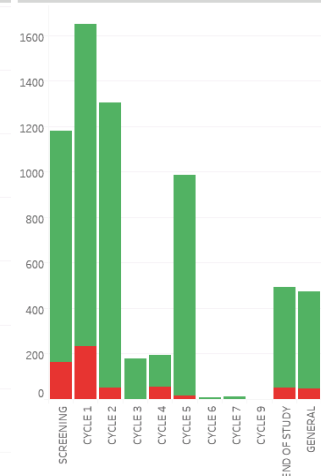


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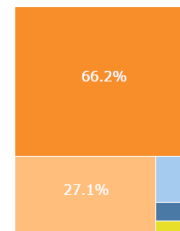
Number of Queries over time



Queries by Visits

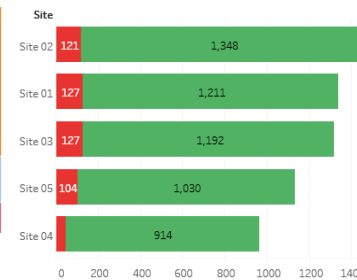


% of Queries by Category

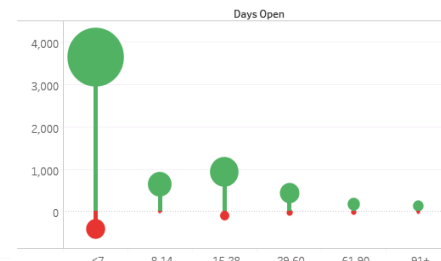


Query Category
CODING
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SAE RECONCILIATION

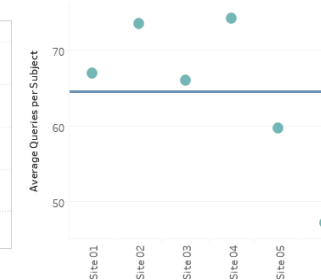
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						Please complete Blood Pressure Diastolic.	2017-03-07	CLOSED
						Please complete Date.	2016-11-01	CLOSED
						Please select Position.	2016-11-14	CLOSED
						Please complete Result.	2016-10-25	CLOSED
						END OF STUDY	2016-12-05	CLOSED
						GENERAL	2017-06-22	CLOSED
						SCREENING	2017-05-30	CLOSED
							2017-04-11	CLOSED
							2017-10-11	OPEN
						OTHER	2016-11-08	CLOSED
						CYCLE 1	2017-08-21	CLOSED
						CYCLE 2	2017-09-14	CLOSED
							2017-09-19	CLOSED