Paper DV07

Power BI in Clinical Data exploration, powerful visuals that answer relevant questions

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ABSTRACT

Nowadays, dynamic data visualization is vital for clinical study conduct and decision making. Power BI is a user-friendly business analytics service by Microsoft which provides interactive visualizations and business intelligence capabilities, offering unique integration options with Python, R and SQL. Although a leader in Business Intelligence (BI) and Analytics Platforms, its potential in clinical research is currently unexplored. To test it in this capacity and help our clinical and medical teams, we utilized it to design modern-looking, interactive dashboards, with the aim to improve the way we access, review and interact with data. As a result, we developed several tools that facilitate monitoring, analyzing and testing the study data in real time throughout the study, confirming that Power BI is perfectly suited to answer the needs of clinical and medical teams.

INTRODUCTION

Terumo Corporation was founded in 1921 in Japan. Since then Terumo developed more than 100 different medical devices in multiple fields. The objectives of the European Medical and Clinical Division (EMCD) are to organize, manage and conduct clinical trials by respecting all regulatory requirements and Good Clinical Practice, to communicate clinical data to wider audience, to manage all medical aspects of company products, and to contribute to the new products and new therapies development. This paper focus on some of the clinical studies investigating devices in the Terumo Interventional Systems product portfolio (Figure 1). One of the fields is radial intervention, which is an interventional therapy performed to access and visualize lesions inside the arteries of a patient. By accessing the arteries starting from a puncture in the wrist, the procedure is minimally invasive and increases the patient's comfort during and after the procedure. Once the arteries are accessed, a guide wire can be placed to reach the diseased artery that needs to be treated. If the disease is located in the arteries of the heart we talk about coronary artery disease, if the disease is located in the arteries of in any other part of the body, for example arteries of the neck, we talk about peripheral vascular disease. Both disease types can be treated by placing a stent at the location of the lesion to open the artery. One of coronary artery stents in the Terumo product portfolio is the Ultimaster™ stent, which has been thoroughly investigated in many clinical trials.

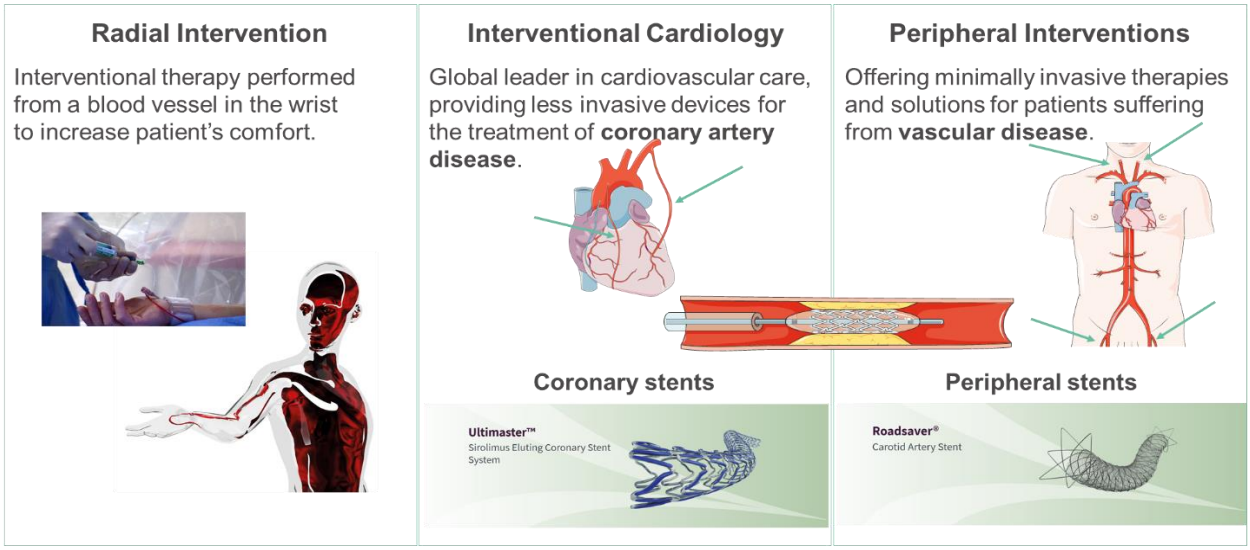

Figure 1 – *Terumo's clinical research fields and product portfolio*

In 2019, Terumo closed its biggest study ever with the Ultimaster™ stent, the e-ULTIMASTER study, which is one of the largest prospective worldwide registries in its field, enrolling up to 37 000 patients from 378 sites across 50 countries. Patients included in the study were treated with a coronary stent because they had a narrowing of the arteries supplying blood and oxygen to the heart. By placing one or more stents at the location of one or more lesion the blood flow to the heart was restored and symptoms were relieved. The patient was followed up for 1 year. The primary endpoint was to validate efficacy and safety of the device based on a composite endpoint of different serious adverse event up to 1 year after the procedure.

Throughout the study, various data were collected at different levels, going from patient-level data including demographics, medical history and clinical status, to procedural level, lesion level and stent level data. In fact, each patient could have multiple narrowings or lesions at different locations in the arteries. For each lesion treated, several lesion characteristics were collected such as the vessel location, the severity of the narrowing, the complexity of the lesion (e.g. calcified lesion), and the lesion location in the vessel, e.g. at the bifurcation site which is the place where the artery splits into a side branch and therefore it makes it more complex to treat. On top of that, each lesion could be treated by placing one or multiple stents with its specific characteristics, such as the length and the diameter of each stent.

Together with the large number of patients, the complexity of the data makes this a challenging study in terms of how to present and visualize this huge amount of data collected. e-ULITMASTER's legacy data was captured through EDC system and extracted in SAS readable format. Over the years, all interim analyses were made on CDISC non-standardized data. Before producing the final analysis for the clinical study report, it was internally decided that an additional effort should be made in order to improve the traceability of the data and the transparency of the analysis results.

WHY DATA VISUALIZATION

After e-ULTIMASTER's Database Lock, Terumo organized a Publication Committee Meeting inviting the top 15 enrollers to discuss all possible future publications. During this meeting, we realized that the main investigators of the study had many questions, not all we could answer on the spot. In fact, they knew the status of their own patients, but were clueless of the status of the other sites.

The main questions were: How many sites participated to the study? How many subjects where enrolled ? How did the enrollment go? What is the quality of the data collected? What is the typical profile for inclusion in the study?

To preserve confidentiality of the data, we could not share the full database with the investigators. Nevertheless, we had to find a way to answer their questions.

In general, the most popular Data visualization platforms used in research and development are Spotfire from TIBCO and Qlik Sense. Terumo was already using Power BI which is part of the Microsoft Office 365 suite. Data visualization activities had already been implemented in some departments at Terumo, mostly used in Finance and IT. We could have easy access to Power BI as it is available for Terumo employees. While outside of our comfort zone, we decided to investigate if Power BI could answer our needs.

WHY POWER BI

In 2021, Microsoft has been positioned as a leader in the Gartner Magic Quadrant for Analytics and Business Intelligence Platforms, and this for the 14th consecutive year (Figure 2). It is also the third year that Microsoft is considered the best in completeness of vision and the best in the ability to execute within the leaders' quadrant.

Power BI has many advantages including:

- User friendly interface
- Consolidate multiple data source (Excel, CSV, XML, Text, …)
- Interactive reports and geo-map visualizations
- Extended capacities by integration of R, Phyton and SQL
- Consistent reporting and analyses
- View reports across multiple platforms and devices
- In constant evolution

The only disadvantage met so far is that you cannot directly import your SAS datasets in PowerBI, so you first need to convert them in CSV or Excel file.

Figure 2 - *Gartner Magic Quadrant 2021 for Analytics and Business Intelligence Platforms.*

It is the second time that Terumo presents PowerBI dashboard implementation at a PHUSE Connect Event. Last time we focused on the "how to" and presented the PowerBI Desktop Interface, showing how to import and manipulate your data and how to select the right visual and create a dashboard. We also presented 4 different dashboards and their added value. This year, we decided to focus on something different and to present some technical options and their clinical applications in 4 different dashboards. Would you wish to access the previous paper (DV09, EU CONNECT 2020), you can have it on the PHUSE archive or simply contact the author.

TERUMO'S POWER BI DASHBOARDS

STUDY HOMEPAGE

In order to ease the access for any reader we thought about having a study homepage regrouping all developed dashboards for the e-ULTIMASTER study (Figure 3). As every study has its own sets of specific dashboards, some readers working simultaneously on multiple studies might be lost trying to find the right data in the right dashboard or even completely miss a specific dashboard.

By generating a study home page, the end-user has an overview and by clicking on the needed dashboard, it jumps directly to it.

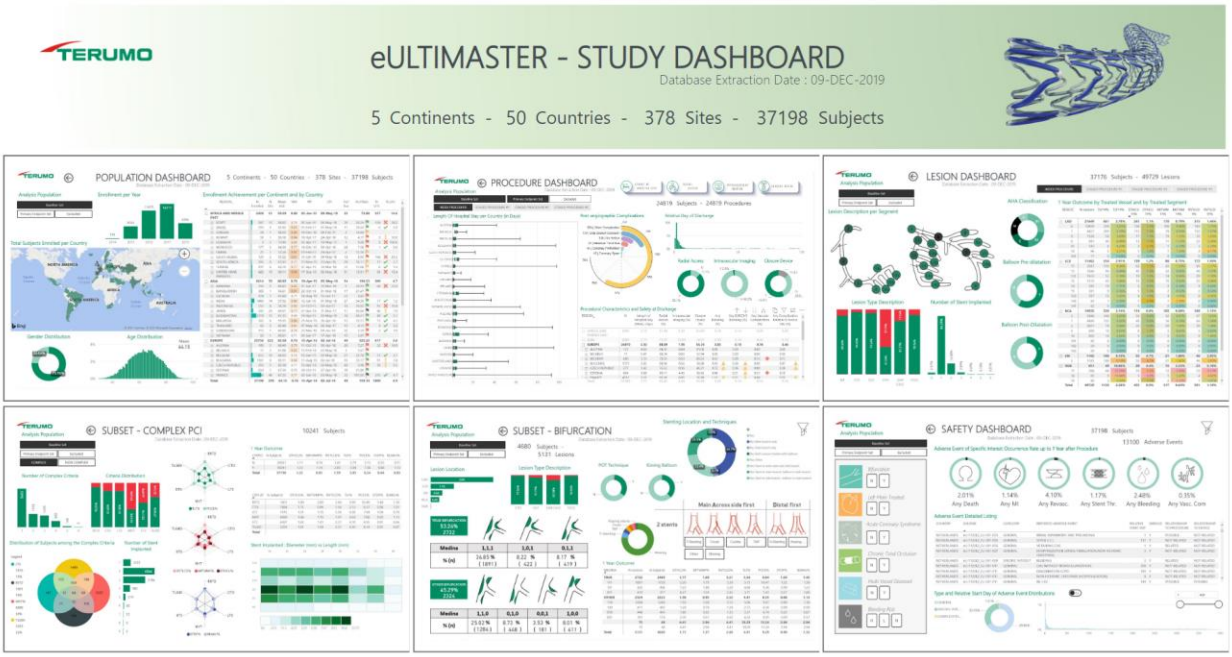

Figure 3 – *e-ULTIMASTER Study Homepage Dashboard*

As already mentioned before, three out these 6 dashboards have already been presented in a previous presentation, so let's discover some news one, starting with the one displaying the Procedural Data!

PROCEDURAL DASHBOARD

In this dashboard (Figure 4) we focus on some procedural characteristics, as for example the length of hospital stays after the procedure. In the graph on the left, the distribution is shown per country. We can also visualize the complications related to the procedure and specific adverse events occurring after the procedure, but before discharge from the hospital.

For the discharge outcomes in the lower right corner, we defined a conditional formatting comparing the sub-rate with the global rate, flagging in orange when values are 1-2x the mean and in red when values are more than twice the mean values. All this can be viewed per site, per country and per continent as it has been integrated in a hierarchy. Thus, it is possible to identify with a few clicks, those sites with high event rates. This is a very interesting and useful option because it is important to closely follow-up the safety. By quickly identifying possible safety concerns, immediate action can be taken while the study is ongoing.

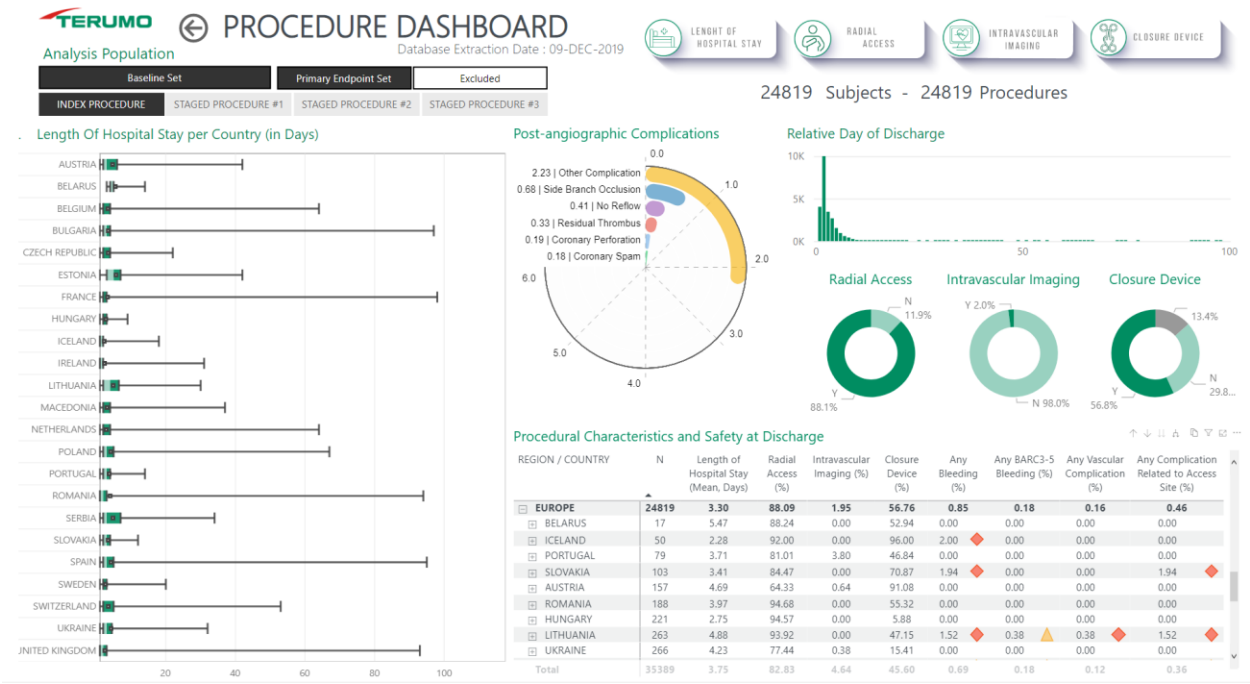

Figure 4 – *Procedural Dashboard.*

If the reader wants to observe the distribution of another known predictor, the visual can be switched by using the button on the upper right part of the dashboard (Figure 5). When clicking on one of these icons, the visual presented on the left part of the dashboard changes. Not only the displayed variable changes, but also the type of visual and its configuration. In this example, when selecting to focus on the radial access, instead of a box plot a histogram will be displayed, with a trendline presenting the global mean value. Similar outputs will be given for both the intravascular imaging use and the use of a closure device.

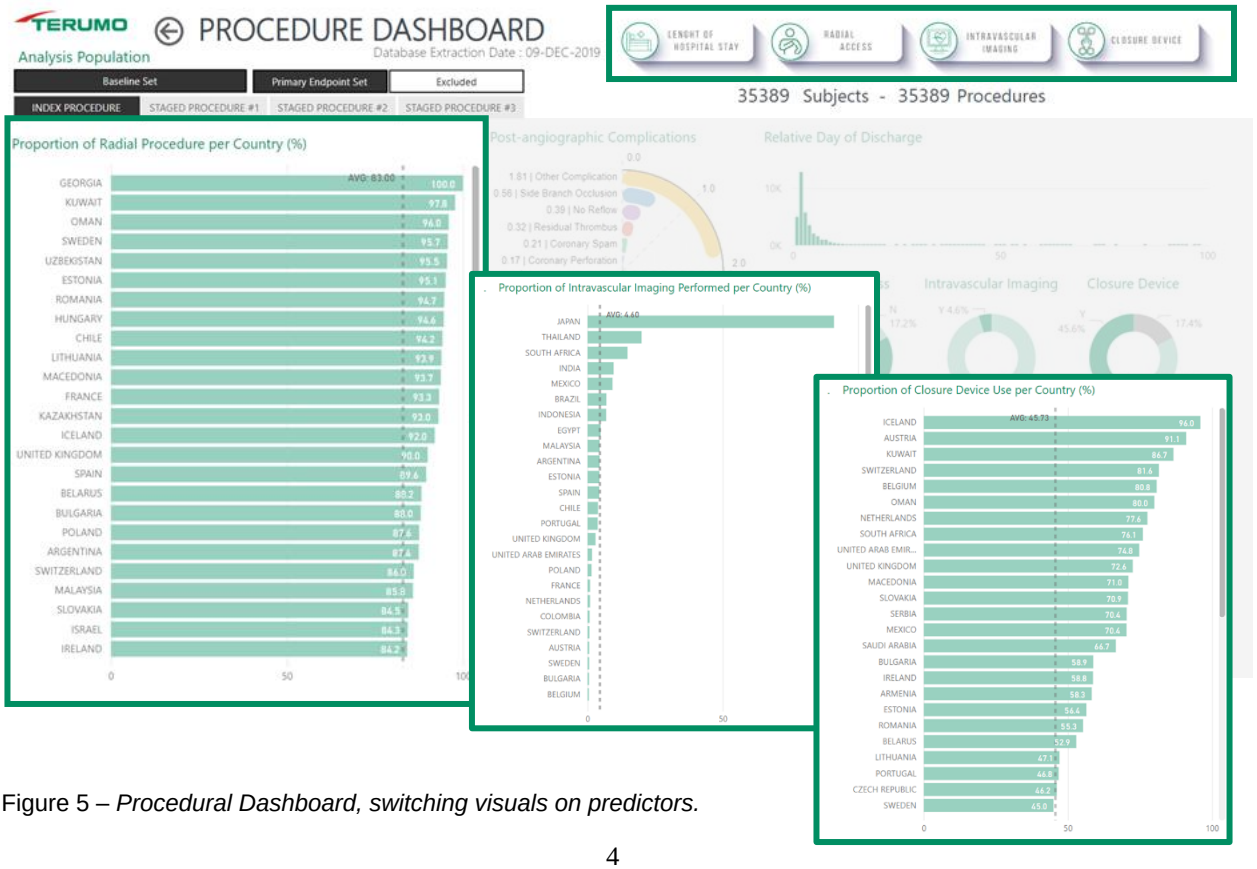

Figure 5 – *Procedural Dashboard, switching visuals on predictors.*

SAFETY MONITORING DASHBOARD

The second idea was to facilitate the monitoring and review of the Adverse Events of Specific Interest. The "Safety Monitoring Dashboard" (Figure 6) visualizes the adverse events of specific interest of this study, i.e. death, myocardial infarction (MI), revascularization, stent thrombosis, bleeding and vascular complications, within 1 year after the procedure. All adverse events were collected in the eCRF and all the relevant ones were adjudicated by a clinical event committee. After 4 publications and many subgroup analyses for congress presentations based on this study in the last 2 years, we know quite well what are the major predictors, but we wanted to see how they interact with each other.

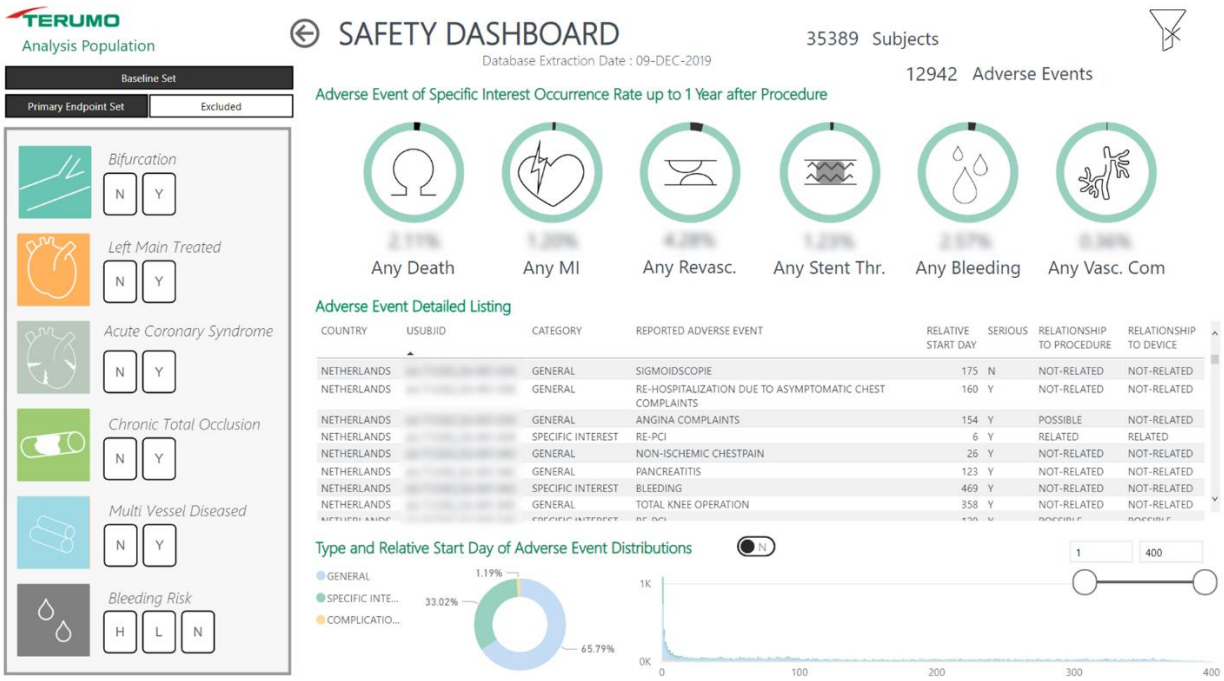

Figure 6 – *Safety Monitoring Dashboard*

This dashboard offers at a glance the risks of adverse events in various important and high-risk subsets and allows to explore how the combined presence of multiple risk features (left side) effects on the outcomes. By using this type of slicer (displayed on the left side) the filtering is cumulative. This makes it easy to identify how many subjects correspond to the combined criterium and what are the specific outcomes up to 1 year after the procedure. This can be a useful feature if we want to assess the feasibility of performing a specific subgroup analysis.

In the second part of the dashboard all CRF reported adverse events are listed, together with the relative start day, seriousness, and relationship to the procedure and to the device. This option can be of particular interest to identify possible safety concerns while the study is still ongoing.

At the bottom (Figure 7), we can see the distribution in proportion per type of adverse events and its distribution over time presenting the relative start day from the procedure date up to 1 year. We can directly identify that most of the adverse events are occurring in acute or subacute phase. By default, this distribution is displayed as a numeric distribution, and filtering can be made by using the cursor or by typing a specific value. By using the switch button, values can be categorized in bins, with either automatic setting (dividing the full distribution by number or size of bins) or with personalized setting, as here for example the values have been categorized per month, expect for the first month where is was categorized per week.

Figure 7 – *Safety Monitoring Dashboard, switching visuals on slicers.*

As many clicks and selections can be made, it is sometimes difficult to know how to reset them all and go back to initial settings. Therefore, we added a “reset” button in the upper right corner (figure 7). This button doesn’t act as an action button but is linked to a bookmark. A bookmark is used to freeze a dashboard in a specific configuration, for example selecting a specific study population or applying a specific filter. Resetting all reader’s action is just an example of an application of a bookmark, but it can also be set to go directly to a specific subset or display.

As for example, let’s say that during the study you want to closely follow-up all adverse events of specific interest occurring in the first week post-procedure, for subjects with a high bleeding risk and having a bifurcation lesion in the left main vessel, you can define a specific bookmark and go to this subset with one click instead of clicking 5 times.

BIFURCATION SUBSET DASHBOARD

The third initiative tried to identify specific characteristics of subjects having a bifurcation lesion and to identify how these anatomical or procedural details could impact the outcome up to 1 year after the procedure (Figure 8). By its nature, a bifurcation is more complex to treat as it is at the location of the artery where it splits into a side branch. Depending on how many and where exactly the lesion(s) is(are) located, the technique to place the stent might be different.

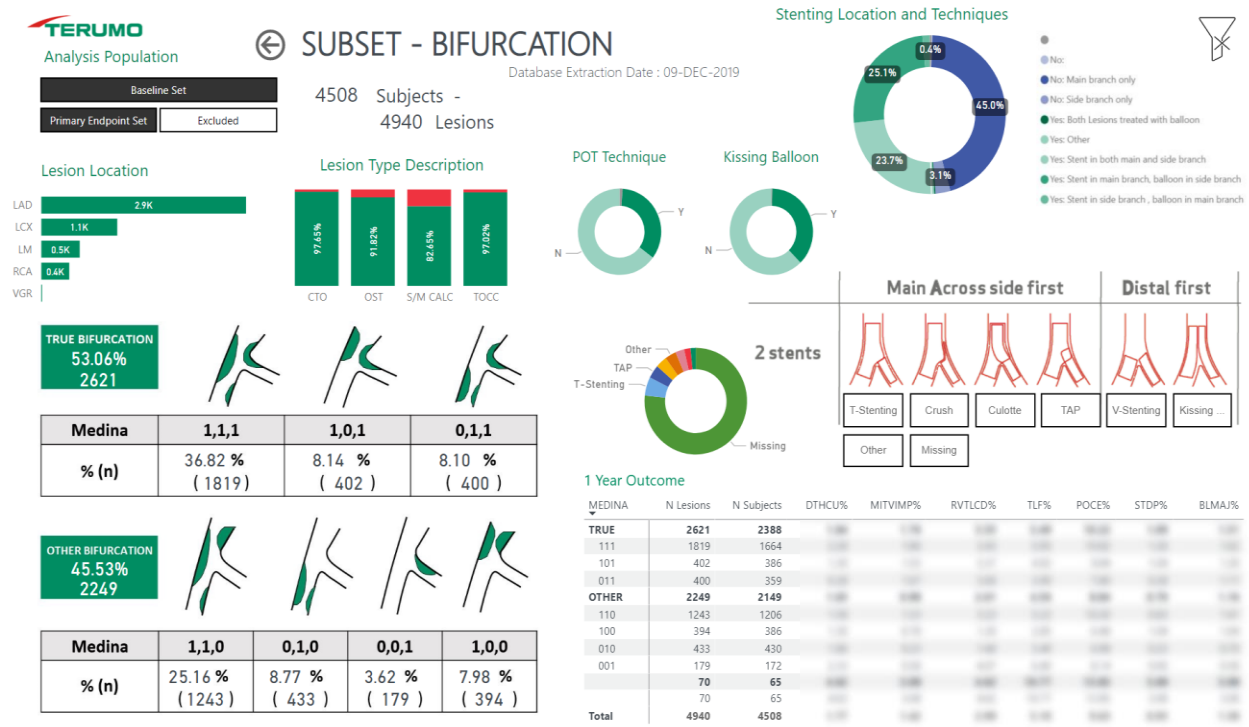

Figure 8 – *Bifurcation Subset Dashboard.*

The dashboard is divided in 3 major parts, the left side is displaying anatomical characteristics while the upper right part focuses on the procedural details and the lower right part displays important outcome parameters up to 1 year after the procedure.

Having all this information centralized in 1 dashboard in a very interactive way with clear visuals is particularly useful to explore the data and it supports discussions of which analyses might be interesting to perform.

DISCO-RADIAL BASELINE DASHBOARD

This last-born Terumo dashboard has been built for the DISCO-RADIAL study (Figure 9). This study is a randomized controlled trial in the field of radial intervention, comparing the conventional puncture site versus a distal puncture site. Even though blinding of the subject or the investigator is impossible, no comparison between the two groups have been done so far as this study is still actively enrolling subjects. However, its overall population characteristics are closely monitored throughout the study.

In this dashboard we added a new technical option to not only count subjects based on some selection criteria but also to identify subjects them in case some further checks and queries are needed.

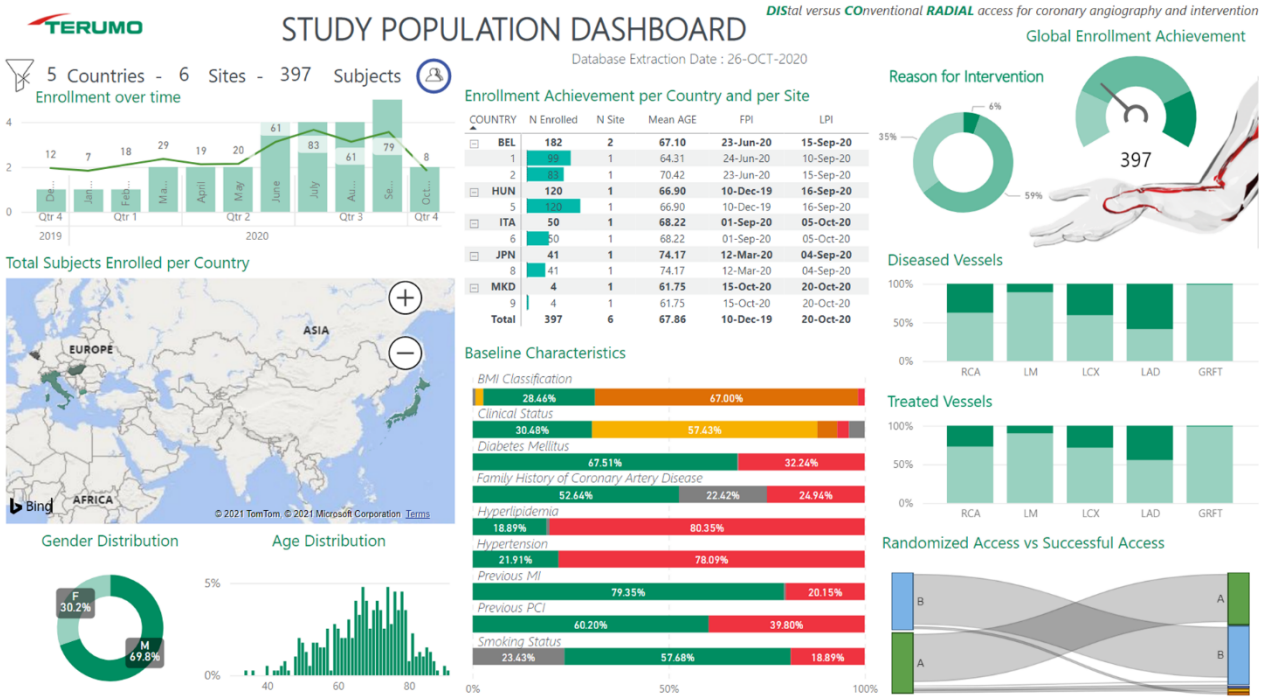

Figure 9 – *DISCO-RADIAL Baseline Dashboard.*

An example could be the identification of subjects having an acute clinical status at baseline to ensure that the inclusion criteria are well respected. When clicking on the red part of the clinical status bar, you'll get a selection of 12 subjects (Figure 10). If you want to verify at which site they have been recruited, by just hoovering your cursor on the blue circle the list of 12 subjects appears in the tooltip window. Imagine that this is relevant, and you want to share this list of subjects with your CRA to initiate some specific follow-up, you could take a print-screen.

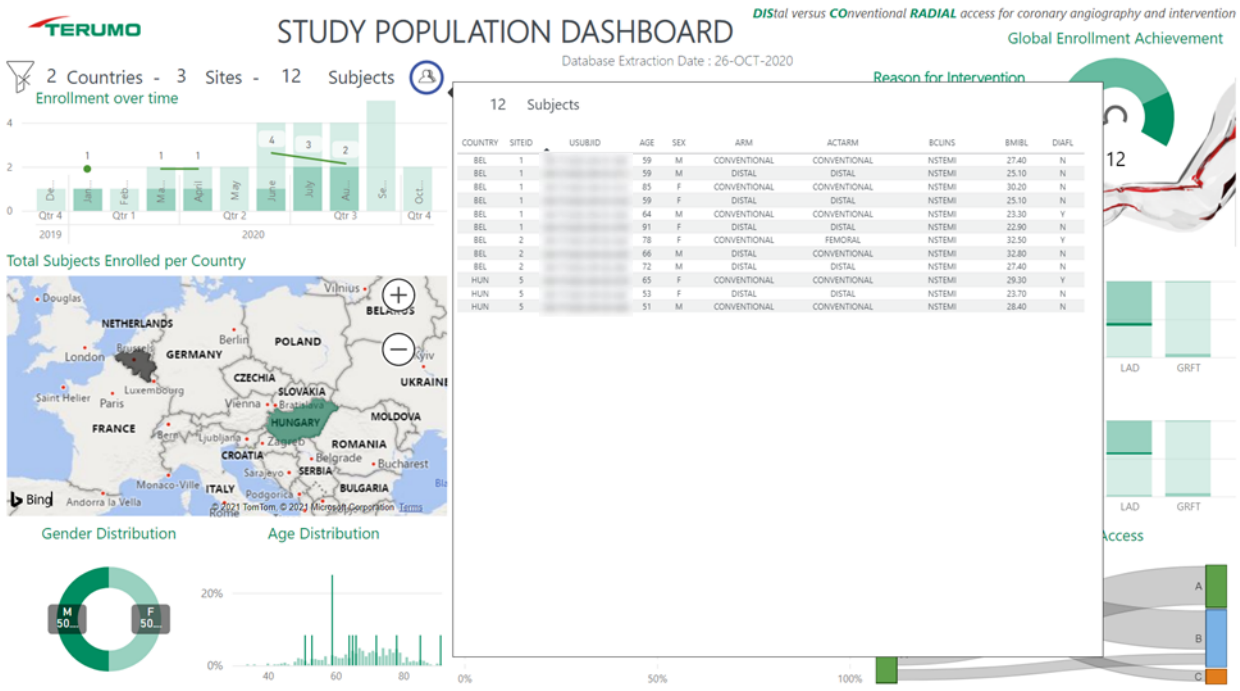

Figure 10 – *DISCO-RADIAL Baseline Dashboard, display subject list in the tooltip*

Nowadays everybody loves to also have a listing in excel where they can filter and take notes. If you right click on the blue circle, a menu window opens, with the option to “Drill-Trough”, which would represent like a jump to the tooltip window while keeping all selections active (Figure 11).

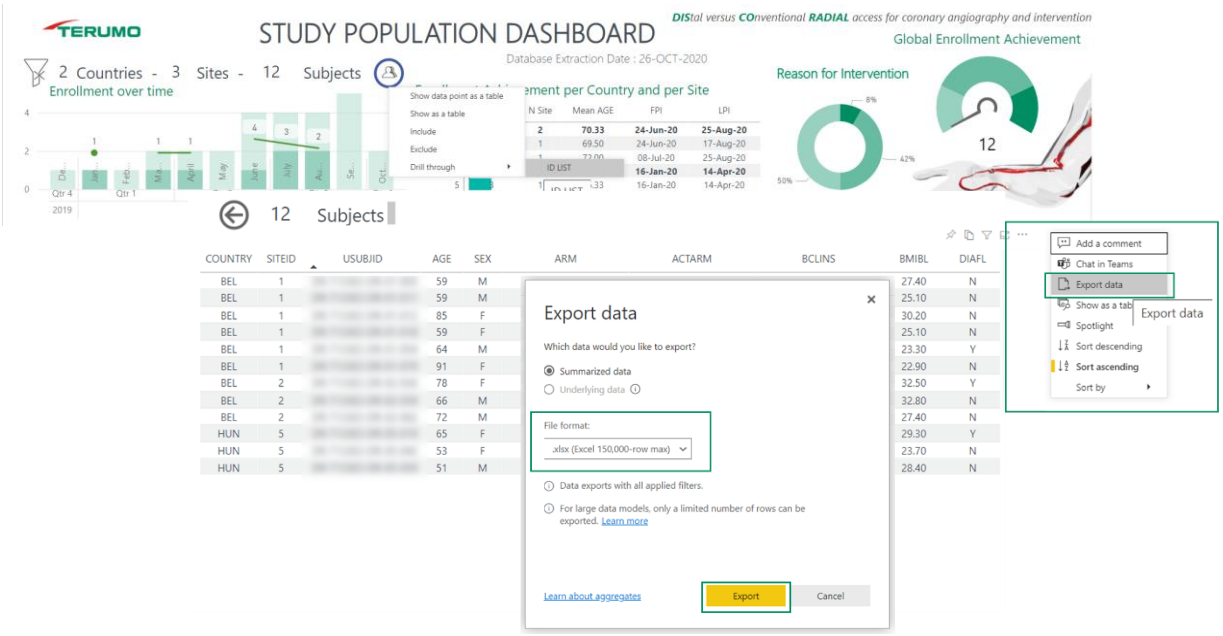

Figure 11 – *DISCO-RADIAL Baseline Dashboard, subject list export in excel file*

On the upper right corner of the list, 5 icons are displayed with the last one representing 3 dots. When clicking there you can choose to add a comment, for example on this visual, but you can also export the data and select in the sub window to export in an excel format (Figure 11).

TARGET SPECIFIC AUDIENCE DASHBOARD

The last concept that we want to introduce today is the possibility to create a dashboard by pooling different study visuals into one to get a more global picture. For example, for us as Statistician and Medical Specialist, a first step is always to understand what is the population that we are working on. For that we mainly look at basic features such as number of subjects included, proportion of gender and distribution of age and country.

We are fully aware that one dashboard cannot fit the need of every reader. Each major clinical study stakeholder wants to see something different (Figure 12). However, it would be too time consuming to produce and to maintain so many dashboards.

The peculiarity of this type of global dashboard is that you do not have to program anything. Each and every visual presented in a programmed dashboard can be pinned and added to a global dashboard. These are easier to develop as they require just a few click and no maintenance is required. When the source dashboard will be refreshed with new data, the global dashboard will automatically be refreshed as well. You can then create as many target audience specific dashboard as you need and tailor the visuals to a specific reader.

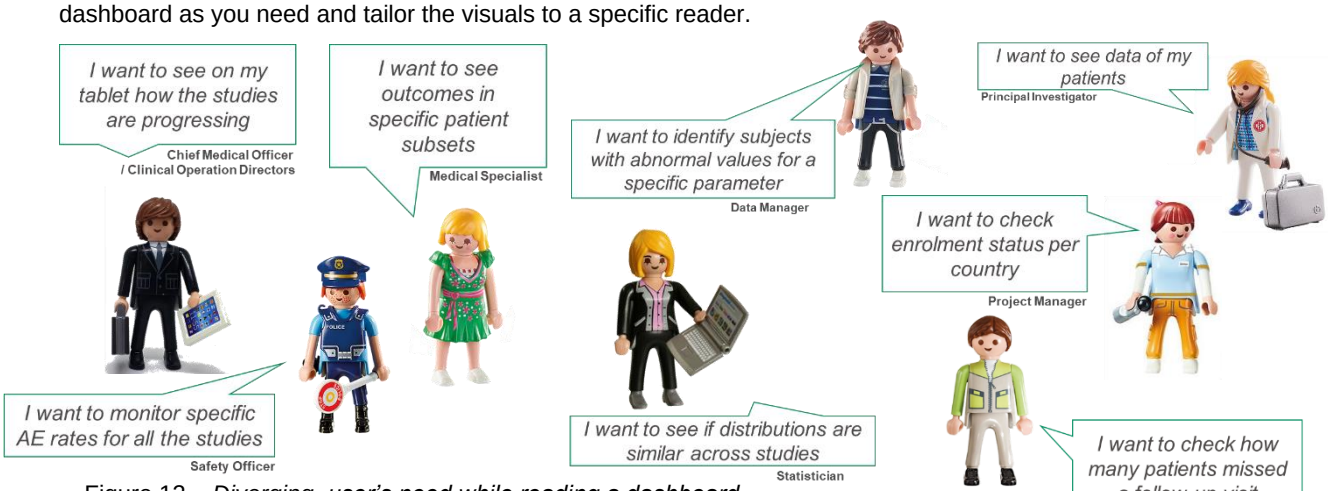

Figure 12 – *Diverging user’s need while reading a dashboard*

In the example in Figure 13, we grouped 4 different studies outputs, and in only one quick look we can assess the achievement of the enrollment and final target, but also the geographical distribution. We can also see that in all studies we have a majority of males. The studied population from e-ULTIMASTER study is in general younger than population from the other studies.

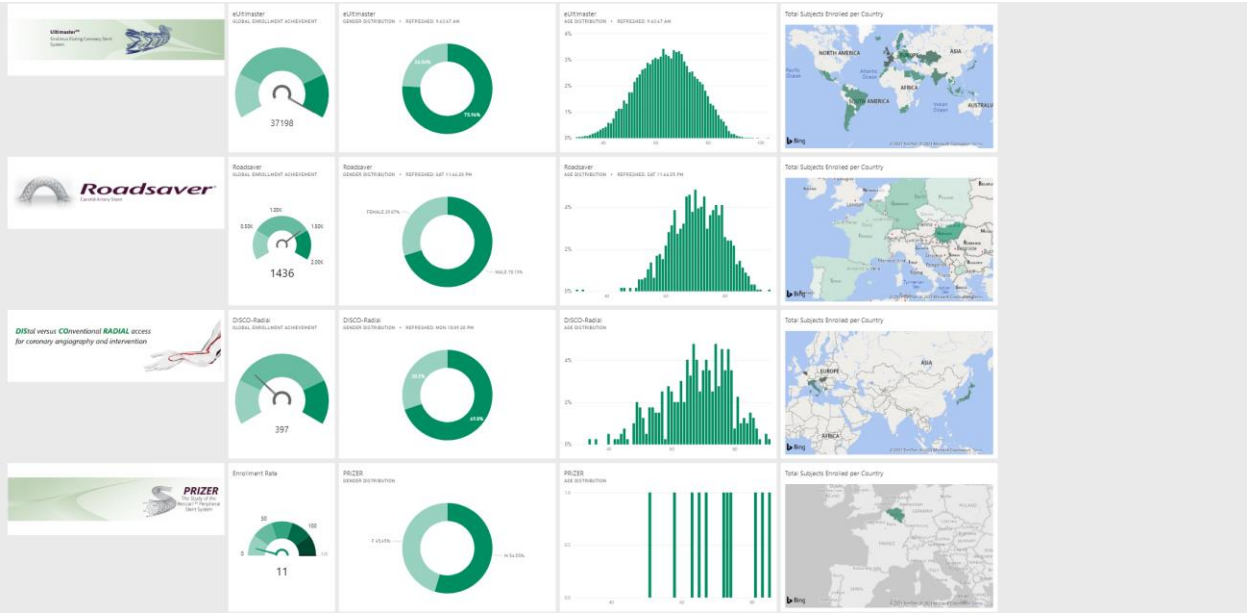

Figure 13 – *Global Trends Dashboard combining visuals from different study dashboard*

Once you selected the visual you want to pin, click on it and a set of icons will appear in the upper right corner (Figure 14). Click the first one with the pin symbol and a popup window will appear. There you can choose the targeted dashboard, either an existing one or a new one and you can choose the theme, either the current theme or a destination theme.

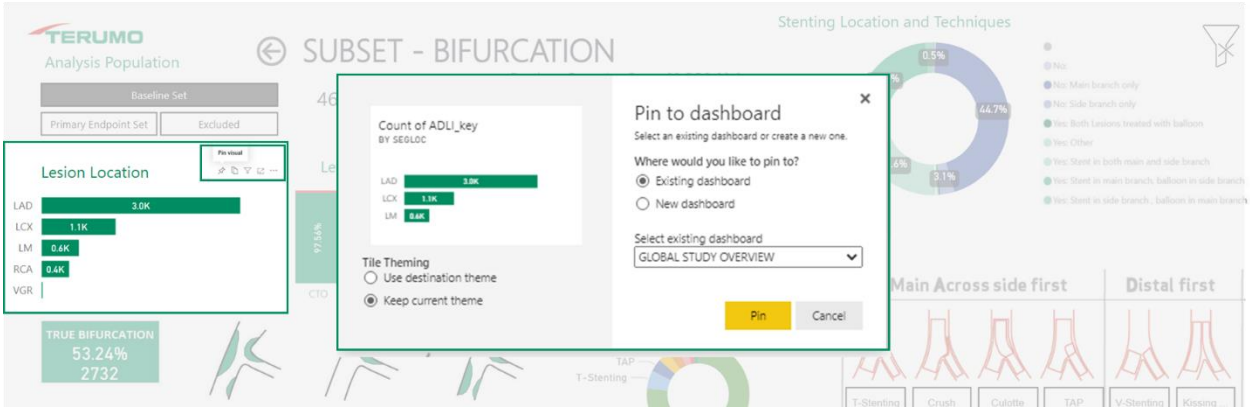

Figure 14 – *Procedure to pin a visual to a global dashboard*

CONCLUSION

As a conclusion, the most important is understand where to start from. You need to clearly define your user's story, identify what is missing, what is the question you want to answer and what is your audience expecting. Keep in mind that for some of your readers, it will be the first time that they see such dashboards and graphs and you do not want to scare them.

Define the data to be used depending on your needs, if you want to refresh every day, maybe it is better to start on raw data. On the other hand, if your audience consists of medical experts and you want to derive many parameters and avoid having to revalidate every step, maybe you should go for standardized data.

Start small and increase complexity progressively. Do not overcomplicate things. Do not link data randomly. Keep in mind that the level of complexity is not always proportional to the efficiency of your dashboard. Progress step by step and start from a medical question, does X impact Y?

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Create and use R visuals in Power BI : https://docs.microsoft.com/en-us/power-bi/visuals/service-r-visuals

2021 Gartner Magic Quadrant for Analytics and Business Intelligence Platforms : https://powerbi.microsoft.com/en-us/blog/microsoft-named-a-leader-in-2021-gartner-magic-quadrant-for-analytics-and-bi-platforms/

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