
Remote Monitoring and Weekly Data Extraction

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Remote monitoring

- Aims
 - » Monitor recruitment
 - » Quality control
 - »
- Weekly report from KKS Charité

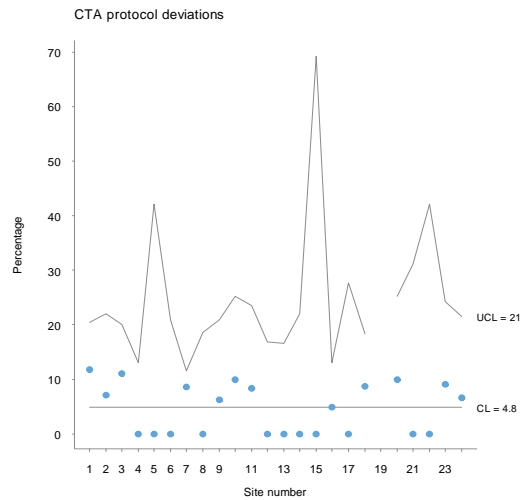
Statistical Process Control

- Idea
 - » Data driven procedure to monitor process quality
 - » Use data to define control limits
 - » If control limits are exceeded take action!

Example

- CTA-protocol deviations (real data)
 - » Use the proportion of protocol deviation per site (definite violations/CT readings)
 - There is a total 24 violations among 465 readings from October 2015-Feb. 2017
 - » Calculate (individual) control limits
 - » Plot proportion and control limits

Control chart



Interpretation

- Looking at the chart the process is in control!
- The control limits are not exceeded!
- But be aware;
 - » Predefined limits must be maintained, e.g. Protocol deviations/CT based management (>1% for each item/on a per patient basis):
 1. Patients received ICA even though CT was negative
 2. Patients received ICA even though CT was < 20% stenosis

Conclusion

- Remote monitoring helps to improve the quality of the DISCHARGE trial
- Statistical process control is an additional tool for process control
- Since this a data driven approach protocol regulations must be kept in mind!

Reference

- Statistical process control is often used in engineering and emerging in health sciences

See e.g.

- » Montgomery, Douglas (2009). Introduction to Statistical Quality Control. 6th edition, John Wiley & Sons
- » Lloyd P. Provost, Sandra K. Murray (2011). The Health Care Data Guide: Learning from Data for Improvement. John Wiley & Sons.

Thank you for your attention

Any questions?

