TFS
SUSTAINABILITY REPORT

2019

TFS
It's all about trust

TABLE OF CONTENTS

WORD FROM THE CEO

TFS considers a sustainable environment, not preferable to the business, but integral to the organization across the board. It takes passion to accomplish great things and a company's success depends on the commitment of its employees. TFS corporate culture underpins this approach and thrives on delivering quality services considering sustainability as a pillar in partnering with the customers in their clinical journey. TFS is proud of our diverse teams and our continuous improvements in sustainability. This statement confirms the company's long-lasting commitment across the board. The most important sustainability focus area for TFS involve equal opportunities, patient safety and data integrity, compliance with regulations, talent development, business ethics and anti-corruption. TFS also places great importance on equal opportunities and diversity.

TFS operates in an industry focused on improving and refining the delivery of better healthcare outcomes, in order to contribute to public health. TFS' in-depth knowledge of regulatory and local clinical trial requirements allows us to contribute to global trials helping to bring treatments to patients faster.

Since our foundation over 20 years ago, TFS has always set the highest expectations for our business conduct and integrity. Our motto, "It's all about trust," summarizes this value clearly. Operating with integrity is the cornerstone of the TFS culture for all our employees. At TFS, we strive to ensure that everything we do is guided by our values and is in compliance with the governmental regulations and overall regulatory framework within which we operate.

Our work and contribution to sustainability improvements has an important social, economic and environmental impact. However, since we operate as a consultancy organization and service provider, our definition of and approach to sustainability differs from traditional manufacturing industries.

Bassem Saleh
CEO

WORD FROM CEO cont.

At TFS our sustainability focus stems from our unassailable commitment to ensure adequate action and oversight in areas such as:

The **TFS Code of Conduct**, which outlines our corporate commitment to transparent and ethical behavior.
The **Working Environment,** which must be safe and stimulating, and encourage empowerment, engagement and development of our employees.
Ethical Research, which is upheld to the highest ethical, medical and scientific standards. No matter where we operate in the world, we remain committed to conducting clinical trials in accordance with the ethical principles that have their origin in the Declaration of Helsinki, as well as International Council on Harmonization (ICH) Good Clinical Practices (GCP) and other relevant guidelines.
The **Environment,** which concerns everyone on the planet. As a sustainable company, TFS must do its part to reduce climate impact and contribute to a better environment.
The **Vendors** collaborating with TFS, who should be able to demonstrate that they comply with the principles and requirements of our sustainability policies, or have their own sustainability policies with the same principles.

Consistent and long-term sustainability efforts lead to both environmental benefits and value. Our aim is to meet the expectations placed on us by our various stakeholders which take into account our business model and long-term, sustainable development. Building a successful, transparent, trusted and ethical company means we do not compromise our sustainability goals and that sustainability considerations are an integral part of our business activities.

Bassem Saleh
CEO

TFS IN BRIEF

TFS is a Contract Research Organization (CRO) supporting biopharmaceutical companies through the entire clinical development process by providing a broad range of professional services, information and partnering solutions. TFS was founded in 1996 and has grown to become the leading global mid-size clinical CRO focusing on small and mid-size Biotech customers. TFS employs more than 700 professionals throughout 15 countries and currently delivers clinical research services in more than 40 countries. We provide end-to-end solutions including full clinical development services, strategic resourcing and flexible single services. Our partnering approach with customers is based on our four business principles – commitment, flexibility, value creation and global reach.

The depth and breadth of services, along with therapeutic expertise and scientific knowledge ensure end-to-end, flexible solutions to meet the needs of TFS customers. Through therapeutically aligned business units TFS provides the best expertise, extensive site and key opinion leaders' network. Our core therapeutic specialties are Dermatology, Hematology and Oncology, Ophthalmology as well as Internal Medicine and Neurology.

TFS provides clinical development services within two business areas:

TFS Clinical Development Services (CDS) provides full-service clinical development support at all stages of the clinical development process, from early clinical development to post-authorization surveillance, including: development program planning, scientific advice, clinical operations, site coordination, data management, biostatistics, regulatory affairs, pharmacovigilance / safety monitoring, medical monitoring, medical writing, quality assurance, training and financial project management of clinical projects.

TFS Strategic Resourcing Solutions (SRS) provides resourcing solutions, from flexible staffing solutions to customized Functional Service Provider (FSP) programs. With the FSP model customers can focus on their core business and TFS will ensure adherence to timelines, quality and costs. TFS is a trusted strategic outsourcing partner that can provide our customers with a fully operational team of clinical professionals in all functions and therapeutic areas. The team can be situated on site or work from one of TFS' regional offices. TFS' SRS managers ensure close management and oversight of all outsourced staff to ensure high quality performance.

As a service provider, TFS does not have its own brands or products, as do manufacturing companies.

Vision and Values

TFS bases its philosophy and values on trust. TFS has an enduring commitment to the highest ethical standards thereby ensuring the safety and care of patients in our clinical development programs and contributing to public health in general.

Our values are:

Trust: It's all about trust. We are a trusted strategic partner for our clients. We work with trust, transparency and honesty.

Quality: We focus on quality, it is an attitude. We deliver the highest quality outcomes for our clients. We are committed to our values and we protect our company culture.

Passion: We have a positive and committed attitude towards the customer's project. We are driven and engaged.

Collaboration: We believe in diversity and the power of global teamwork. Shared goals and mutual support lead to greater success.

Client focus

As the leading global mid-size clinical CRO, TFS has the experience and infrastructure to conduct its clients' clinical trials. TFS guides clients from clinical development planning to regulatory filing, providing flexible solutions while ensuring budget and deadlines are met and reducing clients' risks and delays.

Expertise

The depth and breadth of our service offerings, along with our therapeutic expertise and scientific experts, key opinion leaders and international project managers, ensure the best minds are working towards the success of clinical development programs.

Ownership and legal form

Since 2019, TFS Trial Form Support AB is 100% owned by Ratos Group, a publicly listed company.

TFS
It's all about trust

Governance Structure

The Board, composed of three external members, oversees TFS. The TFS Executive Committee is made up of the CEO and several (Executive) Vice Presidents, representing the main functional areas: Quality and Compliance, Business Development, Finance, Human Resources, Information Technology, Clinical Development and Strategic Resourcing.

The TFS Executive Committee is supported by a team of Operational Leaders, focused on areas such as Project Management, Clinical Operations, Site Management, and Biometrics.

TFS Executive Committee

DR. BASSEM SALEH
CHIEF EXECUTIVE OFFICER

DR. SUZANNE PAVON
EVP QUALITY AND COMPLIANCE

LARS WADELL
EVP FINANCE AND
CHIEF FINANCE OFFICER

YOUNG SHON
EVP INFORMATION TECHNOLOGY AND
CHIEF INFORMATION OFFICER
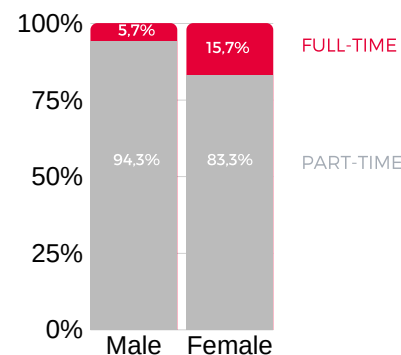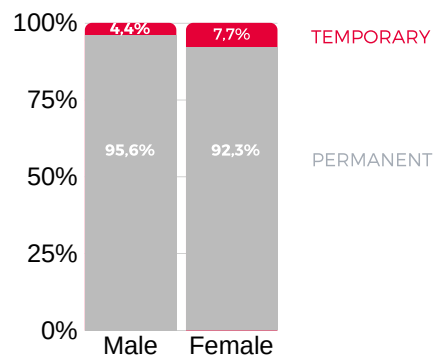
NINA HOLST
EVP AND HEAD OF SRS

ANDREIA DE MELO CABRAL
EVP AND HEAD OF HR

TFS employees

As of 31st of December 2019, TFS had 650 employees 15 countries (see appendix 1). The majority (93%) of TFS employees work in Europe and 7% work in the USA.

The number of TFS employees by contract and gender:

TFS
It's all about trust

Collective bargaining agreements

Collective bargaining agreements are in place in Spain, France and Italy; employees in these countries are covered by its content. These countries represent 38% of TFS staff.

Vendors and Suppliers

Since TFS is a service provider and not a manufacturer, we collaborate mostly with other service providers, referred to as Vendors, or in some cases, Subcontractors.

Suppliers are used for IT equipment and infrastructure, for example, companies that provide services related to offices and its equipment, and travel arrangements.

Finance

In 2019, the net sales was €87.3M including professional fees and reimbursable expenses. Consolidated balance sheet was €45.8M. Equity accounts for €7.1M. Total debt with financial institutions at €4.2M.

External Initiatives

In order to increase the impact of our efforts to help create a better world, TFS has formed partnerships with and taken inspiration from global organizations:
.
- TFS is a supporting partner of Plan International's 'Because I am a Girl' initiative Plan International is a development and humanitarian organization that advances children's rights and equality for girls.
- TFS's Code of Conduct is based on the United Nations (UN) Global Compact's 10 principles.
- TFS respects the UN Universal Declaration of Human Rights.
- TFS follow the UN Guiding Principles on Business and Human Rights.

TFS
It's all about trust

Memberships of Associations

TFS, its local offices or individual employees may be members of national and international associations. A non-exhaustive list is provided in the GRI Index below, Appendix 1.

TFS AND SUSTAINABILITY

TFS' 20+ year history, strong and active leadership, and the professionalism and dedication of all TFS employees contribute to our credibility and stability. TFS wants to ensure the success of clinical trials and clinical development programs, and we are convinced that sustainable business creates value and is a prerequisite for a sound and prosperous growth of the company, the people and the community.

Precautionary Principle

TFS strongly believes that consistent and long-term environmental work creates both environmental benefits and value. Our aim is to meet the expectations placed on us by our different stakeholders, considering our business model and long-term, sustainable development. In our operations, wherever possible, we work to reduce our environmental impact by preventing and reducing pollution and contribute to long-term, sustainable development through active and systematic environmental work.

TFS utilizes new technology innovations to reduce climate impact by, for example: contributing to recycling, having energy efficient offices, using eco-labelled office equipment, implementing a travel policy which requires avoiding unnecessary travel and reducing carbon emissions, moving towards a "green fleet" of environmentally classed company cars, and exploiting communication technology to facilitate travel-free meetings and interactions between our global locations.

However, despite the initiatives listed above, since TFS is not a production company that uses raw materials, water and energy, or generating waste and air pollution directly as a result of its service provision, historically climate and environmental issues have not been a main focus for TFS. TFS is actively determining how the precautionary principle applies to our business and can be implemented in the TFS strategy. With the implementation of a Facilities department, TFS is now able to ensure that our sustainability priorities also include increased and appropriate focus on environmental factors, which have received less attention in the past. TFS has begun to develop risk management related to environmental issues, including plans to define a supply chain program that will provide direction for the company strategy to managing environmental risk. By implementing a robust supplier engagement program, the company will gain stronger visibility to identify the environmental risk.

In 2019, TFS aimed to align corporate and supply chain environmental risk management goals, allowing us for the first time to assess the effectiveness of the strategies we have implemented to reduce our environmental impact. Business travel, particularly emissions from air travel is the major contributor to our environmental impact. Across a 12 month period, TFS has recorded a 12% decrease in CO_2 emissions as per reduced flights sourced from agencies and correlated efficiencies to overall decrease travel. TFS office footprint rental linking back to right-sized facilities over 2019 has also decreased by 19% and the volume of printing has dropped by 21%. Energy consumption is also an issue that we are studying in order to further minimize our climate impact. TFS will identify a relevant KPI for CO_2 emission reduction in 2020. This KPI will be linked to business travels.

Significant Changes in TFS

During 2019, TFS opened its new headquarters office in Lund Sweden. TFS has made many significant changes to its organizational structure and operating model and has implemented several advancements/initiatives to improve efficiency and quality of our services, starting with the appointment of a new CEO Bassem Saleh in December 2019 and then implementing a new organizational structure for TFS CDS and TFS SRS. This new structure aligns our operational delivery into two business areas and four business units, with a better focus and shift in our customers mix to enrich with small and mid-size Biotech's for our CDS business.

In addition, TFS continued leadership development through driving catalyst leadership meetings and correlated implementation of management projects, recruited more than two hundred new members to the TFS team; some were people who returned to TFS, promoted more than 30 employees, implemented a new Performance Management process and re-launched the Employee Engagement Survey in 2019.

TFS has become a truly global service provider. Our new Headquarters is a symbolic representation of what TFS wants to be. Expertise, innovation and great minds as well as recently introduced new operational alignment will enable us to execute our strategy and seize the many opportunities to come.

Focus on Sustainability

The company's focus for 2019 was establishing a new foundation on which TFS will grow.

Approach to Sustainability

Sustainability Reporting, Structure and Responsibilities

In 2015 TFS became part of the Ratos group. As a result, corporate responsibility and sustainability became a reporting topic for TFS with 2016 as the first reporting year. The 2019 report is therefore the fourth TFS sustainability report. The reporting cycle is annual; the reporting period for the 2019 report is 1st January – 31st December 2019. The previous report, covering the period 1st January – 31st. December 2018 was issued on 26th March 2019.

Within TFS, Sustainability Reporting is a responsibility of the Quality & Compliance department. The TFS Executive Committee is responsible for the information contained within the report. The contact point for questions regarding the report or its content is Suzanne Pavon, EVP, Head of Quality, Compliance and Corporate Legal (Suzanne.Pavon@tfscro.com)

This report has been prepared in accordance with the GRI Standards: Core option. To ensure compliance to GRI standards, the report has been prepared following guidelines from Enact, a consultancy company specializing in sustainability and corporate responsibility, and recommended by Ratos. The GRI Content Index can be found in Appendix 2.

No significant changes have been made in 2019 in relation to the list of material topics or topic boundaries from 2017. The 2019 report has been re-organized and llustrations have been used to improve the layout, but no other changes have been made to the reporting approach. A new employee survey was conducted in 2019 but no formal re-evaluation of other stakeholders / priorities was done in 2019, so the following two sections may contain restatements of some information from the 2018 report.

The report has not been assured by third party but PricewaterhouseCoopers AB (PwC) have issued an auditor's opinion in accordance with the Swedish Annual accounts act.

TFS Stakeholders and their Priorities

TFS has identified its main stakeholders and their key concerns, as listed below:

Stakeholder	Sustainability Issues
TFS Employees	• Work-life balance • Career opportunities • Talent development • Equal opportunities
TFS management and board	• Patient safety and data integrity • Business development • Structured and controlled work process • Business ethics and anti-corruption • Compliance with regulations
TFS owners	• Financial strength and resilience • Business ethics and anti-corruption • Business growth
TFS clients	• Compliance with regulations • Business ethics and anti-corruption • Employees (talent development, equal opportunities)
TFS vendors and subcontractors	• Compliance with regulations • Business ethics and anti-corruption
Regulatory authorities	• Compliance with regulations

Communication with stakeholders is conducted via a range of methods and platforms, some examples of which are described below.
.
- Employees provide feedback via regularly conducted employee surveys. (See focus area A: Equal Opportunities and focus area D: Talent Development).
- The Business Development team liaises directly with clients and is supported by the Marketing department which uses social media platforms such as LinkedIn and Twitter.
- The Business and Contracts department liaises with TFS vendors and TFS Project Managers collaborate closely with vendors during the contracted services.
- Communication with regulatory authorities mainly takes place as required by relevant regulations.

Materiality Analysis and Areas of Focus

An analysis of the company's role and impact on society and its stakeholders was carried out in 2017 in order to ensure appropriate measures are taken and prioritized. The materiality-matrix below is a presentation of TFS' most material sustainability issues, and how they relate to its business and operations.

Materiality is determined from both a stakeholder significance and economic, environmental and social impact.

Sustainability topics discussed for 2019 have not been modified since approved in 2017.

	Significance for TFS → Low ... High
High (Significance for TFS stakeholders)	• Career opportunities • Work-life balance • Structured and controlled work proces	• Equal opportunities • Patient safety and data integrity • Compliance with regulations • Talent development • Business ethics and anti-corruption
Low	• Energy consumption • Emissions	• Business development • Business growth • Financial strength and resilience • Deliverables within time and budget

Risks

TFS recognizes the connection between enterprise risk management and sustainability management. During 2017 TFS performed a risk analysis to connect our sustainability material topics to risks identified. Integration between risk management and sustainability management has continued to be explored in 2019.

Below is a summary of the main risks identified per material issue, and for environmental matters.

Equal opportunities:
- Discrimination and/or harassment.
- Breaches to Code of Conduct: these could result in unethical conduct and legal implications but are also likely to affect employee engagement and motivation, and cause damage to our company name.

Patient safety and data integrity:
- Safety reporting non-compliance which might lead to a negative impact on the safety of trial subjects.
- Inadequate systems and processes to manage clinical studies might lead to non-compliance and unreliable results as well as reputation damage which has financial consequences.
- Systems and procedures not complied with; see previous item.

Compliance with regulations:
- Negative health authority inspections with critical findings might lead to regulatory consequences, damage to company reputation and have financial consequences.
- Inadequate systems and processes to manage clinical studies; see above: patient safety and data integrity.
- Systems and procedures not complied with; see above: patient safety and data integrity.

Talent development:
- Difficulties with attracting and retaining key employees.
- Inadequate investment in continuous skills training.
- Non-compliance with regulations/procedures regarding development and training might result in audit and inspection findings.

All three risks mentioned might result in not meeting the project expectations and could ultimately lead to situations where patient safety might be in jeopardy or that collected data are not reliable and fit for regulatory purposes.

Business ethics and anti-corruption:
- Legal liability due to breach of contract by misconduct.
- Breach of confidentiality by employees.
- Whistleblowing mechanism / system.

Environment
- Poor environmental efficiency
  - Energy inefficient offices
  - Pollution due to travelling

TFS Focus Areas and Agenda for Sustainability

TFS' sustainability topics have been prioritized and a materiality analysis performed. The five key / material topics for TFS concerning TFS sustainability efforts have been identified as follows:

A. Equal opportunities
B. Patient safety and data integrity
C. Compliance with regulations
D. Talent development
E. Business ethics and anti-corruption

Focus Area A: Equal Opportunities

Materiality of the Focus Area

TFS places great importance on equal opportunities and diversity. TFS employees are the company's most important resource. Although the work is guided and regulated by policies and procedures, it is TFS employees who complete the work. The professionalism, qualifications and dedication of TFS employees ensure that the agreed and required results can be achieved.

TFS employees are expected to treat colleagues and clients alike with professionalism and respect. TFS recognizes the enormous importance of establishing and maintaining our clients' trust, and our own personal conduct is central to this. TFS endeavors to instill a positive feeling in our clients by being flexible and eager to help, and by showing commitment to their projects. Likewise, all employees should help to create a professional and fun working environment, by interacting with each other in a friendly and respectful manner.

In this context, differences between individuals and cultures are accepted and seen as an asset, since heterogeneous working groups offer a wide variety of experience, which is of great importance to the company.

Non-compliance in this focus area could occur as a result of TFS' activities, and would not only have potential legal implications, but would also likely negatively impact employee engagement and motivation, and TFS' reputation.

The TFS Management Approach

At the foundation, the TFS Code of Conduct expresses TFS' commitment to being a non-discriminatory workplace and to offer all individuals equal opportunities.

The TFS Human Resources department has issued the Global Ethics and Diversity Policy and Action Plan in which TFS expresses its determination to attain equality and to be non-discriminatory, by offering all individuals equal opportunities, regardless of gender, age, ethnic origin, religion, functional handicap, or sexual orientation.

In addition, this policy defines how TFS works actively for equality between men and women, by offering the same possibilities regarding employment, education, promotion, salary and development in their work and by facilitating all employees to combine employment with parenthood.

TFS ensures equality by working with 'Job Evaluation' which ranks jobs / positions in a logical, transparent and neutral way on a pre-determined scale, and connects jobs with salary ranges. TFS compares salary levels for different positions internally, as well as by external benchmarking to ensure that similar possibilities are offered in terms of roles or career paths regardless of gender, nationality or other distinguishing characteristics.

Evaluation of the TFS management approach

TFS' approach can be evaluated by analyzing the actual diversity in our workforce, further specified in 5.1.4. GRI Disclosure 405-1.

TFS regularly conducts anonymous employee surveys to gain an understanding of employee satisfaction and engagement at TFS. The survey helps TFS to collect employees' opinions on topics such as: Work Environment, Benefits, Work Tasks, Communication & Information, and Training and Management.

The questionnaire used for the employee survey in 2019 included a specific question to directly assess the employees´ perception of TFS as an equal opportunities employer.

TFS employees were asked if they considered TFS to be an equal opportunity employer, to which 80% of the employees agreed that TFS is an equal opportunity employer. Moreover in the survey section regarding well-being in the workplace, employees were asked to what extent they felt bullying or discrimination occurs, to which 88% responded that they were not aware of any discrimination happening in the workplace. TFS has zero tolerance towards all forms of discrimination and harassment and makes active efforts to completely eliminate discrimination and harassment from the workplace.

GRI Disclosure 405-1

Diversity of governance bodies and employees

As the relevant GRI Standard, connected to this material topic, GRI 405: Diversity and equal opportunity has been selected; specifically GRI 405-1: Diversity of governance bodies and employees. In the table below the results for this GRI disclosure are presented.

Governance bodies	Gender	Male	67 %
		Female	33 %
	Age	Under 30 years	11 %
		From 30 -50 years old	56 %
		Over 50 years old	33 %
Rest of employees	Gender	Male	24 %
		Female	76 %
	Age	Under 30 years	4 %
		From 30 -50 years old	74 %
		Over 50 years old	72 %

The figures show that in our overall workforce the absolute majority of staff (76%) are female. The percentage of female employees did increase slightly from 2018 to 2019 from 75% to 76%.

In 2018, 3 (23%) out of 13 members of the governance bodies were female. The percentage of female members in the governance bodies rose to 33% in 2019. Notably, the gender representation in the TFS executive committee was well-balanced, 50%, by the end of 2019. TFS is now one of the few companies that has achieved gender equality in its executive committee.

The above disclosure also illustrates that the age group under 30 years is underrepresented in TFS' workforce compared to the other categories. In the 2017 Sustainability Report, TFS planned to investigate this further and where needed develop an action plan. Potential reasons for the low representation of the under 30 age group may include TFS' lean organization that does not include many levels of hierarchy and our drive to attract and offer experienced professionals to best serve our clients. In 2019, a tailored internship program welcoming talents globally was implemented to attract younger talent to TFS and we expect to see an increase in this underrepresented age group in our work force in the coming years.

Focus Area B: Patient Safety and Data Integrity &

Focus Area C: Compliance with Regulations

Materiality of the Focus Areas

The healthcare industry is highly regulated. The conduct of clinical trials is governed by numerous national and international laws and regulations, which are designed to protect the rights, safety, and well-being of clinical trial participants, and to define the manner in which clinical trials should be designed, conducted and reported in order to ensure that clinical trial data are credible. The most important of these requirements are defined in the International Council on Harmonization (ICH) Guideline for Good Clinical Practices (GCP).

TFS is committed to ensuring compliance with all applicable legal and regulatory requirements, with patient safety and data integrity as our top priorities.

These priorities are essential for TFS and its business. Serious non-compliances or issues in these areas may have significant negative impact for TFS and result in serious consequences, including, but not limited to: negative regulatory authority inspection results, delays or impediments to marketing authorization approvals, injury or death of a study participant, damage to TFS' reputation, loss of business, etc.
These areas must be well-managed, for the sake of TFS, its clients, the regulatory authorities who oversee clinical research, and, most importantly, for study participants and the public who may ultimately benefit from the clinical developments TFS supports.

An additional challenge in these areas is created by the fact that issues / non-compliances may occur as a result of TFS activities, or may be caused by TFS collaborators, including TFS vendors and/or staff at investigational sites involved in a clinical trial. For this reason, TFS must remain vigilant and ensure proper selection and oversight procedures for these external parties.

Since these two principles are so closely linked, the focus areas **Patient Safety** and **Data Integrity** and **Compliance with Regulations** are not separated in this report. As the regulations are designed to safeguard patient safety and data integrity, compliance with regulations is both a means and an end in itself.

Regulatory Context

As a company working in the pharmaceutical, biotechnology and medical device industry, TFS is required to conform to international, national and local legislation and regulations by authorities, such as the European Medicines Agency (EMA), US Food and Drug Administration (FDA), UK Medicines and Healthcare Products Regulatory Agency (MHRA), etc., as well as to various guidelines that define Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Pharmacovigilance Practice (GVP) and ISO guidelines regarding Medical Devices.

The TFS management approach

To ensure that TFS operates in accordance with the relevant requirements, TFS has developed and continue to improve our Quality Management System (QMS).

Written procedures

Company policies and procedures are developed within the framework of the relevant regulatory requirements. Regulated activities performed by TFS are governed by internal processes defined in controlled documents which make up our Quality Management System. In December, 2018, the QMS was re-structured to include: the Quality Manual, Policies, Standard Operating Procedures (SOPs), Work Instructions (WIs) and other supportive tools.

In addition, non-regulated activities (i.e. support functions such as Human Resources and Finance) are supported by Business Operating Procedures and supportive tools to ensure appropriate ownership of procedures and clarity of expectations for employees. In these areas, also relevant requirements such as (local) labor and tax laws are taken into account.

All QMS and corporate procedural documents are available to all employees, and all TFS employees are trained on applicable procedures according to their role and responsibilities. TFS Quality & Compliance maintains the QMS and is responsible for ensuring that appropriate documents controls are applied to QMS documents.

Training

TFS Quality & Compliance also maintains the e-learning system (TFS Academy) for training and implementation of an improved LMS, Master Control, is ongoing and will go live in Q2 of 2020. It is the responsibility of every TFS employee to fulfil their training requirements, under the supervision of their Line Manager. Training requirements that support compliance to regulations include: regulatory background, TFS procedures and study-specific protocols and procedures, client SOPs, etc.

It's all about trust

Issue detection, escalation and management

As part of the TFS QMS, there are several mechanisms defined for the prevention, detection, escalation and management of issues and non-compliances, including client complaints. These include but are not limited to: a SOP on issue management and escalation, a SOP on serious breach reporting, and a SOP on suspected intentional misconduct / fraud.

TFS also uses an external whistleblowing system to allow all employees to report suspicious or undesirable conditions or situations, anonymously if preferred.

All escalation and reporting mechanisms are available for all TFS employees.

Audit

Quality & Compliance perform routine internal audits on a risk-basis, to ensure that any non-compliances that are not detected during in-process checks will be detected and addressed on a system level. Audits may also be triggered or conducted 'for cause' to investigate potential issues. In addition, TFS is regularly audited by its clients and inspected by regulatory authorities.

Corrective and Preventive Actions (CAPA)

Any issues detected during these activities are investigated, and CAPAs are put in place as appropriate to resolve them. This may include re-training of employees, revision of processes, and/or other appropriate actions to ensure that the issues are addressed.

Evaluation of the TFS management approach

The QMS at TFS supports compliance with regulations. In 2019, TFS has implemented enhanced reporting tools and has established more robust quality objectives and will continue to develop them in 2020.

Harmonized and robust procedures have been put in place, which reflect current regulatory requirements as well as the TFS way of operating. The following additional initiatives are planned for 2020 (list is indicative and non-exhaustive):

- Continued implementation of the Harmony project, where all QMS and corporate procedures will be reviewed and revised as appropriate to ensure standardization throughout TFS and compliance with all relevant regulations and industry best practices.
- The new Learning Management System, Master Control will be implemented to allow for improved training management and the ability to run management reports which will contribute to further improvements.
- The internal audit program will be expanded in scope to include more areas/departments and ensure client audit/inspection readiness. An updated audit management SOP will be released.
- Implementation of effectiveness checks for audit CAPAs and update of the CAPA SOP to reflect the revised requirements.

Qualitative indicator

It is particularly difficult to identify meaningful and objective metrics for areas such as compliance, patient safety and data integrity. Metrics in these areas are difficult to evaluate objectively. For example, in general, there is a distinct correlation between the total number of audit observations and the number of hours spent auditing, meaning that the number of audit findings, or even the average number of findings per audit, would not provide useful information, since not all audits have the same scope / duration.

It is also difficult to interpret these types of metrics without their context. For example, in a clinical study with relatively low numbers of adverse event reports, the number of events itself does not indicate if there really were few events to report, or if there were issues with under-reporting. In-depth analysis and trending is needed to determine the reason, or even if there is a significant reason to be determined.

For these reasons, TFS relies on qualitative indicators for these two areas, as described in the sections entitled TFS Management Approach and Evaluation of TFS Management Approach (above). Quality objectives and KPIs have been developed for 2020 to support the overall TFS values and objectives. These reflect the initiatives mentioned above and will ensure the continued development and improvement of the TFS QMS.

With the work planned on QMS Management Reports, TFS hopes to be able to identify useful metrics in this area to report on in future years.

Focus Area D: Talent development

Materiality of the Focus Area

TFS' employees are the company's most important resource. The education, qualification, training and development of TFS staff is vital to achieve our company goals, to deliver on client agreements, and to comply with regulations.

In addition, Good Clinical Practice guidelines require that individuals involved in conducting a clinical trial should be qualified by education, training and experience to perform his or her respective task.

Lack of such qualification might result in not meeting the project expectations and could ultimately lead to situations in which patient safety might be in jeopardy or that collected data are not reliable and cannot be used for regulatory purposes.

Since regulations and therefore training requirements both apply for TFS and its' collaborators the impact may occur as a result of TFS activities or may be caused by TFS collaborators, for example TFS vendors and staff at investigational sites involved in a clinical trial.

The TFS management approach

In order for TFS to ensure that employees are trained and developed in accordance with the regulatory requirements and in line with personal development objectives, the approach consists of several elements:

Job descriptions are defined for all functions, clearly defining the basic tasks and responsibilities of the function. A new standard operating procedure released in Dec-2018, and which took effect in Jan-2019, requires employees to sign their job description to confirm their awareness of their assigned responsibilities.

- An SOP defines the procedures for training and development of TFS staff.
- Training curricula define the training requirements per function.
- A Learning Management System (LMS), TFS Academy, tracks the curricula, allows training to be performed and recorded, and stores training records and CVs.
- Annual performance dialogues take place between employees and their Line Managers to discuss development goals and targets.
- Personalized training opportunities are offered to employees to build general and functional competence.

All TFS staff are expected to complete all required training within the assigned timeframe. Employees are not permitted to work on studies where TFS standard operating procedures are used until they have received relevant SOP training and passed the tests.

Evaluation of the TFS management approach

Several instruments are used to evaluate training and talent development efforts at TFS:

The performance dialogue and annual review of competency provides Line Managers with input on individual employees' needs. During this dialogue, training and development are key topics to be discussed / assessed, in order for TFS employees to deliver on their objectives. On an individual basis, improvement processes may be initiated to allow the TFS employee to develop skills to meet the standards required for their role, and to build up skills that allow evolution into other roles and challenges.

Employee training and qualification is standardly evaluated during TFS internal audits. The topic is also standardly reviewed during client audits and regulatory inspections. In the audit / inspection context, records are reviewed as evidence of compliance with training procedures and general employee qualification.

The current LMS, TFS Academy, allows for training to be assigned and completed, but does not allow for sufficiently robust reporting and tracking of all relevant metrics; with the implementation of the new LMS, Master Control, in Q2 of 2020, this deficiency should be fully resolved. More complete metrics and reports will allow TFS to identify compliance gaps and/or other issues, and to implement the necessary improvements to ensure appropriate training assignments and offerings, prompt completion of all training requirements, and availability of records for review and evaluation.

The TFS employee survey also includes a section on Training. Similar to the 2017 survey, it has still been indicated by TFS employees in the 2019 survey that more attention should be paid to the training provided at TFS, to ensure its adequacy and appropriateness.

As evidenced by the initiatives described above, training has become one of the most highly prioritized improvement areas at TFS and investments in technology and highly skilled personnel have been made to improve functional and general training and competence development.

GRI Disclosure 404-3

Percentage of employees receiving regular performance and career development reviews.

As relevant GRI Standard connected to this material topic, GRI 404: Training and Education has been selected; specifically GRI 404-3: Percentage of employees receiving regular performance and career development reviews.

The percentage of employees receiving performance and career development reviews in 2019 was 52%. This low percentage is attributable to the restructuring and extensive change management that happened in TFS in 2019. TFS has taken serious actions to ensure that employees receive regular career development reviews annually and HR has enforced appropriate measures to reverse this decline.

Focus Area E: Business Ethics and Anti-Corruption

Materiality of the Focus Area

Business ethics and anti-corruption are for the majority of TFS stakeholders a material sustainability topic.

In addition to business ethics, the clinical trial services provided by TFS are governed by ethical principles having their origin in the Declaration of Helsinki, as well as Good Clinical Practices and other similar guidelines. These are designed to ensure the protection of clinical trial participants and the public, and include, for example: ensuring that the anticipated benefits of clinical research justify the risks, that all clinical trials are approved by an Ethics Committee prior to their start, and that all study participants provide documented informed consent prior to their participation.

Non-ethical or corrupt behavior has the potential to harm the participants of clinical trials, the conduct of those trials and the clinical data produced, and as a result could harm people who will use the drugs, if they have been erroneously approved. Therefore, the impact of non-ethical or corrupt behavior can be significant on TFS activities and deliverables, and is considered completely unacceptable to TFS, TFS' clients and the relevant RAs.

Impact in this area may occur as a result of TFS activities, or may be caused by TFS collaborators, for example TFS vendors and/or staff at investigational sites involved in a clinical trial.

The TFS Management Approach

All TFS employees and representatives are expected to demonstrate honesty and integrity in dealing with other employees, clients, suppliers, business partners, organizations and regulatory authorities.

TFS have implemented procedures and policies to achieve this.

Ethical Research:
TFS is committed to conducting clinical trials in accordance with the ethical principles that have their origin in the Declaration of Helsinki, Good Clinical Practice and other requirements. TFS has SOPs in place to ensure that all clinical studies receive independent ethics committee approval before any participants are included, that informed consent forms are designed to contain all required information, that all participants provide consent prior to the start of their participation, that the consent of participants is verified by TFS monitors, etc.

Anti-Bribery and Anti-Corruption:
TFS has zero tolerance for all forms of corruption and makes active efforts to ensure that it does not occur.

TFS has had an Anti-Bribery & Corruption Policy (ABAC) in place since 2012 and all employees are required to perform training on and comply with this policy. Responsibilities for all TFS employees regarding ABAC are described in the ABAC policy.

Code of Conduct:
In 2016, TFS implemented its Code of Conduct, which is included in the training curriculum for all employees. The TFS Code of Conduct outlines our corporate commitment to transparent and ethical behavior, and provides guidance in various work situations such as conflicts of interest, gifts, entertainment, and compliance with the laws and regulations that apply to our business.

The Code of Conduct defines TFS' commitment to ethical research, patient safety and data integrity, respect for people and human rights, good business ethics, and the environment, and highlights each employee's responsibilities in terms of care for the company's assets, technology resources, accounting and financial reporting, confidential information, and personal responsibility and routines.

Whistle Blowing:
As previously reported, in 2017 TFS was in the process of establishing a whistle blowing function. The whistle blowing guideline was finalized and implemented in May, 2018, and has been included in the training curriculum for all employees. As part of this guideline, a whistle blowing team has been established, which includes the Chief Executive Officer, Executive VP Human Resources and Executive VP Quality & Compliance, who are responsible to follow up on and investigate any reported issues.

Reporting may be done internally, or if an employee prefers to remain anonymous, through an external system, WhistleB. WhistleB does not save IP addresses or other meta-data that can be related to the person sending the message. The person sending the message also remains anonymous in the subsequent dialogue with the whistleblowing team. TFS has a service agreement in place with WhistleB, and the system has been tested; no whistle blowing cases were reported via WhistleB in 2019.

Evaluation of the TFS Management Approach

Business ethics and anti-corruption is currently monitored:
- During TFS internal audits-
- During external audits and inspections

Audit findings are resolved and if deemed necessary a preventative action may be required to prevent future occurrences. In 2018, anti-corruption training was added as a mandatory requirement for all TFS staff. It was investigated and ultimately decided that TFS will not require business partners to complete the TFS anti-corruption training. Instead, during vendor assessments, TFS vendors are asked to confirm that they have an anti-bribery and anti-corruption policy or SOP. The responsibility to be trained on this topic remains with the vendor.

TFS

It's all about trust

## GRI Disclosure 205-2
Communication and training about anti-corruption policies and procedures.

As a relevant GRI Standard connected to this material topic, GRI 205: Anti-corruption has been selected; specifically GRI 205-2: Communication and training about anti-corruption policies and procedures. The percentage of TFS employees who have completed the TFS anti-corruption training in 2019 was 99%.
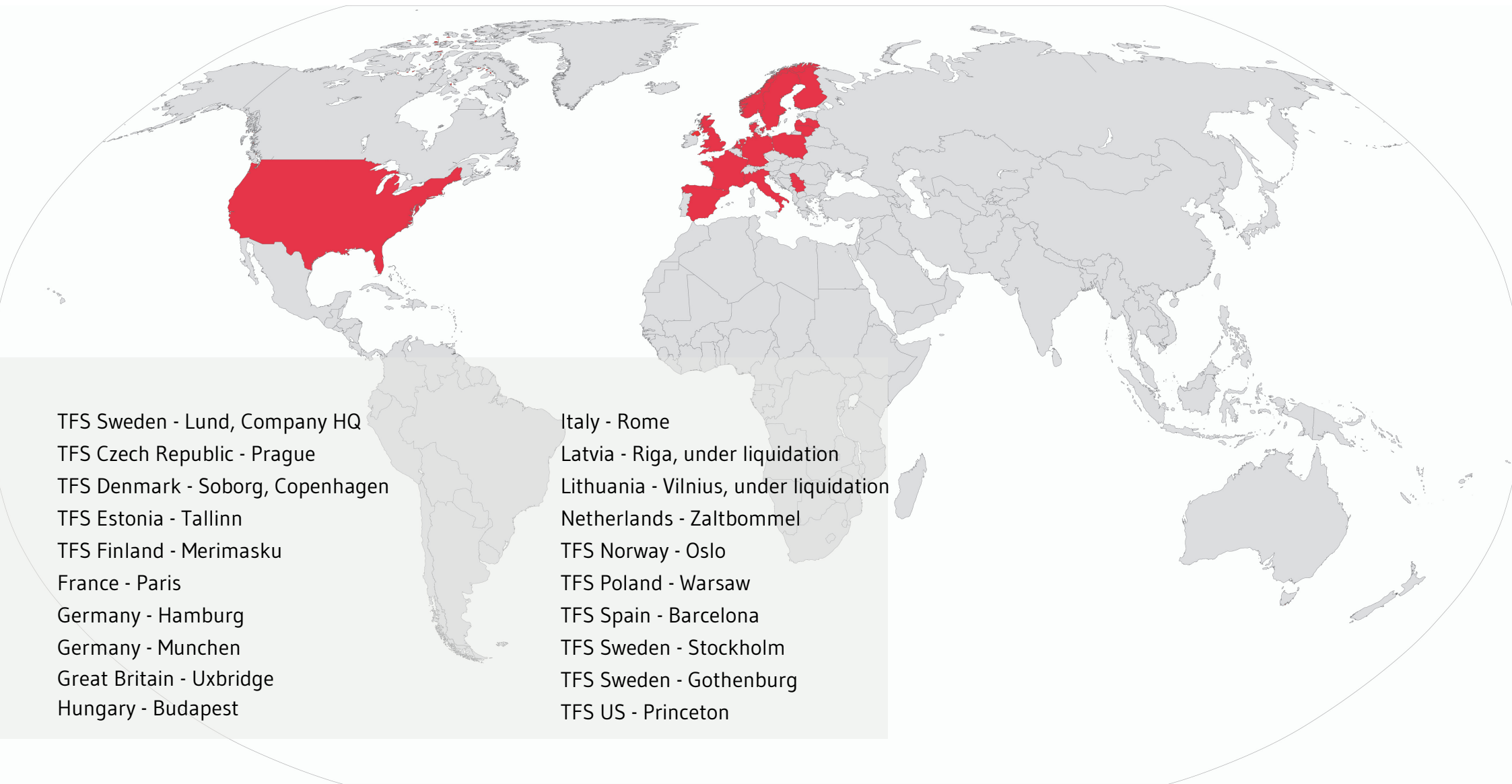
TFS Sweden - Lund, Company HQ

TFS Czech Republic - Prague

TFS Denmark - Soborg, Copenhagen

TFS Estonia - Tallinn

TFS Finland - Merimasku

France - Paris

Germany - Hamburg

Germany - Munchen

Great Britain - Uxbridge

Hungary - Budapest

Italy - Rome

Latvia - Riga, under liquidation

Lithuania - Vilnius, under liquidation

Netherlands - Zaltbommel

TFS Norway - Oslo

TFS Poland - Warsaw

TFS Spain - Barcelona

TFS Sweden - Stockholm

TFS Sweden - Gothenburg

TFS US - Princeton

TFS
It's all about trust

APPENDIX 2

GRI Content Index
GRI 101: Foundation 2016 (does not include disclosures)
GRI 102: General Disclosures 2016 (core)

Number of Disclosure	Disclosure	Page number (s) and/or URL(s)	Comments
Organizational Profile			
102-1	Name of the Organization	Title page	
102-2	Activities, brands, products and services	P.5	
102-3	Location of headquarters	Appendix 1, P.10	
102-4	Location of operations	Appendix 1	
102-5	Ownership and legal form	P.6	
102-6	Markets served	Appendix 1, P.7	
102-7	Scale of the organization	P.7-8	
102-8	Information on employees and other workers	P.7	TFS do not report numbers per country due to confidentiality reasons
102-9	Supply chain	P.8	
102-10	Significant changes to the organization and its supply chain	P.10	
102-11	Precautionary Principle or approach	P.9	
102-12	External initiatives	P.8	
102-13	Membership of associations	P.9	TFS is a member of association of CROs: ssociation of Clinical Research Organizations (ACRO) and the European CRO Federation (EUCROF). Local offices are members of national associations: • TFS Spain: Asociación Española de Compañias de Investigación Clínica (AECIC) & Asociación de Medicina de la Industria Farmacéutica (AMIFE) • TFS Italy: Italian Association of Contract Research Organisations (AICRO) • TFS France: Association Françaises des CROs (AFCRO) • TFS Netherlands: Associatie van Clinical Research Organisations in Nederland (ACRON) • TFS Sweden: Apoteksocieteten • TFS Finland: Lääketeollisuus • TFS Germany: Bundesverband Medizinischer Auftragsinstitute e.V. (BMVA) • TFS Germany: BfArM Bundesinstitut fürArzneimittel und Medizinprodukte • TFS Germany: BPM Bundesverband der Personalmanager

APPENDIX 2 CONT.

GRI CONTENT INDEX

GRI Content Index
GRI 101: Foundation 2016 (does not include disclosures)
GRI 102: General Disclosures 2016 (core)

Number of Disclosure	Disclosure	Page number (s) and/or URL(s)	Comments
			Individual TFS employees may be members of professional associations such as: the Drug Information Association (DIA), Research Quality Association (RQA), Association of Clinical Research Professionals (ACRP), Association for Clinical Data Management (ACDM), or European Medical Writers Association (EMWA). To encourage membership in professional organizations, encourage employee development and ensure engagement within the industry, TFS pays for employee memberships to approved associations.

Strategy

102-14	Statement from senior decision-maker	P.3-4

Ethics and Integrity

102-16	Values, principles, standards and norms of behavior	P.6

Governance

102-18	Governance structure	P.7

Stakeholder engagement

102-40	List of stakeholder groups	P.12
102-41	Collective bargaining agreements	P.8
102-42	Identifying and selecting stakeholders	P.12
102-43	Approach to stakeholder engagement	P.12
102-44	Key topics and concerns raised	P.12

Reporting practice

102-45	Entities included in the consolidated financial statements	Appendix 1
102-46	Defining report content and topic Boundaries	P.11
102-47	List of material topics	P.13
102-48	Restatements of information	P.11
102-49	Changes in reporting	P.11
102-50	Reporting period	P.11
102-51	Date of most recent report	P.11
102-52	Reporting cycle	P.11
102-53	Contact point for questions regarding the report	P.11
102-54	Claims of reporting in accordance with the GRI Standards	P.11
102-55	GRI content index	Appendix 2
102-56	External assurance	P.11

APPENDIX 2 CONT.

GRI CONTENT INDEX

GRI Content Index
GRI 101: Foundation 2016 (does not include disclosures)
GRI 102: General Disclosures 2016 (core)

Number of Disclosure	Disclosure	Page number (s) and/or URL(s)	Comments

GRI 103: Management Approach 2016 and GRI 205: Anti-corruption 2016

103-1	Explanation of the material topic and it Boundary	P.24	
103-2	The management approach and its components	P.24	
103-3	Evaluation of the management approach	P.25	
205-2	Communication and training on anti-corruption policies and procedures	P.25	Further definition of training metrics are not available: the current training and eLearning system in use (TFS Academy) cannot support this requirement since these data are not specified in the system.

Social standards

GRI 103: Management Approach 2016 and GRI 404: Training and education 2016

103-1	Explanation of the material topic and its Boundary	P.22	
103-2	The management approach and its components	P.22	
103-3	Evaluation of the management approach	P.23	
404-3	Percentage of employees receiving regular performance and career development reviews	P.23	

Approach 2016 and GRI 405: Diversity and Equal Opportunity 2016

103-1	Explanation of the material topic and its Boundary	P.15	
103-2	The management approach and its components	P.16	
103-3	Evaluation of the management approach	P.16	
405-1	Diversity of governance bodies and employees	P.17	Other indicators of diversity where relevant (such as minority or vulnerable groups) are N/A

Company specific topics and disclosures

GRI 103: Management Approach 2016 and GRI 404: Patient Safety and data integrity

103-1	Explanation of the material topic and its Boundary	P.18	
103-2	The management approach and its components	P.19-20	
103-3	Evaluation of the management approach	P.20-21	
Own indicator	Patient safety & data integrity	P.21	

APPENDIX 2 CONT.

GRI CONTENT INDEX

GRI Content Index
GRI 101: Foundation 2016 (does not include disclosures)
GRI 102: General Disclosures 2016 (core)

Number of Disclosure	Disclosure	Page number (s) and/or URL(s)	Comments

GRI 103: Management Approach 2016 and Own indicator: Compliance with regulations

103-1	Explanation of the material topic and its Boundary	P.18	
103-2	The management approach and its components	P.19-20	
103-3	Evaluation of the management approach	P.20-21	
Own indication	Compliance with regulations	P.21	