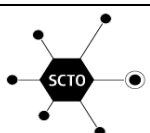


CTU Bern Annual Report 2019

Date 14 April 2020
Author CTU Bern Directorate and Quality Management
Approval Sven Trelle, Director CTU Bern



1. Introduction

CTU Bern’s main aim is to improve the quality of clinical research projects at the University of Bern and Inselspital Bern. To achieve this, we support clinical researchers by providing training, consulting, collaborations, and services. We are dedicated to continuously improve our work. One important aspect is monitoring indicators that aim to measure quality related to processes within CTU (and take action if they hint to issues). This Annual Report summarizes this effort and makes it transparent to the public.




The evaluation is based on the CTU Key Performance/Process Indicators (KPI) as defined in the SOP “Quality Management Review” and its Appendix “Key Performance Indicators CTU Bern”. The Indicators cover a variety of topics. For some, quantitative goals were defined and certain thresholds pre-specified that should hint to whether actions are needed to address potential weaknesses. For others, a qualitative assessment was deemed more appropriate.

The displayed results cover the period of January – December 2019.

1.1. KPI Evaluation

Each KPI is evaluated using a quantitative or qualitative assessment and measured against a threshold defined for each KPI.

To exhibit the KPIs evaluation results, a color-coding system is used, displaying the KPI status compared to its threshold. The following color codes apply.

KPI Status	KPI Status	KPI Status
		
≥80% (green) or qualitative evaluation	<80% (yellow) or qualitative evaluation	≤50% (red) or qualitative evaluation

2. KPI Status Summary


KPI	Status
Actions from previous QMR	
Significant changes relevant to CTU QMS	
Risks	
– Total number of identified risks 2019	
– Number of newly identified risks 2019	
– Number of errors requiring update to risk register	
– % of risks adequately mitigated below a risk score of 12	
Adequacy of available resources and working environment:	
– Finances	
– Overtime %	
– Sick leave % above 2.5	
– Reasons for resignation	
Customer satisfaction	
– Consulting	
– Services	
Quality Objectives	
Institute Performance	
– Consulting	
– Projects	
Teaching / GCP Courses	
– Participants	
– Quality rating	
Scientific Output and Grants	
– Publications	
– Citation Ratio	
– Grants	
Nonconformities & CAPAs	
– New CAPAs	
– CAPAs closed on time	
Audit Compliance	
– Internal	
– External	
Performance External Providers (Vendor)	

3. KPI Evaluation

3.1. Actions from Previous Quality Management Review (QMR) 2018

KPI to measure QMR progression and success over time.

	KPI Definition	Threshold
#1	Number and overview of status of action items originating from previous year's QMR	No threshold, KPI primarily used for context
#2	Percentage of these action items closed	≥80% (g) <80% (y) ≤50% (r)

	KPI Results/Evaluation	Status
#1	Five action items originated from 2018 QMR.	
#2	Four of the five action items were closed, equaling to a closing rate of 80%. One action relating to an internal KPI item remained open/unsolved and resulted in a further corrective and preventive action.	

	Action Plan
N/A	No further actions resulting from 2018 Action Items; follow up on unsolved KPI is managed via CAPA system.

	Details
	N/A

3.2. Continuous Development of CTU Bern

3.2.1 Significant Internal/External Changes Relevant to the CTU QMS

To create awareness and facilitate a proactive management of internal and external changes and their impact to the CTU quality management system, and to illustrate trends in regard to internal changes.

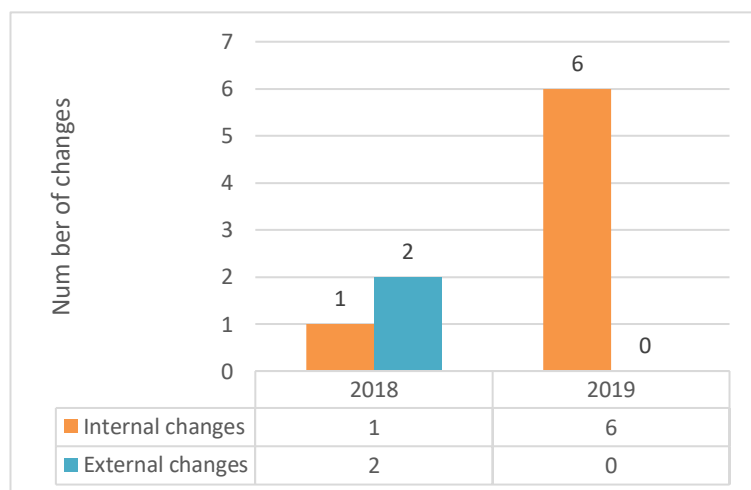
KPI Definition	Threshold
#1 Evaluation of internal/external changes that impacted CTU in the current QMR period	Qualitative assessment

KPI Results/Evaluation	Status
#1 CTU Bern successfully integrated six internal changes into its Quality Management System (QMS). No external changes were addressed. Compared to 2018, CTU Bern faced an increase of internal changes and a decrease of changes with external origin in the current QMR period.	●

Action Plan
N/A No actions required. All changes were adequately managed and implemented via respective processes and/or document amendments (as applicable).

Details

Table 1: Comparison of significant changes to CTU Bern QMS between 2018 and 2019



3.2.2 Risk Review (risks and opportunities)

To allow awareness creation and illustrate the proactive management of risks and opportunities and their impact to the CTU quality management system.

KPI Definition	Threshold
#1 Total number of risks identified and recorded	Qualitative assessment
#2 Number of new risks identified in current QMR period	Qualitative assessment
#3 Number of errors that required a risk register update in QMR period	Qualitative assessment
#4 Percentage of risks adequately mitigated and as such below a risk score of 12 (CTU-internal threshold for high risk)	≥ 95% (g) <95% (y) <80% (r)

KPI Results/Evaluation	Status
#1 Total number of identified risks in 2019 is 73 (compared to 64 in 2018). The increase is due to new SOPs implemented, as risks are derived for every SOP at CTU Bern.	●
#2 Number of new identified risks and mitigation actions within QMR period is 25 . The annual revision of the risk register allowed to summarize or resolve some risks to the division of Clinical Investigation (CI), which lead to a lower number of CI risks. Quality management (QM) division risks were newly added to the risk register as they were not part of the register in the previous QMR period.	●
#3 Number of new risks based on errors within QMR period is one .	●
#4 All risks are mitigated below a score of 12 due to the introduction of re-assessment of a risk after risk treatment (residual risk).	●

Action Plan

- AI Amend KPI to account for number of errors related to already identified risks and therefore potential need to adjust mitigation actions.

Details

Table 2: Number of risks identified per CTU division 2018-2019

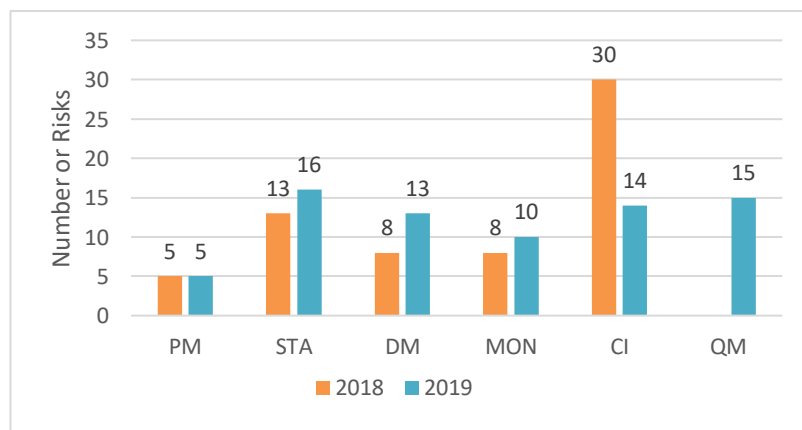


Table 3: Summary of risks identified at CTU Bern

1) <u>Overall</u> number of identified and recorded risks in 2019					73
PM 5	STA 16	DM 13	MON 10	CI 14	QM 15
2) Number of <u>new</u> identified risks and mitigation actions within QMR period					25
PM 0	STA 3	DM 5	MON 2	CI -16	QM 15
3) Number of <u>new risks based on errors</u> within QMR period					1
PM 0	STA 0	DM 1	MON 0	CI 0	QM 0

3.2.3 Adequacy of Resources and Working Environment

To ensure adequate financial resources within CTU Bern by measuring CTU account balances against project revenues and staff costs.

To ensure adequate working conditions at CTU by monitoring overtime as measure of sufficient staffing, sick leave data as an indicator for stress, and reasons for resignation to ensure that resignations are not related to the working environment (stress, supervision, etc.).

KPI Definition	Threshold
#1 Balance between CTU accounts of project revenues and staff costs	Staff costs covered: ≥ 2 months (g) < 2 months (y) negative balance < staff costs for 2 months (r)
#2 Percentage of employees with more than 100 hours overtime, whereas overtime is overhours plus vacation hours left at the end of the QMR period (and therefore transferred into the new year)	≤5% (g) >5% (y) >10% (r)
#3 Percentage of employees with health-related absences more than 2.5% of their working time	≤5% (g) >5% (y) >10% (r)
#4 Reasons for resignations within the current QMR period	No threshold i.e. qualitative assessment

KPI Results/Evaluation	Status
#1 The balance across CTU accounts improved as compared to 2018 but was still insufficient .	●
#2 The percentage of employees with more than 100h overtime is 27.6% (N = 58). The average overtime is 76.8 hours. 16 employees accumulated overtime between 100-300hours.	●
#3 The percentage of employees with health-related absences more than 2.5% of their working time is: 39.7% (N = 58). Sick leave mean is 3% and above BFS benchmark of 2.5%. Sick leave median is 1.74%, which therefore indicates outliers with exceptionally high rate of absence.	●
#4 Resignation reasons see details in table 5 below.	●

Action Plan	
AI	Finances: Hourly rates were adjusted in 2018 as a result of insufficient financial reserves. Hourly rates will not be changed in 2020. The following additional measures will be implemented to improve the financial situation: 1) improving the refundable working time to at least 60% per employee on average; 2) closer monitoring of project budgets; 3) improving efficiency of invoicing practice; 4) better understanding of financial aspects by all employees; 5) focus on larger projects rather than small projects.
AI	Overtime: Evaluate the need for a yearly threshold for max. vacation h to be moved to the next year. Closer and more regular monitoring of overtime and vacation planning.
AI	Sick Leave: KPI figure to be re-assessed because the benchmark is too strict.

Details

Table 4: Sick leave and overtime at CTU Bern 2019

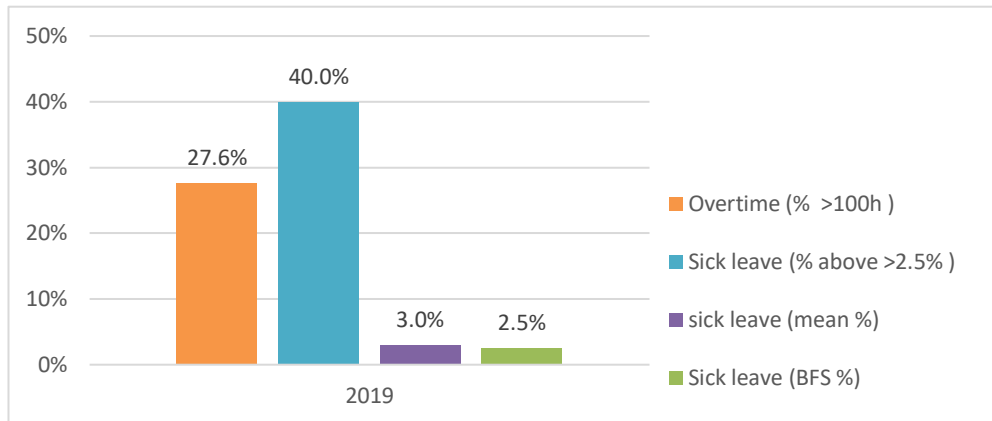
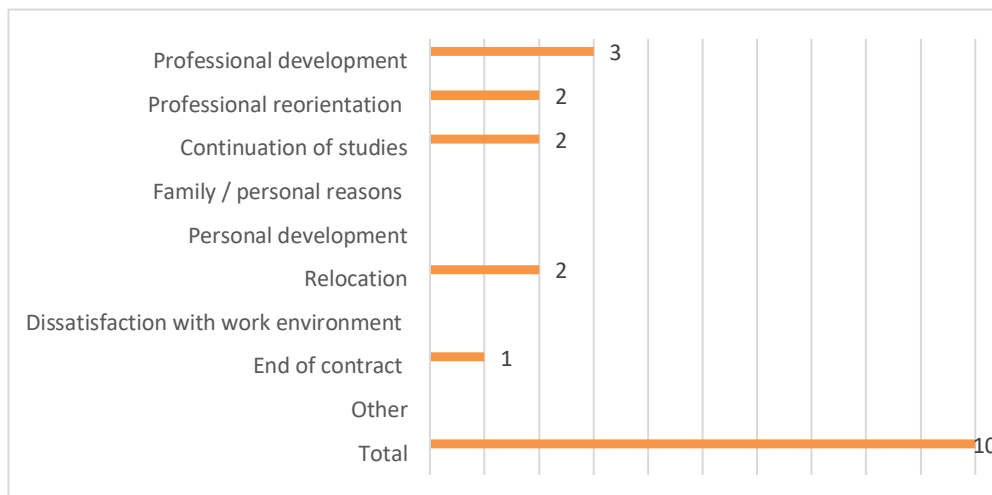


Table 5: Reasons for resignation at CTU Bern 2019



3.3. Process Performance and Conformity of Products and Services

3.3.1 Customer Satisfaction

Proof of customers satisfaction regarding CTU consulting quality, availability/accessibility, response time, competence, and friendliness of CTU staff members, and price/performance ratio.

KPI Definition	Threshold
#1 Percentage of satisfied customers (score ≥ 5) over all consulting in the current QMR period	$\geq 80\%$ (g) $< 80\%$ (y) $< 67\%$ (r)
#2 Percentage of satisfied customers (score ≥ 5) per service in the current QMR period	$\geq 80\%$ (g) $< 80\%$ (y) $< 67\%$ (r)
#3 Qualitative results i.e. comments	$< 20\%$ critical comments

KPI Results/Evaluation	Status
#1 The percentage of satisfied customers over all consulting is 86.4% .	●
#2 The percentage of satisfied customers over all services is 92.3% .	●
#3 For services, one out of five comment (20%) was of critical nature. According to the division's head, the received negative comment was unclear. Comment was followed up with customer but resulted in no further feedback.	●

Action Plan

A1 Discuss low rate of sent surveys (STAT; MON; CI divisions), Initiate surveys for PM division.

Details

Table 6: Customer satisfaction with consulting at CTU Bern 2019

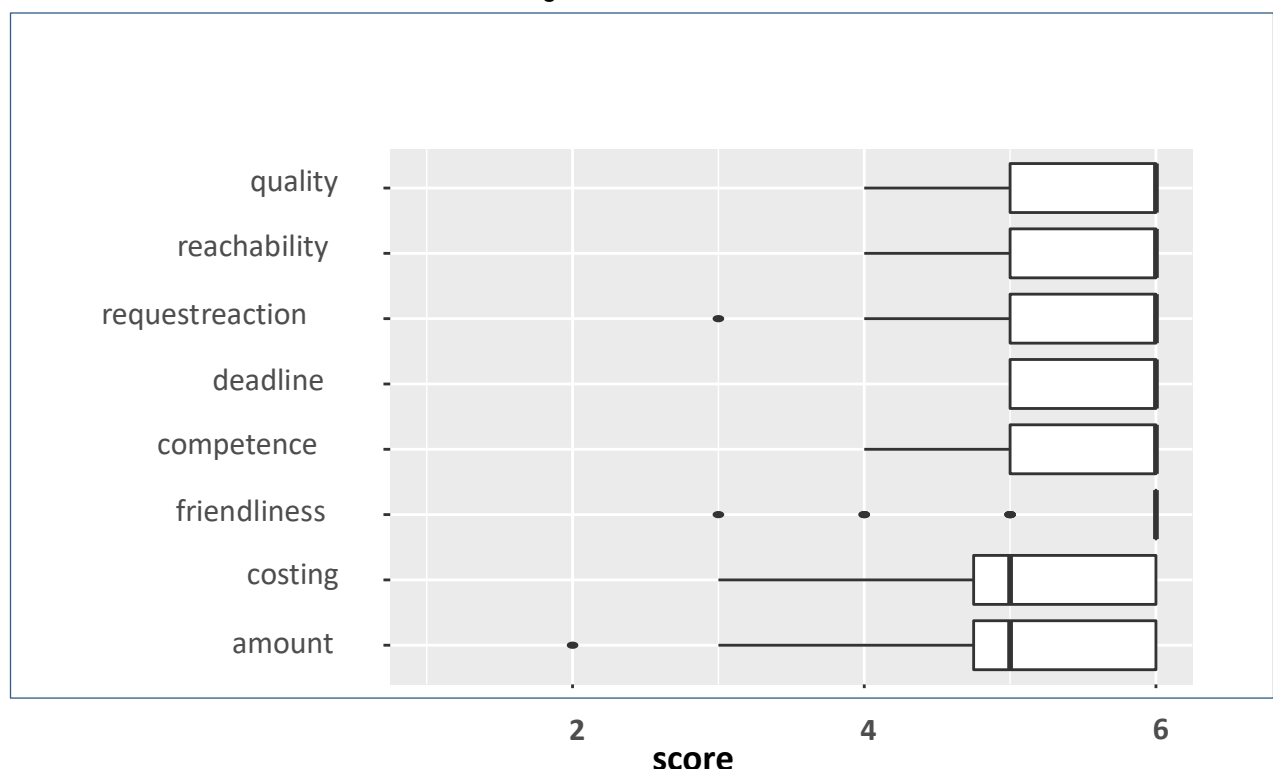
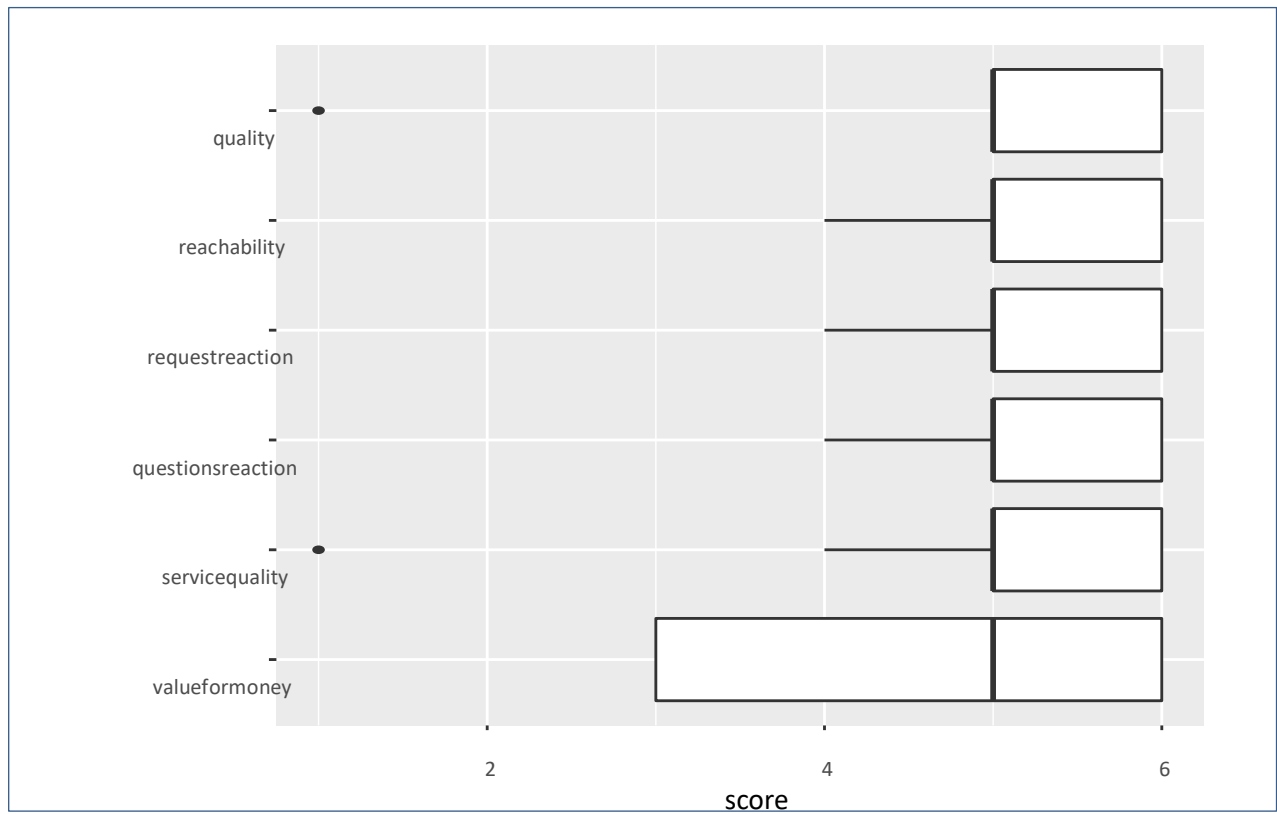


Table 7: Customer satisfaction with services at CTU Bern 2019



3.3.2 Evaluation of Quality Objectives

KPI to measure the capacity of CTU Bern to determine and implement quality objectives to ensure continuous development and improvement of CTU Bern.

KPI Definition		Threshold
#1	Percentage of annual CTU quality objectives closed within set timeframe.	≥ 80% (g) < 80% (y) < 50% (r)

KPI Results/Evaluation		Status
#1	Objectives were only partially formalized and as such not completed , as other major priorities were addressed throughout the year.	

Action Plan	
AI	Evaluate feasibility & resource availability to complete defined Quality Objectives by the defined deadline of June 2020. Adjust as necessary. Improve adherence to strategic directions (such as Quality Objectives) once they are defined by regular monitoring and involvement of all staff but especially senior staff members.

Details	
N/A	

3.3.3 Institute Performance and Visibility

a) Consulting

Consulting with researchers is one of the aims of CTU Bern and justification for receiving core funding. Inselspital and institutes of the medical faculty are separate entities that both provide core funding to CTU. The KPI will help to ensure that this objective can be met and that CTU actually serves all internal institutions (and not only a selection).

KPI Definition	Threshold
#1 Percentage change in the number of consulting with person from Inselspital from median of previous three years to current QMR period.	≤10% (g) >10% (y) >20% (r)
#2 Percentage change in the number of consulting with persons from institutes of the medical faculty of the University of Bern from median of previous three years to current QMR period.	≤10% (g) >10% (y) >20% (r)
#3 Number of consulting in the current QMR period according to the primary institution (distinct Inselspital clinical departments and institutes of the medical faculty, other University of Bern institutes, external non-profit, external for profit).	≥ 25 Inselspital Clinics, ≥7 med. Fac. Institutes (g) <25 Inselspital Clinics, <7 med. Fac. Institutes (y) <20 Inselspital Clinics, <5 med. Fac. Institutes (r) No threshold for external consulting
#4 Percentage change in the overall number of consultings from median of previous three years to current QMR period.	≤10% (g) >10% (y) >20% (r)

KPI Results/Evaluation	Status
1 The percentage change of consulting for Inselspital in 2019 compared to median of previous three years is: +23.5% (N = 226).	●
2 The percentage change of consulting for University of Bern in 2019 compared to median of previous three years is: +76.7% (N = 76).	●
3 A minimum of one consulting has been performed in 36 different Inselspital clinical departments, and 13 different institutes of the medical faculty of the University of Bern.	●
4 The percentage change in the overall number of consulting in 2019 compared to median of previous three years is 40.6% (N = 343).	●

Action Plan

N/A No actions required as all KPIs green.

Details

See following pages

Table 9: Duration of CTU consulting 2019

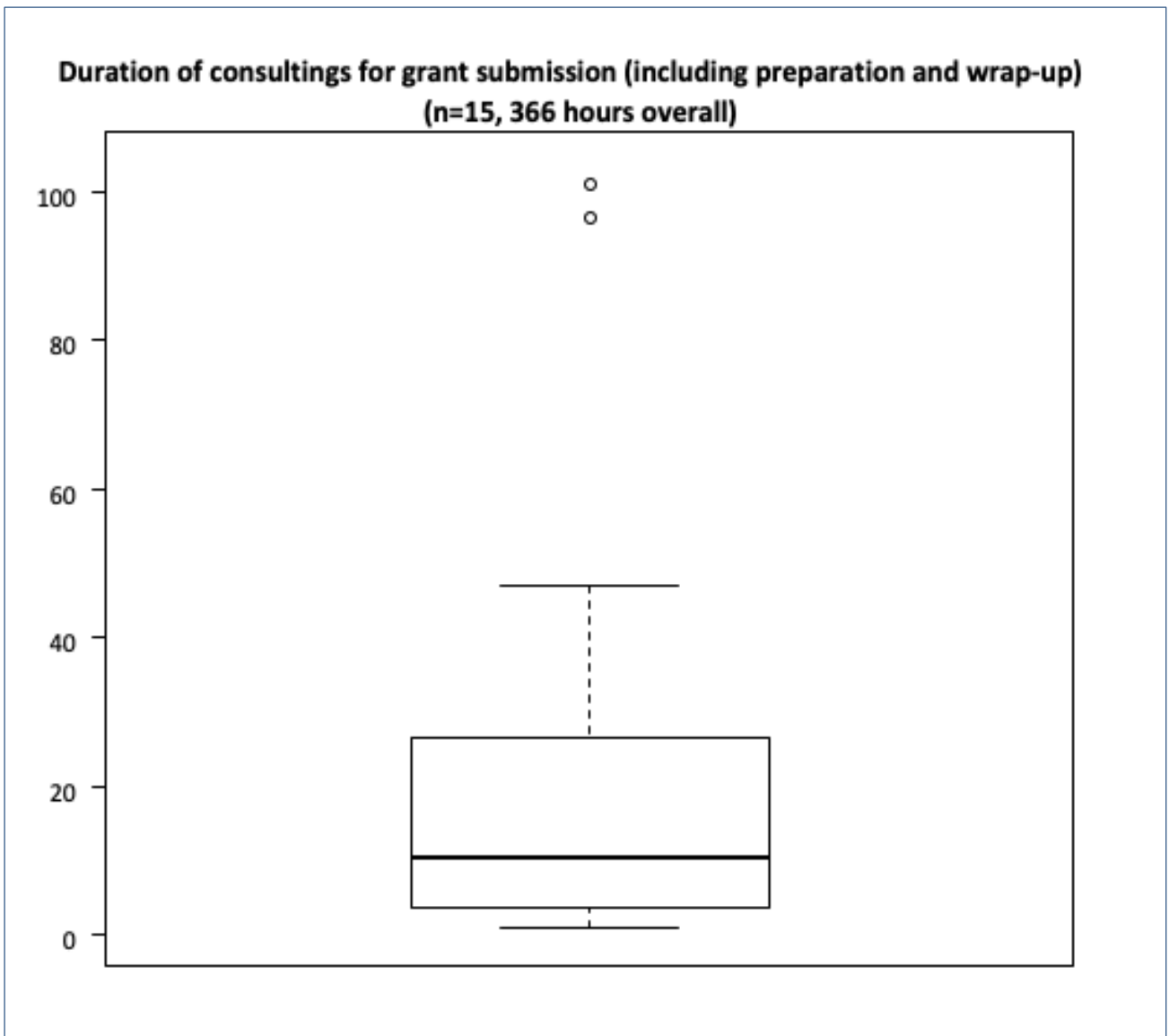


Table 10: Total number of CTU consulting 2015-2019

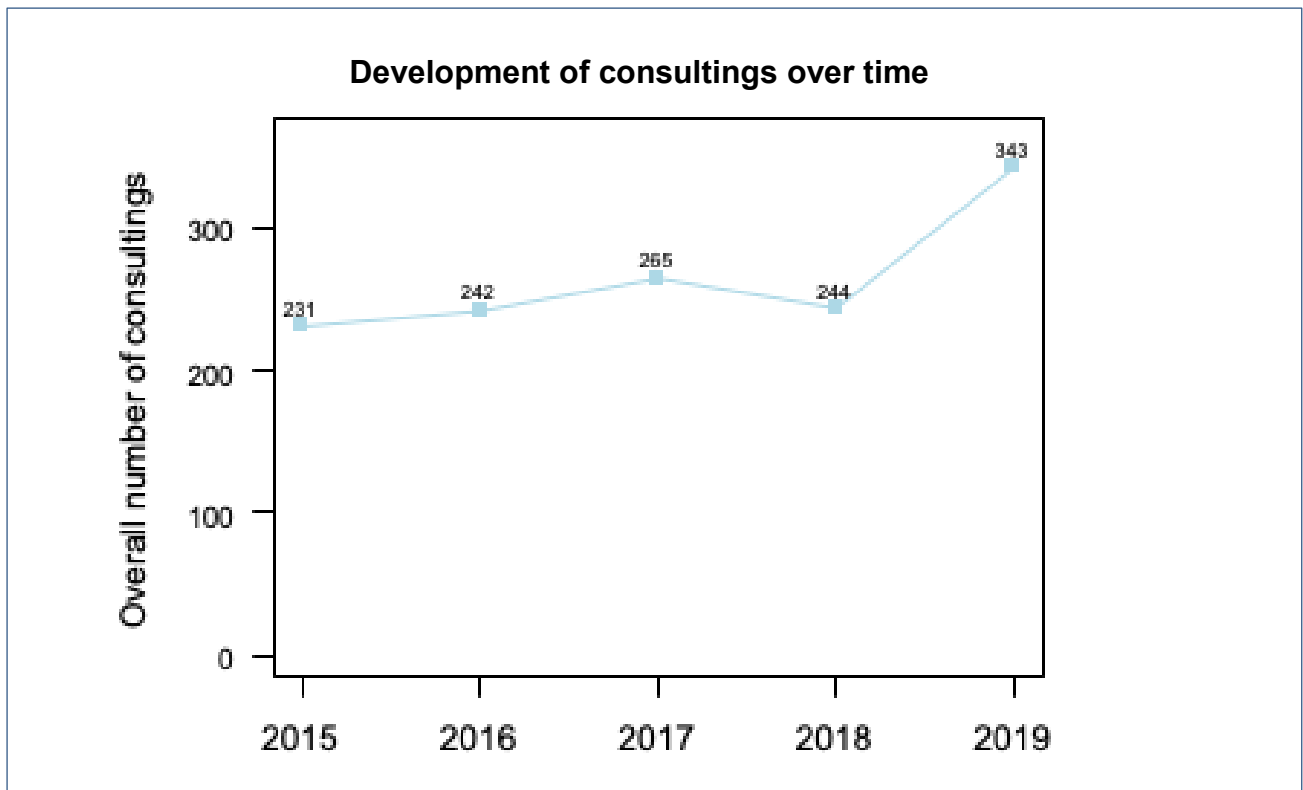
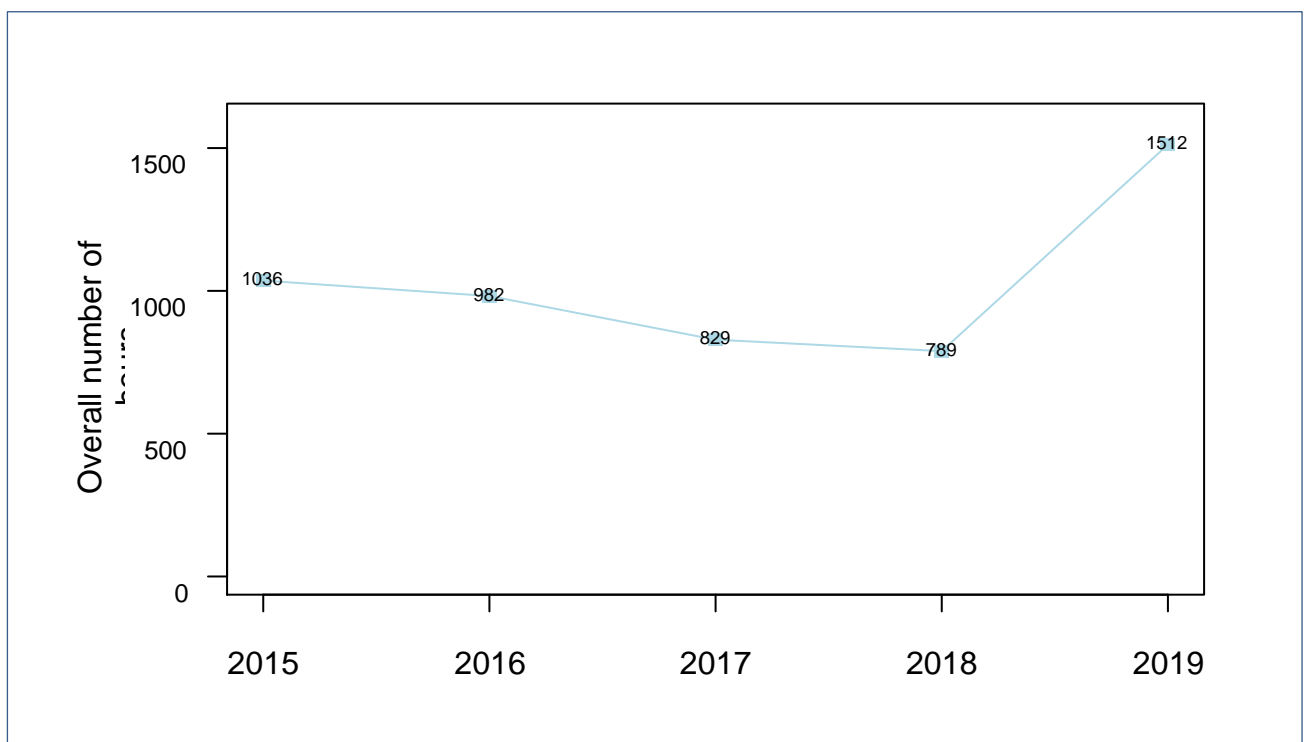






Table 11: Number of CTU consulting hours 2015-2019



b) Projects

The KPIs will help to identify if there is a trend in one of the main service areas of CTU Bern and if sustainability and achievement of main objectives of CTU Bern are actually reached.

KPI Definition	Threshold
#1 Percentage change in the overall number of projects (with at least eight recorded working hours in current QMR period) from median of previous three years to current QMR period.	Decrease $\leq 10\%$ (g) $> 10\%$ (y) $> 20\%$ (r)
#2 Percentage change in the number of projects (with at least eight recorded working hours in current QMR period) with Inselspital or University of Bern as sponsor from median of previous three years to current QMR period	Decrease $\leq 10\%$ (g) $> 10\%$ (y) $> 20\%$ (r)
#3 Percentage change in the overall number of clinical trials (with at least eight recorded working hours in current QMR period) from median of previous three years to current QMR period	Decrease $\leq 10\%$ (g) $> 10\%$ (y) $> 20\%$ (r)
#4 Percentage change in the number of projects (with at least eight recorded working hours in current QMR period) supported by the main CTU divisions i.e. data management, monitoring & regulatory affairs, statistics & methodology from median of previous three years to current QMR period	$\leq 20\%$ (g) $> 20\%$ (y) $> 30\%$ (r)

KPI Results/Evaluation	Status
#1 Percentage change in the overall number of projects is: +13.4% (N = 178).	
#2 Percentage change in the overall number of projects with Inselspital or University is: +16.8% (N = 146).	
#3 Percentage change in the overall number of clinical trials is: +22.1% (N = 83).	
#4 Percentage change in the number of projects for Data Management is: 0% (N = 113). Percentage change in the number of projects for Monitoring & Regulatory Affairs : 14.3% (N = 64). Percentage change in the number of projects for Statistics & Methodology is: -4% (N = 97).	

Action Plan

N/A No actions required as all KPIs green.

Details

See following pages

Table 12: CTU projects according to contract partner institution

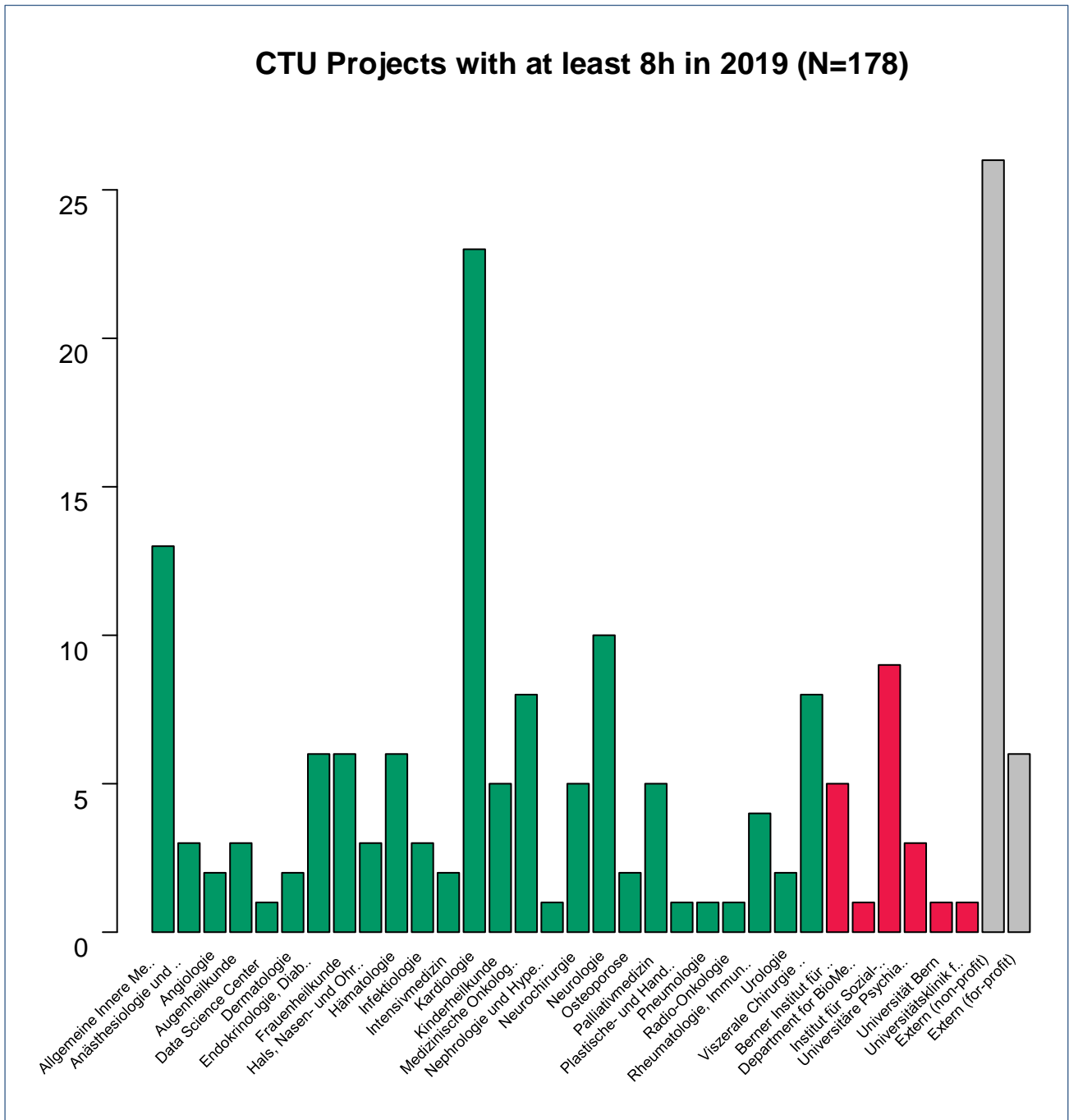


Table 13: Distribution of number of projects over all CTU divisions 2019

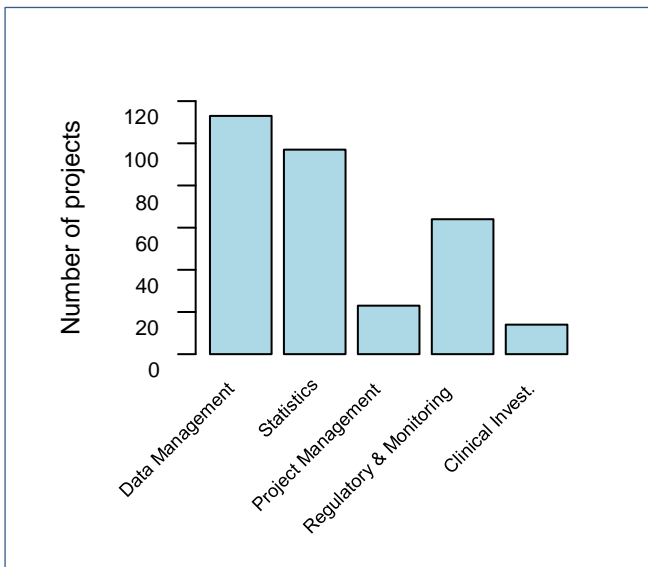
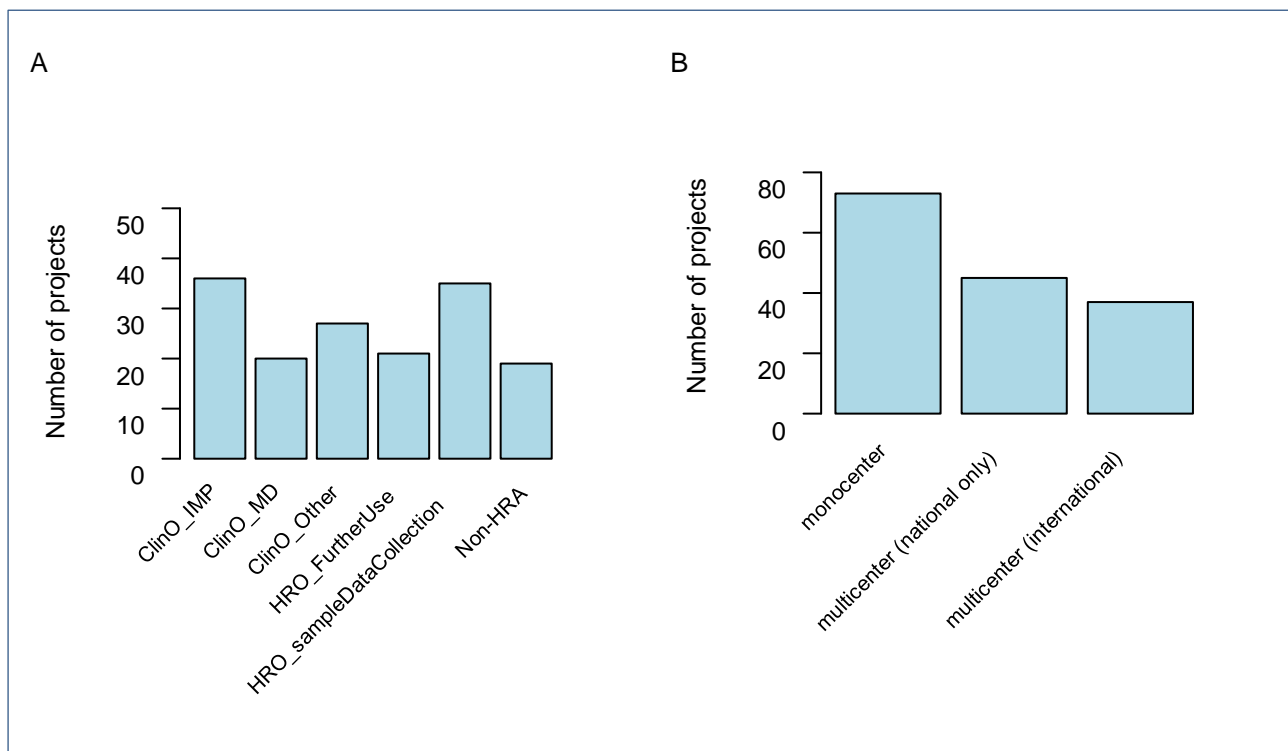


Table 14: Characteristics of projects: applicable ordinance (A) and number of sites (B)



3.3.4 Teaching/GCP Courses

CTU Bern aims to provide high quality education that is of relevance for participants (beside regulatory requirements). Attendance to courses by CTU is an indicator of acceptance by local researchers and evaluation by participants is the main measure to quantify quality.

KPI Definition	Threshold
#1 Percentage change in the overall number of participants of basic and advanced GCP courses from median of previous three years to current QMR period.	Decrease $\leq 10\%$ (g) $>10\%$ (y) $>20\%$ (r)
#2 Mean grade for quality of presentation and topic's relevance across all basic and advanced GCP courses evaluation sheets in current QMR period.	Mean grade <5 (r)
#3 All GCP courses provided by CTU Bern are approved by Swissethics.	At least one GCP course not approved by Swissethics (red)

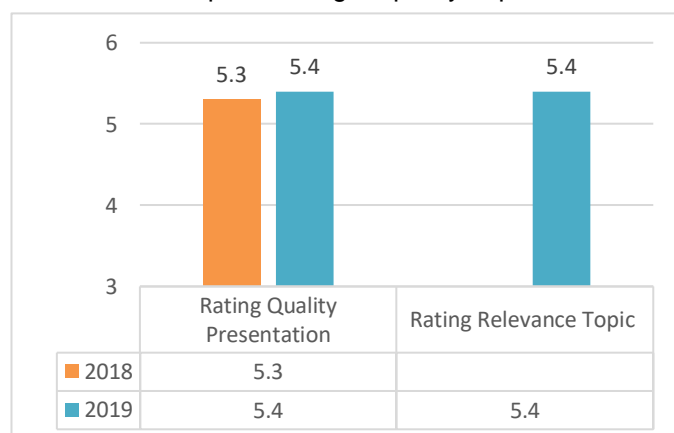
KPI Results/Evaluation	Status
#1 Percentage change in the overall number of participants in Basic GCP course is +1% (N = 109) Percentage change in the overall number of participants in Advanced GCP course is -36% (N=74) No CGP Refresher coursed have been provided in current QMR period	● ●
#2 Mean grade for quality of presentation and topic's relevance across all basic and advanced GCP course is: 5.4	●
#3 All GCP courses provided by CTU Bern are approved by Swissethics.	●

Action Plan

- AI Reinststate GCP Refresher Course (as part of regular CTU lectures). Obtain Swissethics approval / accreditation for course.

Details

Table 15: Participants rating of quality of presentation and relevance of topic



3.3.5 Scientific Output and Grants

CTU Bern aims to increase the number of projects supported by independent, competitive grants. This funding ensures sufficient resources and independence. The KPI ensures that this strategy can be fulfilled.

KPI Definition	Threshold
#1 Percentage change in the overall number of original publications (as supplied to the medical faculty by the library) with CTU Bern from median of previous three years to current QMR period.	Decrease $\leq 10\%$ (g) $> 10\%$ (y) $> 20\%$ (r)
#2 Relative Citation Ratio of original publications (as supplied to the medical faculty by the library) with CTU Bern contribution from the last five years including the current QMR period.	≥ 1.0 (g) < 1.0 (y) < 0.8 (r)
#3 Number of submitted grants with CTU Bern contribution (consulting, partner, or applicant) submitted to the Swiss National Science Foundation, Innosuisse, European Union funding bodies, charities or other funding bodies with peer review in the current QMR period.	≥ 8 (g) < 8 (y), < 5 (red)

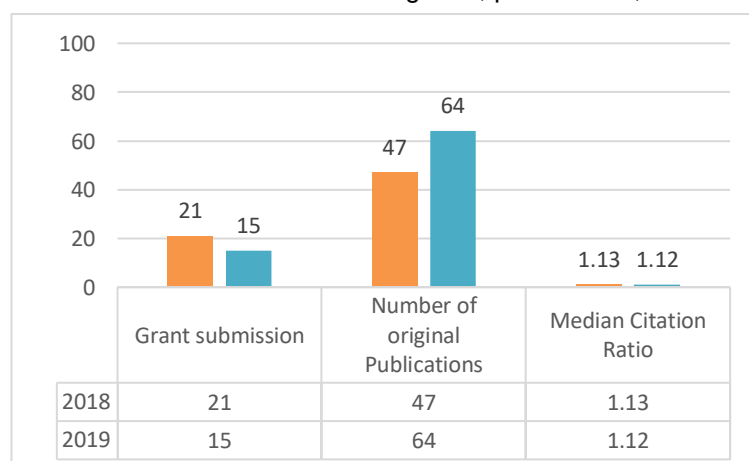
KPI Results/Evaluation	Status
#1 CTU Bern overall number of original publications in 2019 is 64, which equals as +36% compared to the median of previous three years.	●
#2 The relative Citation Ratio of original publications of the last five years, including the QMR period is 1.12	●
#3 CTU Bern submitted 15 grants in total, 9 as a partner and 6 as contributor.	●

Action Plan

N/A No actions required as all KPIs green.

Details

Table 16: Overview of submitted grants, publications, and median citation ratio 2018-2019



3.3.6 Nonconformities & CAPAs

Assess CAPA completion rate of identified errors, audit and internal review nonconformities. Evaluating the effectiveness of implementing corrective and preventive actions and closing these within an adequate timeframe for any issues identified at the CTU.

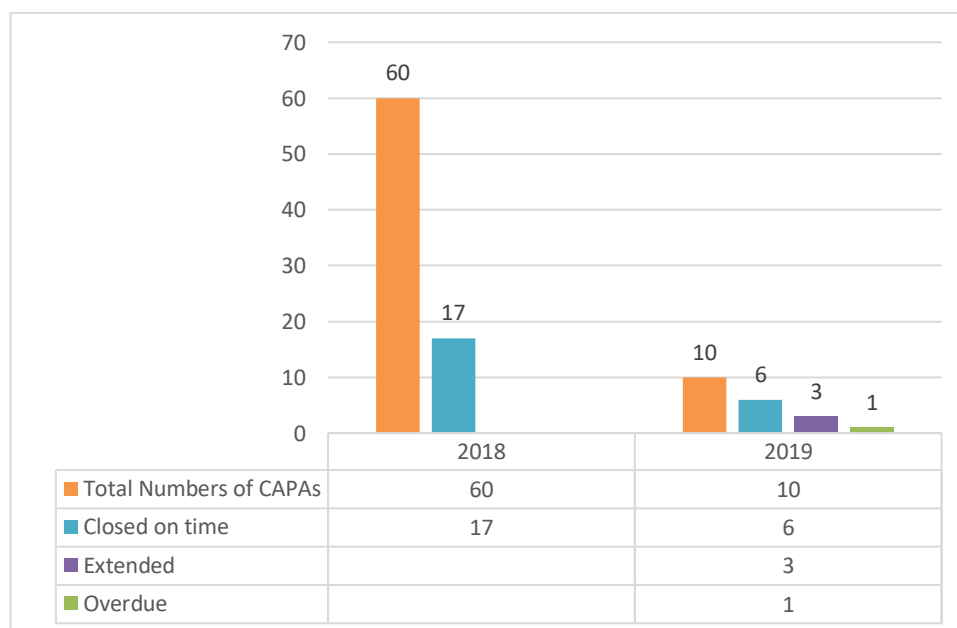
KPI Definition	Threshold
#1 Number of identified corrective and preventive actions (CAPA) resulting from nonconformities (NC) identified from Internal Quality Reviews, Audits or Errors	Qualitative assessment
#2 Percentage of CAPA closure rate in time (according to due date)	> 80% (g) <80% (y) ≤ 50% (r)

KPI Results/Evaluation	Status
#1 Number of CAPAs opened in 2019 is ten .	●
#2 Six (60%) of the opened CAPAs were closed on time/as planned. Three CAPAs were extended, as their managing required more time and one CAPA remains overdue.	●

Action Plan	
AI	Install monthly CAPA due date monitoring to further improve on CAPA closure rate.

Details

Table 17: CAPA closure rate 2018-2019



3.3.7 Internal Audit Compliance

To measure the capacity of CTU Bern to determine and conduct internal audits and to ensure adherence to processes and facilitate continuous development and improvement of CTU Bern. Evaluate adherence to yearly internal audit plan.

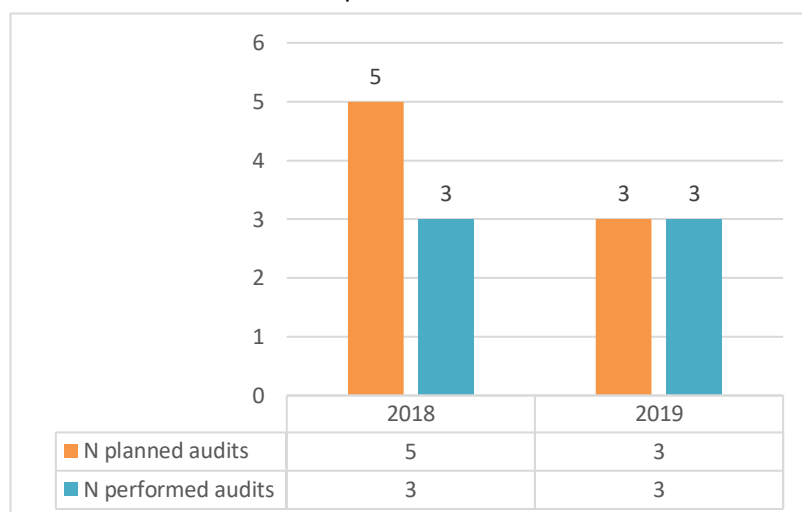
KPI Definition	Threshold
#1 Completion rate and adherence to yearly CTU internal audit plan.	Qualitative assessment

KPI Results/Evaluation	Status
#1 Three of three planned internal audits were performed in 2019 (completion rate of 100%).	●

Action Plan
N/A No actions required as KPI green.

Details

Table 18: Internal audit compliance CTU Bern 2018-2019



3.3.8 External Audit Compliance

Evaluate CTU compliance towards external customer expectations and certification body requirements.

	KPI Definition	Threshold
#1	Quantitative and qualitative evaluation of identified findings/ observations from external audits hosted at CTU Bern in QMR period.	N of findings: No threshold Classification: 0 critical findings (g) ≥ 1 critical finding(s) (r) Certification body: certification obtained/ maintained All assigned CAPA closed as per defined due dates

	KPI Results/Evaluation	Status
#1	Two external audits were hosted at CTU Bern <ul style="list-style-type: none"> ▪ One audit hosted for Scope I trial ▪ One audit hosted to obtain ISO 9001:2015 Certification <p>Zero critical findings in total of both audits.</p> <p>All other findings successfully clarified and/or assigned CAPA closed.</p> <p>ISO 9001:2015 Certification was obtained upon closure of one major and two minor findings.</p>	

	Action Plan
N/A	No actions required as KPI green.

	Details
N/A	

3.3.9 Performance of External Providers

To measure the compliance of the CTU to only use approved/certified vendors for clinical research related services.

	KPI Definition	Threshold
#1	Vendor performance review based on CTU qualification and evaluation process.	100% of qualified and approved vendors vs SLAs in place (g)

	KPI Results/Evaluation	Status
#1	CTU Bern exclusively cooperates with qualified or approved vendors. Two CTU vendors are qualified and six vendors are approved due to long standing operational relationship. One vendor qualification was withdrawn in 2019.	

	Action Plan
N/A	No actions required as KPI green.

	Details
N/A	

4. Additional Key Figures for Inselspital Directorate Research and Teaching (Direktion Lehre und Forschung)

New research databases from Inselspital supported by CTU Bern: **49**

- thereof basic/light service: **39**
- thereof full service: **10**

Management secuTrial installation: **526h**

Management REDCap installation: **365h**

Management SharePoint projects: **299h**

5. Revision Index

Version	Section	Summary of changes	Reason for change(s)
01.01	4.	Correcting REDCap zero to REDCap light Removal of Share File Support	Correction Service no longer offered