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**UNIVERSITÄT
BERN**

Faculty of Medicine

CTU Bern

CTU Bern Annual Report on Key Performance Indicators 2018

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Abbreviations

CAPA	Corrective And Preventive Actions
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
FTE	Full Time Equivalent
KPI	Key Performance Indicator
SCTO	Swiss Clinical Trial Organisation
SOP	Standard Operating Procedure

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 report summarizes this effort and makes it transparent to the public.

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.

KPI Status Overview

KPI ¹ Number	Name	T ²
1.	Actions from previous management review	
1.1	Number of CAPA	n/a
1.2	% of CAPA closed in time	n/a
2.	Continuous Development of CTU Bern	
2.1	Significant CTU Changes	Green
2.2	Risk Reviews	Yellow
2.2.1	Overall number of risks identified	Yellow
2.2.2	Number of new risks identified	Yellow
2.2.3	Number of errors that required a risk register update	Yellow
2.2.4	% of risks adequately mitigated	n/a
2.3	Resource Adequacy and Working Environment	Yellow
2.3.1	Finances: CTU balance accounts	Red
2.3.2	Personnel: overtime	Yellow
2.3.3	Personnel: health-related absences	Red
2.3.4	Personnel: resignation reasons	Green
3.	Process Performance, Conformity of Products and Services	Green
3.1	Customer Satisfaction	Green
3.1.1	% of satisfied customers for consultings	Green
3.1.2	% of satisfied customers for services	Yellow
3.1.3	Qualitative results	Green
3.2	Quality Objectives	Red
3.3	Institute Performance - Consulting	Green
3.3.1	% change in number of consultings from Inselspital	Green

¹ KPI, Key Performance Indicator

² Indicates whether a pre-specified performance/quality threshold was breached in this year. Green indicates that the particular goal was reached in this year, yellow indicates that the goal was not reached, and red indicates that the threshold was potentially critically breached (grey indicates that no quantitative threshold is applied).

KPI ¹ Number	Name	T ²
3.3.2	% change in number of consultings from University Bern	
3.3.3	Number of consultings in the current QMR (Insel)	
	Number of consultings in the current QMR (Uni)	
3.3.4	% change in the overall number of consultings	
3.4	Projects	
3.4.1	% change in the overall number of projects	
3.4.2	% change in the number of projects with Inselspital or University of Bern	
3.4.3	% change in the overall number of clinical trials	
3.4.4	% change in the number of projects supported by Data Management	
	% change in the number of projects supported by Monitoring	
	% change in the number of projects supported by Statistics	
3.5	Teaching/GCP courses	
3.5.1	% change in the overall number of participants	
3.5.2	Mean grade for quality of presentation	
3.5.3	Mean grade for topic's relevance	n/a
3.5.4	All GCP courses approved by swissethics	
3.6	Scientific output and grants	
3.6.1	% change in the overall number of publications	
3.6.2	Relative Citation Ratio	
3.6.3	Number of submitted grants	
3.7	Nonconformities & CAPAs	
3.4.1	Number of identified CAPA resulting from NC	
3.4.2	% of CAPA closure rate in time	
3.8	Internal audit results	
3.9	Performance of external providers	

KPI Details

1. Actions from previous Quality Management Reviews (QMR)

KPI Details

KPI defined in two ways:

- 1.1.** Number of CAPAs originating from last year's QMR
- 1.2.** Percentage of these CAPAs closed in time

Threshold

1. No threshold defined (KPI primarily used for context)
2. <80% (yellow), <=50% (red)

Results

Not applicable as there was no quality management review in 2017

2. Continuous Development of CTU Bern

2.1. Significant Internal / External Changes CTU

KPI Details

Internal and external changes that potentially have an impact on CTU's quality management system should be proactively managed. To illustrate trends in regard to internal changes.

Threshold

N/A, qualitative assessment

Results

Table 1 Summary of evaluations done during the reporting period

Month	Source of changes		Topic	Actions taken
Mai	EU Regulations (General Data Protection Regulation (GDPR))	External	Change in data privacy regulations	GDPR Project on SCTO level; Guideline dev. 2019
Sept	Swissmedic	External	Electronic submission procedure for clinical studies with medical devices	INSEL SOP adapted with new submission requirements
n/a	CTU structure	Internal	CTU Bern as independent institute	Updates to Quality Manual, Organigram

Action Plan & Root Cause

All changes were adequately implemented via respective document amendments (as applicable).

2.2. Risk review (risks and opportunities)

KPI Details

To illustrate risk awareness and the proactive management of risks and opportunities and their impact on the CTU quality management system:

1. Overall number of risks defined
2. Number of new risks identified in current reporting period
3. Number of errors that required a Risk Register update in reporting period
4. Percentage of risks adequately mitigated and as such below a risk score of 12

Threshold

1. No threshold i.e. qualitative assessment
2. No threshold i.e. qualitative assessment
3. No threshold i.e. qualitative assessment
4. <95% (yellow), <80% (red)

Results

1. Number of identified risks in 2018 is 64
2. Number of newly identified risks and mitigation actions (Risk Register) within reporting period is 0
3. Number of new risks based on reported errors within reporting period is 0
4. Not applicable (see action plan below)

Action Plan & Root Cause

1. As part of the regular Risk Register Review in 2019 the high number of risks for the Clinical Investigation division will be re-evaluated and critically assessed.
2. The number was considered low → a more proactive management of Risk Register might be warranted → a review of adequacy of risks with all heads of divisions will be done in 2019 and risks amended as needed.
3. The number was considered low → a more proactive management of Risk Register might be warranted → it will need to be ensured that an adequate risk review with the respective head of division is done whenever an error is reported through CTU's internal error management system.
4. After review of the methodology behind CTU Bern's Risk Register approach it was noted that current risk scores represent risk scores before implementation of mitigation actions → new risk calculation to be implemented to calculate remaining risk after implementation of mitigation actions.

2.3. Adequacy of resources and working environment

KPI Details

To ensure adequate resources within CTU Bern. Overtime as a measure of sufficient staffing
 Sick leave data to indicate stress. Reasons for resignation to ensure that resignations are not related to the working environment (stress, supervision, etc.)

1. Finances: Balance across all CTU accounts as per last day of current reporting period minus costs for all staff as per last day of current reporting period for three months (costs for Full Time Equivalents (FTEs) covered by cantonal points are deducted) divided by costs for all staff as per last day of current reporting period for three months (costs for FTEs covered by cantonal points are deducted)
2. Personnel: Percentage of employees with more than 100 hours overtime
3. Personnel: Percentage of employees with health-related absences more than 2.5% of their working time
4. Personnel: Reasons for resignations within the current reporting period

Threshold

1. <-50% (yellow), <-100% (red)
2. >5% (yellow), >10% (red)
3. >5% (yellow), >10% (red)
4. No threshold i.e. qualitative assessment

Results

1. The balance across CTU accounts was insufficient
2. The percentage of employees with more than 100h overtime is: 8.2% (N = 49)
3. The percentage of employees with health-related absences more than 2.5% of their working time is: 16.3% (N = 49)
4. N/A

Action Plan & Root Cause

1. Insufficient income → Hourly rates increased; closer project monitoring and reporting of recorded project hours.
2. No action required at the moment (different priorities for 2019)
3. No action required at the moment (different priorities for 2019)
4. No action required at the moment as none of the reasons was of concern

3. Process Performance and Conformity of Products and Services

3.1. Customer Satisfaction

KPI Details

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

1. Percentage of satisfied customers (score ≥ 5) over all consultings in the current reporting period
2. Percentage of satisfied customers (score ≥ 5) per service in the current reporting period
3. Qualitative results i.e. comments

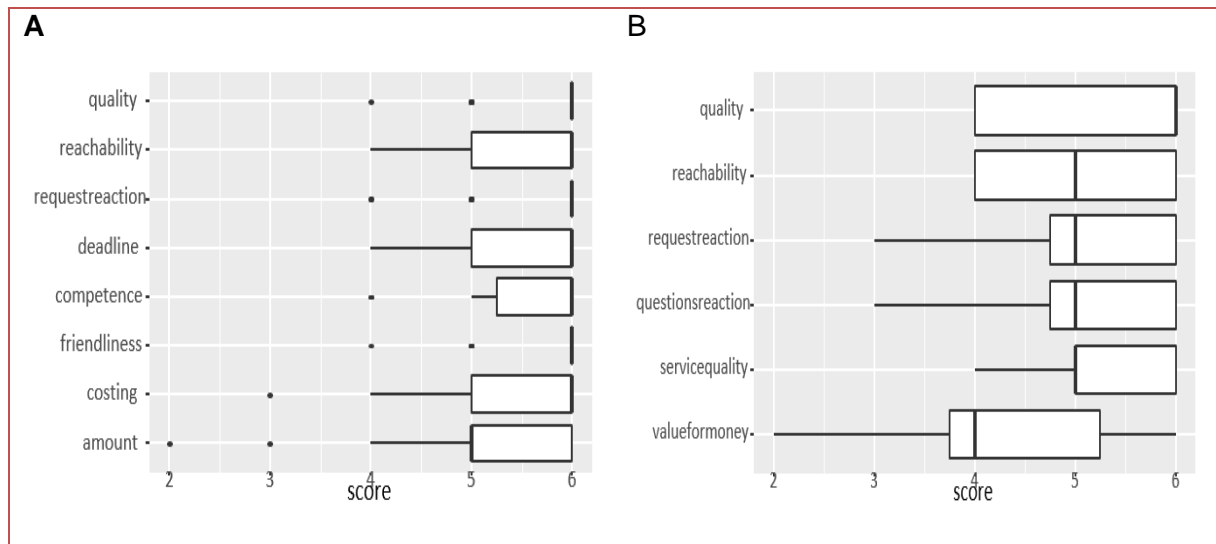
Threshold

1. <80% (yellow), <67% (red)
2. <80% (yellow), <67% (red)
3. No threshold defined, qualitative assessment with a special focus on critical/negative comments

Results

1. The percentage of satisfied customers over all consultings (with available answers) is: 89.4% (N = 104); 2% of negative/critical comments.
2. The percentage of satisfied customers over all services (with available answers) is: 68.8% (N = 16).
3. Negative comments on prices/cost estimates: feedback questionnaire was sent out too early and could not be answered. Low distribution rate as (apart from data management) questionnaire was not sent upon service closure. Negative comments on prices/cost estimates.

Figure 1 Customer feedback on consultings (panel A, N = 104) and completed services (panel B, N = 16)



Action Plan & Root Cause

1. Clarification on cost estimates/prices:
 - a. New costing template lists pivotal assumptions i.e. study parameters
 - b. CTU Newsletter (March 2019) released to explain new CTU costings valid from 01.04.2019
 - c. CTU website updated with reduction scheme and new rates
 - d. Questionnaires only sent out after consulting is closed (status "closed" in projectfacts i.e. CTU's project management software)
 Open Action: Consider to add "not applicable" to questionnaire items
2. Improve initiation of sending out feedback surveys by implementing changes in CTU Bern's project management software (dedicated sections)

3.2. Evaluation of self-determined quality objectives for the reporting period

KPI Details

To measure the capacity of CTU Bern to determine and implement quality objectives to ensure continuous development and improvement of CTU Bern i.e. each year, CTU Bern determines quality objectives for the next twelve months. The KPI measures whether the self-determined quality objectives were met/achieved. The quality objectives for the reporting period were:

1. Communication strategy regarding errors/incidents: Improve internal communication; Work on elements and tools; Team members informed; Proof of use of communication; Documentation of errors, near-errors and measures to improve overall.
2. Internal audits: Standard Operating Procedure (SOP) for internal audits; Templates for audit planning, conduct and documentation; Audit plan for 2018/2019 released; Results from internal audits documented; Staff members aware of audit SOP and results.
3. Computer System Validation: SOP for assessing, documenting and verifying GCP-compliant computerized systems is in place. Staff members are aware/trained.

Threshold

<80% (yellow), $\leq 50\%$ (red)

Results

1. Objective not met due to staff changes in the quality management division. However, internal error management including communication was structured.
2. SOP and templates effective; three of five planned internal audits performed; Additional six internal reviews done for one particular trial; Audit reports with CAPAs in place; Results communicated at staff meetings.
3. Manual for secuTrial in place; Computer System Validation training available.

Action Plan & Root Cause

Consider more conservative planning of self-determined quality objectives; critically assess available resources. Potentially: consider short-term objectives (quarterly or yearly) on smaller scale.

3.3. Institute Performance – Consulting

KPI Details

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

1. Percentage change in the number of consultings with person from Inselspital from median of previous three years to current reporting period
2. Percentage change in the number of consultings with persons from institutes of the Faculty of Medicine of the University of Bern from median of previous three years to current reporting period
3. Number of consultings in the current reporting period according to the primary institution (distinct Inselspital clinical departments and institutes of the Faculty of Medicine, other University of Bern institutes, external non-profit, and external for-profit institutions)
4. Percentage change in the overall number of consultings from median of previous three years to current reporting period

Threshold

1. >10% decrease (yellow), >20% decrease (red)
2. >10% decrease (yellow), >20% decrease (red)
3. <25 different Inselspital clinical departments or <7 medical faculty institutes with at least one consulting in the reporting year (yellow), <20 different Inselspital clinical departments or <5 medical faculty institutes with at least one consulting in the reporting year (red)
4. >10% decrease (yellow), >20% decrease (red)

Results

1. Percentage change of consultings from Inselspital is: -2.7% (N = 178)
2. Percentage change of consultings from University of Bern is: 38.7% (N = 43)
3. Number of consultings at Inselspital departments is: 178. Number of consultings at institutes of the medical faculty of University of Bern is: 43
4. Percentage change of overall consultings is: 0.8% (N = 244)

Action Plan & Root Cause

None as all KPIs are green

Figure 2 Consulting numbers (A) and time effort (B) per institution

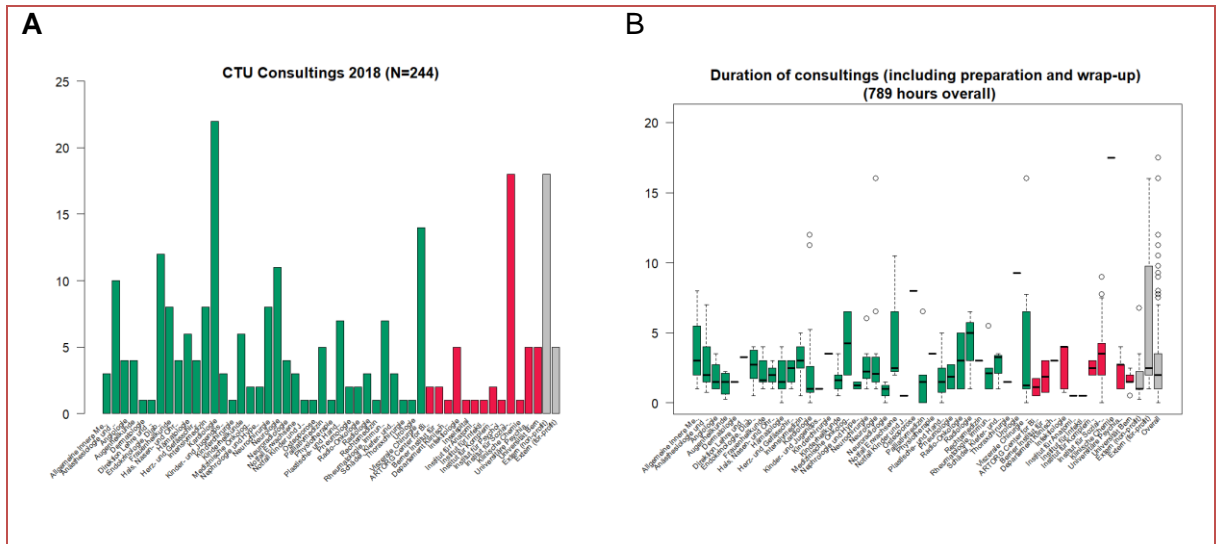
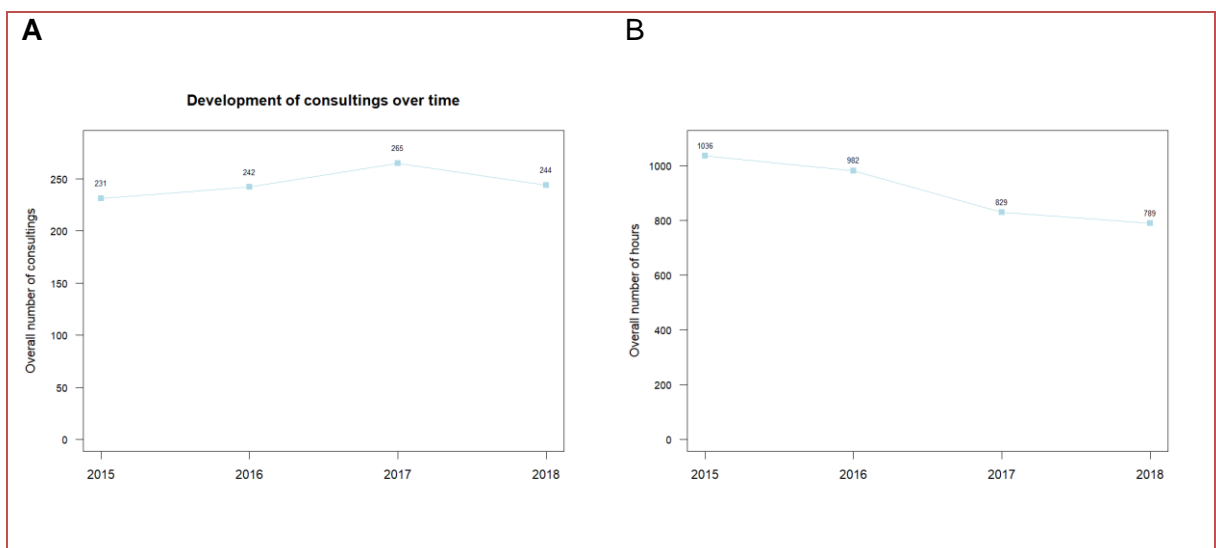


Figure 3 Development of the number (A) and time effort (B) of consultings over time



3.4. Institute Performance – Projects

KPI Details

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 is reached:

1. Percentage change in the overall number of projects (with at least eight recorded working hours in current reporting period) from median of previous three years to current reporting period.
2. Percentage change in the number of projects (with at least eight recorded working hours in current reporting period) with Inselspital or University of Bern as sponsor from median of previous three years to current reporting period.
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.
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.

Threshold

1. >10% decrease (yellow), >20% decrease (red)
2. >10% decrease (yellow), >20% decrease (red)
3. >10% decrease (yellow), >20% decrease (red)
4. >20% decrease (yellow), >30% decrease (red)

Results³

1. Percentage change in the overall number of projects is: 15.3% (N = 181).
2. Percentage change in the overall number of projects with Inselspital or University is: 17.6% (N = 147).
3. Percentage change in the overall number of clinical trials is: 14.7% (N = 78).
4. Percentage change in the number of projects for Data Management is : 13% (N = 113). Percentage change in the number of projects for Monitoring & Regulatory Affairs : - 1.8% (N = 56). Percentage change in the number of projects for Statistics & Methodology is: 11% (N = 101).

Action Plan & Root Cause

N/A as all KPIs are green.

³ Comparison made only with data from 2017.

Figure 4 CTU projects according to contract partner institution

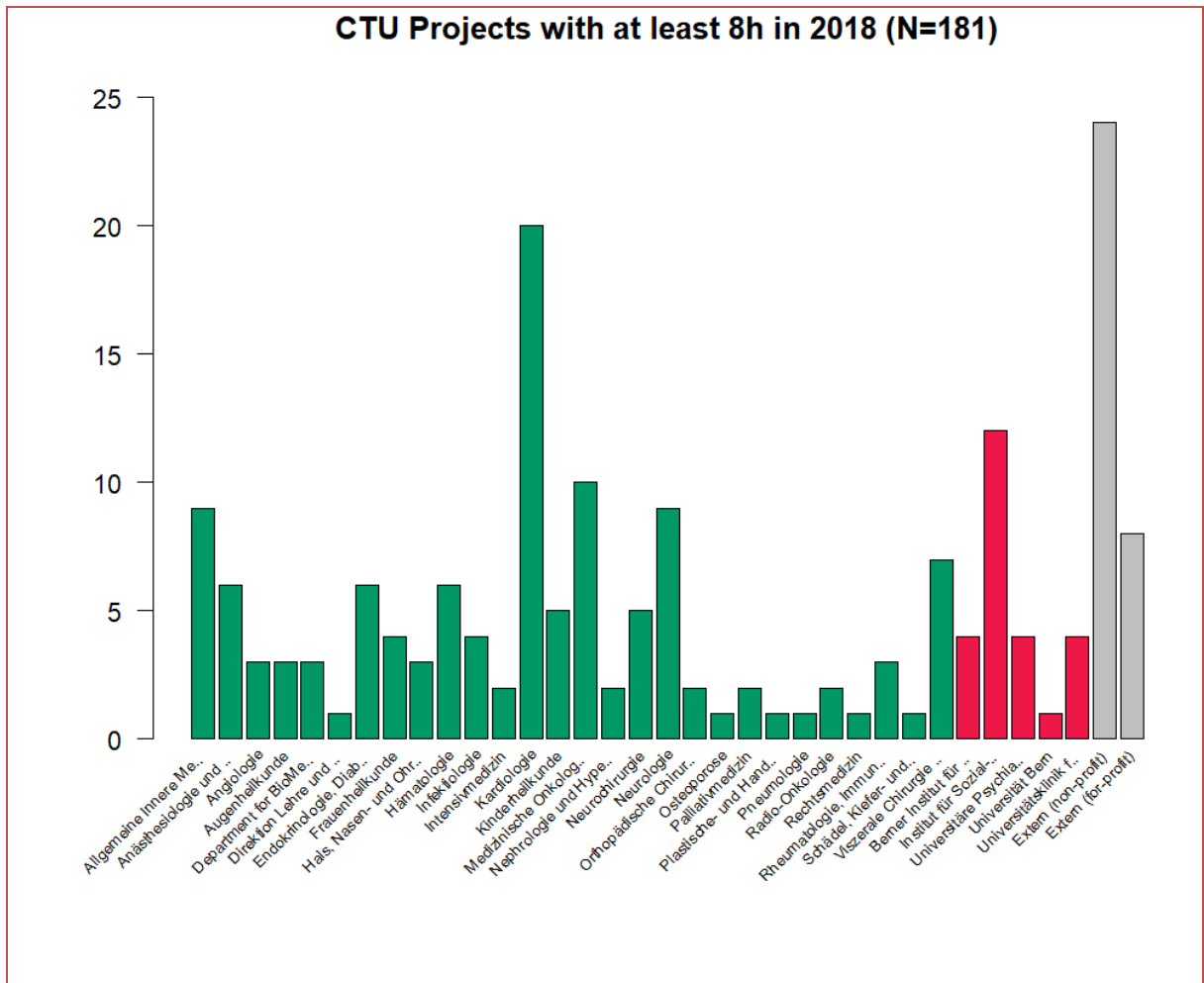


Figure 5 Involved CTU divisions

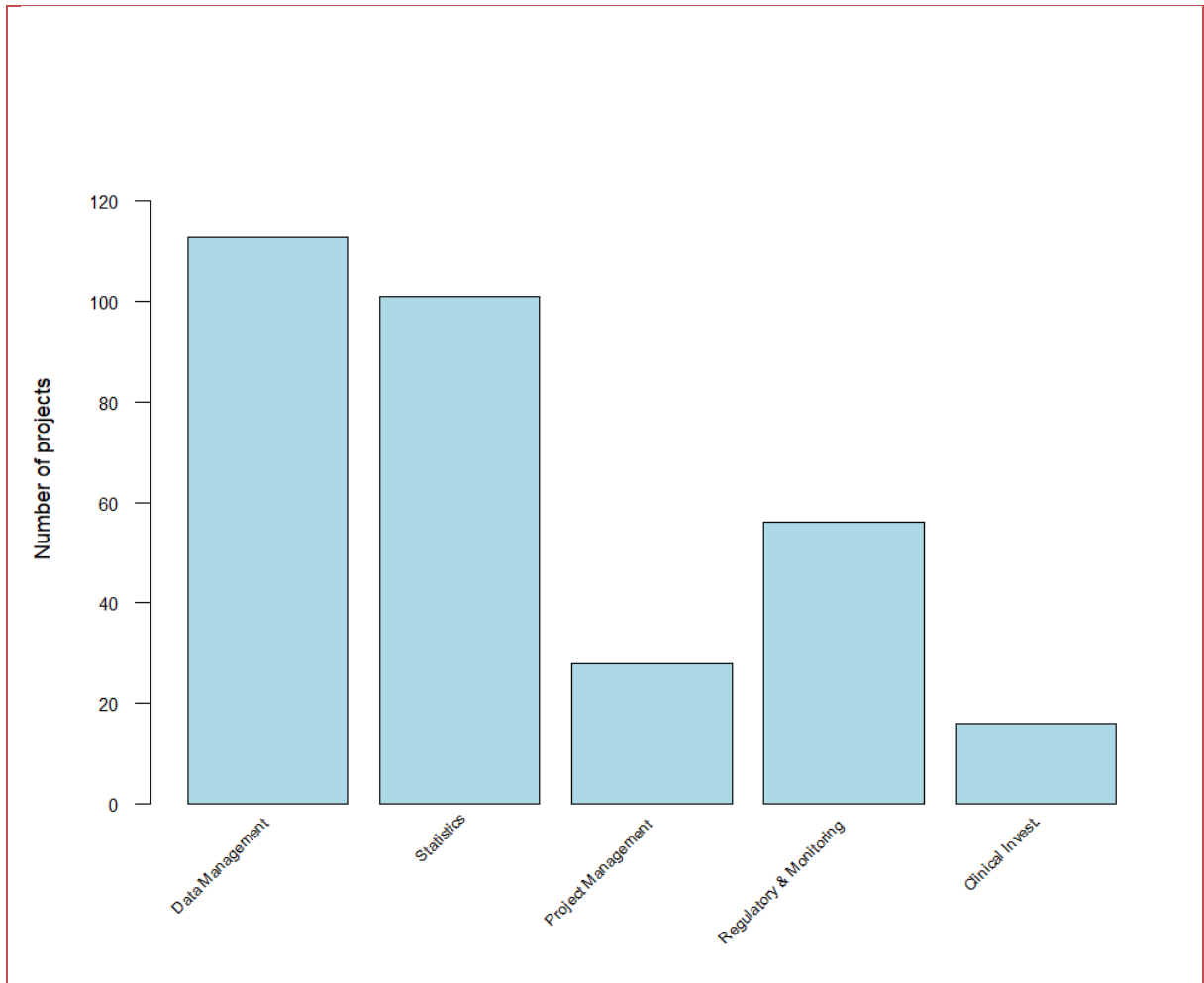
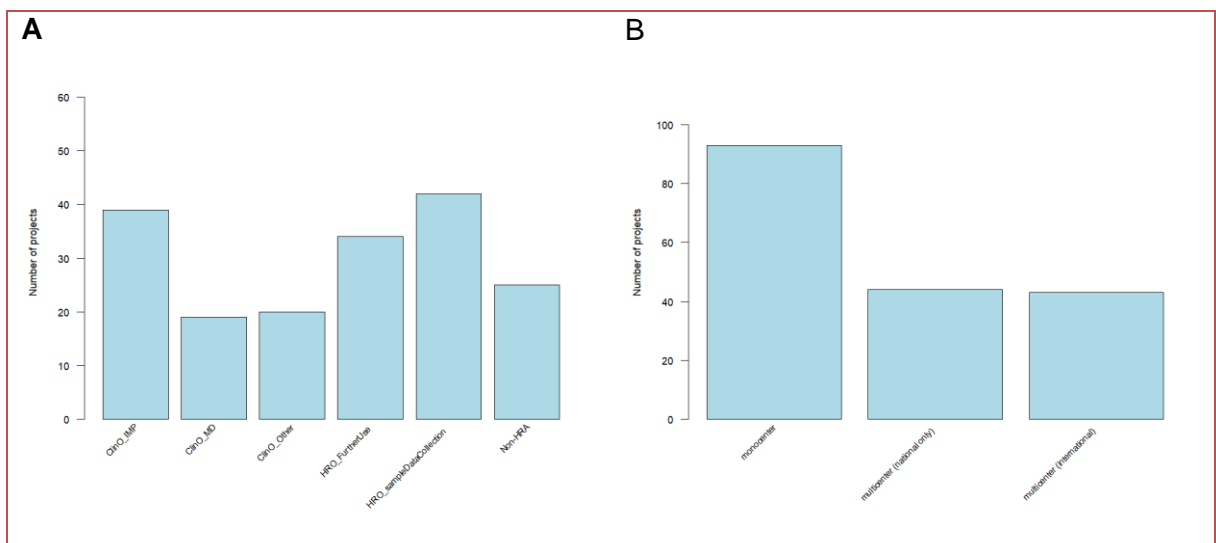


Figure 6 Characteristics of projects: applicable ordinance (A) and number of sites (B)



Selected projects started this year

ESTxENDS: A multicenter randomized-controlled trial to assess the efficacy, safety and toxicology of Electronic Nicotine Delivery Systems as an aid for smoking cessation (<https://clinicaltrials.gov/ct2/show/NCT03589989>)

Friendship Bench Study: A cluster randomized-controlled trial examining the effect of a psychological intervention on antiretroviral therapy outcomes and symptoms of common mental health disorders among adults living with HIV and common mental disorders in rural Zimbabwe (<https://clinicaltrials.gov/ct2/show/NCT03704805>)

OPTICO LM: A single-arm trial to compare Optical Coherence Tomography-derived minimal lumen area, invasive Fractional Flow Reserve and Fractional Flow Reserve from computed tomography in patients with significant left main coronary artery stenosis. (<https://clinicaltrials.gov/ct2/show/NCT03820492>)

Selected projects finished this year

Several large projects in cardiology were finished (all major tasks of CTU Bern completed) in the reporting period including the BIOSCIENCE trial (NCT01443104) and MATRIX (NCT01433627).

3.5. Teaching/GCP courses

KPI Details

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.

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.
2. Mean grade for quality of presentation across all basic and advanced GCP courses evaluation sheets in current QMR period.
3. Mean grade for topic's relevance across all basic and advanced GCP courses evaluation sheets in current QMR period.
4. All GCP courses provided by CTU Bern are approved by swissethics.

Threshold

1. >10% decrease (yellow), >20% decrease (red)
2. Mean grade <5 (red)
3. Mean grade <5 (red)
4. At least one GCP course not approved by swissethics (red)

Results

1. Percentage change in the overall number of participants is: -9.6% (N = 179).
2. Mean grade for quality of presentation across all basic and advanced GCP course is: 5.28.
3. Not analysed this year.
4. All GCP courses provided by CTU Bern are approved by swissethics.

Action Plan & Root Cause

N/A as all KPIs are green.

Figure 7 Involved CTU divisions

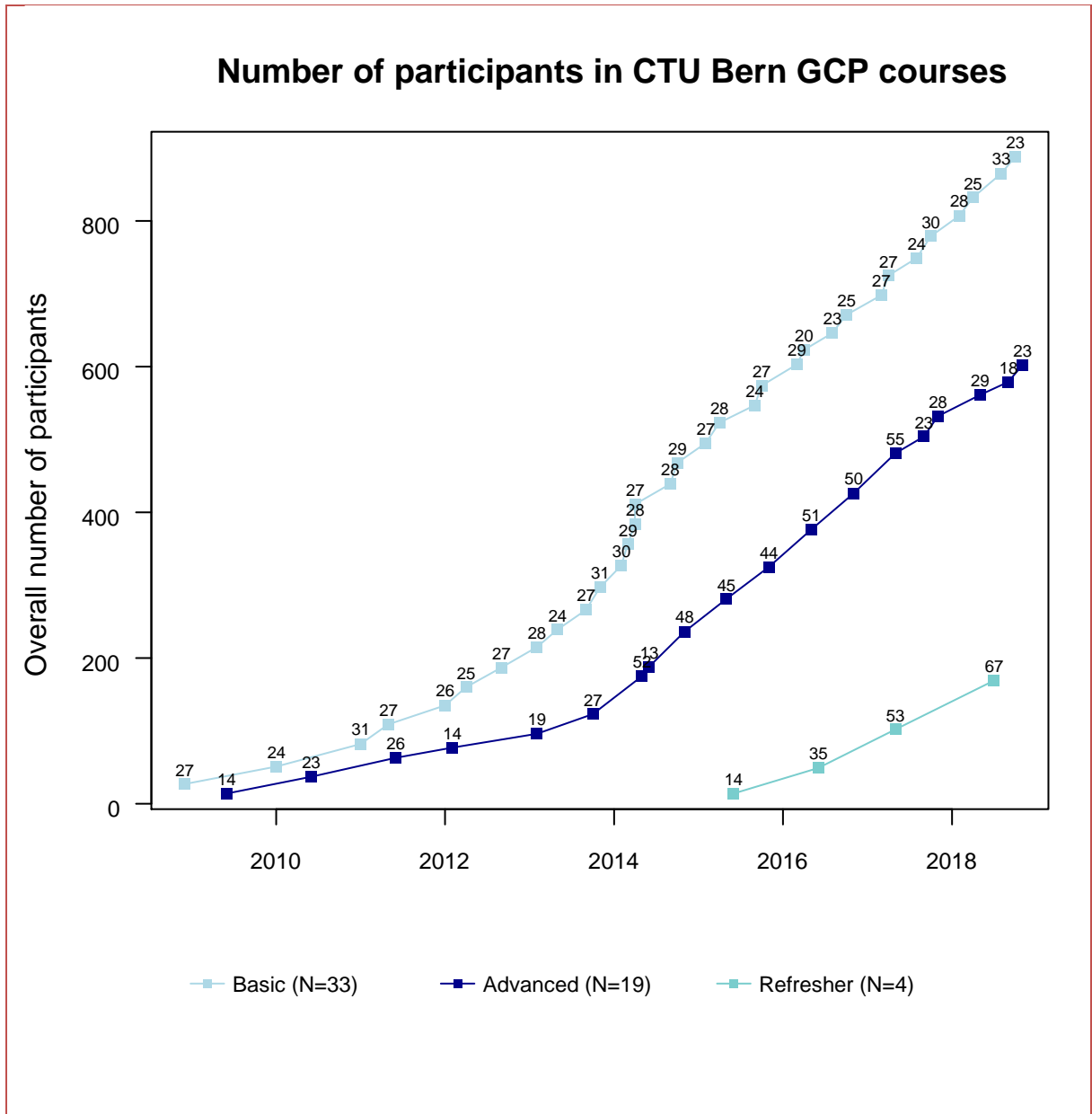


Table 2 Number of CTU course attendees

	University	Inselspital	External	Total
Basic	48	26	35	109
Advanced	29	22	19	70
Refresher	2	43	22	67
REDCap	36	61	26	123

3.6. Scientific output and grants

KPI Details

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.

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.
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.
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.

Threshold

1. Threshold for publications: >10% decrease (yellow), >20% decrease (red)
2. Threshold for citation ratio: <1.0 (yellow), <0.8 (red)
3. Threshold for number of grants: <8 (yellow), <5 (red)

Results

1. Percentage change in the number of publications is: 5.9% (N = 54).
2. The median of the relative citation ratio is: 1.13.
3. The number of grants submitted is: 21.

Action Plan & Root Cause

N/A as all KPIs are green.

3.7. Nonconformities & CAPAs

KPI Details

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.

1. Number of identified corrective and preventive actions (CAPA) resulting from nonconformities (NC) identified from Internal Quality Reviews, Audits or Errors.
2. Percentage of CAPA closure rate in time (according to due date).

Threshold

1. No threshold i.e. qualitative assessment
2. <80% (yellow), $\leq 50\%$ (red)

Results

1. Number of CAPAs: 60 among which 39 closed. 17 out of 39 were closed on time (44%).
2. Percentage of CAPA closed 2 weeks over: 8 out of 39 (21%)

Action Plan & Root Cause

Low percentage on CAPAs closed in time: 17 out of 39 were closed in time; further 8 within 2 weeks of due date => 65% almost within due date. Action – more adequate due dates; stricter CAPA due date monitoring (within QM).

3.8. Internal Audit Results (compliance)

KPI Details

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.

Completion rate and adherence to yearly CTU internal audit plan.

Threshold

No threshold i.e. qualitative assessment.

Results

Planned internal audits: 5; Performed internal audits: 3 + 6 additional. Total met: see evaluation of quality objectives for details.

Action Plan & Root Cause

N/A – internal audit plan for 2019 under review; reduction of internal audits to take into consideration ongoing ISO 9001 certification and expected external audit on SCOPE 1 trial (Boston Scientific; June2019).

3.9. Performance of External Providers

KPI Details

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

Vendor performance review based on CTU qualification and evaluation process.

Threshold

Number approved/ qualified vendors; Number discontinued vendors; % of qualified and approved vendors vs SLAs in place (threshold: 100%).

Results

CTU Bern works with two qualified and six approved vendors. All (100%) of CTU vendors are thus qualified or approved. No vendors were discontinued in 2018.

Action Plan & Root Cause

N/a as all KPIs are green.

4. Additional key figures for Inselspital Directorate Research and Teaching

1. New research databases from Inselspital supported by CTU Bern: N = 53 (434 h)
 - thereof basic/zero service: N = 36
 - thereof full service: N = 15
2. Management secuTrial installation: 645.95 h
3. Management REDCap installation: 322.5 h
4. Management SharePoint projects: 186.2 h
5. Management ShareFile support Inselspital: 28 h