TFS SUSTAINABILITY REPORT 2017

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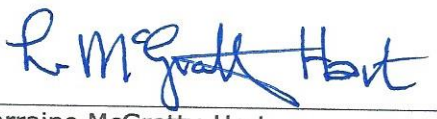

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1. Word from the CEO

Sustainability at TFS is not only measures planned and taken, it is a way of active life decisions and values.

Since our foundation more than 20 years ago, TFS has always set high expectations for our business conduct and integrity. Our value "It's all about trust" couldn't symbolize this standard in a better way. Operating with integrity is the cornerstone of the TFS culture for all our employees around the world. At TFS, we want to ensure that everything we do is guided by our values and our compliance with the governmental regulations and regulatory guidelines within which we have to operate.

TFS is in the business of improving and refining the delivery of better healthcare outcomes to ensure our customers' successes. TFS' in-depth knowledge about regulatory and clinical trial requirements in every country ensures a global trial will move faster to market and result in shorter timelines to get treatments to the patients who need them. Operating as a consultancy and service organization will define the meaning of sustainability differently from traditional manufacturing industries. However, our work and contribution to measures improving sustainability has an important social, economic and environmental impact.

Sustainability at TFS is a cross-functional and organizational commitment, which result in many focus areas. But more importantly, it's all about making active life decisions and adhering to values that supports the greater good of our society at large.

At TFS our sustainability focus centers on areas such as;

The TFS Code of Conduct outlines our corporate commitment to transparent and ethical behavior. This Code serves as a guide to various work situations such as conflicts of interest, gifts, entertainment, and compliance with the laws and regulations that apply to our business.

The Ethical Research is upheld to the highest ethical, medical and scientific standards. No matter where we operate in the world, we must 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) E6 (R2) Good Clinical Practices (GCP) and other similar guidelines.

The Working Environment should be safe and stimulating, and offer involvement, engagement and development of our employees, which we will continuously seek to improve. Our employees are our most important resources and we will strive towards reducing the days of sick leave and any work-related accidents.

The Environment utilizing new technology innovations to reduce climate impact by, contributing to recycling, having energy efficient offices, using eco-labelled office equipment, complying to our travel policies and avoid unnecessary travel and reduce carbon emissions, moving towards a "green fleet" of environmental classed company cars, and communication technology to facilitate travel-free meetings and interactions between our global locations.

The Partners and Suppliers collaborating with TFS must 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 work creates both environmental benefits and value. Our aim is to meet the expectations placed on us by our different stakeholders which take into account our business model and long-term, sustainable development. Sustainability considerations shall be an integral part of our business activities. Building a successful, transparent, trusted and ethical company means we do not compromise our long-term sustainability goals and values.

János Filakovský
CEO

2. Role in society and sustainability strategy

TFS is a global contract research organization (CRO). TFS provides a broad range of professional services, information and partnering solutions to the pharmaceutical, biotechnology and healthcare industries.

TFS's vision is to be recognized by our customers as the top quality provider of clinical trial services and by our employees as an attractive employer.

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.

Customer focus

As the leading global mid-size clinical CRO, TFS has the global and regional experience and infrastructure to conduct its customers' clinical trials. TFS guides customers from clinical development planning to regulatory filing, providing flexible solutions whilst ensuring budget and deadlines are met and reducing customers' 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 working towards the success of clinical development program.

In 2017 TFS has celebrated its 21st anniversary.

Our history and the strong and active leadership and the professionalism and dedication of all TFS employees provide credibility and stability. TFS want to contribute to successful clinical trials 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.

Climate and environment issues concern everyone and as a sustainable company, TFS wants to contribute to a better environment and reduce climate impact.

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 we will, wherever possible, work to reduce our environmental impact by preventing and reducing pollution and contribute to long-term, sustainable development through active and systematic environmental work. Environmental considerations shall be an integral part of our business activities.

TFS is not a production company using raw materials, water and energy and generating waste and air pollution. Therefore, climate and environmental issues have not been a focus for TFS. TFS has to determine how the precautionary principle applies and can be implemented in the TFS strategy. In addition, risk management related to environmental issues has to be developed.

3. TFS in brief

TFS is a full-service CRO providing clinical services within two business areas TFS DevelopTM and TFS PeopleTM.

TFS Develop provides full-service capabilities including development program planning, scientific advice, clinical operations, site coordination, biometrics, regulatory affairs, pharmacovigilance, medical monitoring, medical writing, quality assurance, training and financial project management of clinical projects across all phases of the development continuum.

TFS People offers flexible and tailor-made resource solutions with a fully operational team of clinical professionals experienced in all functions and therapeutic areas. TFS employees support clients in a variety of ways, from tactical short-term assignments to strategic long-term resourcing, and full functional service provision (FSP) within all clinical development services.

As a service provider (services mentioned above) TFS does not have brands or products compared to manufacturing companies. TFS contribute with our service offerings along with our therapeutic expertise and scientific experts towards the success of our customers' clinical development programs.

The TFS processes to achieve this are described and defined in TFS SOPs and the boundaries are also set by regulatory requirements. (See also focus area C; compliance with regulations)

TFS operates in the countries where we have an entity (see Appendix 1).

TFS Trial Form Support AB is owned 60% by Medcro Intressenter AB (owned by Ratos Group) and 40% by Daniel Spasic.

The organisation

The TFS governance structure:

The TFS Leadership Group (TLG) includes the Global Management Team (GMT) and members of Operational Leadership. An organization chart is added in Appendix 3.

The Board with external members is overseeing TFS.

In 2017, sustainability topics were assigned to the Quality Assurance (QA) department; specifically Executive Vice President (EVP) QA, Alistair Bone, assisted by Senior QA Manager, Theo van Delft. As of April 2018 Alistair Bone has retired and Lorraine McGrotty-Hart has taken over.

In 2018 TFS will evaluate the responsibility assignment for sustainability issues.

TFS employees

By the 31st December 2017, TFS had 694 employees in 14 countries. Most TFS employees work in Europe, 94,5%, and 5,5% work in the USA.

TFS has implemented an ERP (Enterprise Resource Planning) solution to manage the HR and Finance data. The below table has been created using the reports available in the ERP.

The number of TFS employees by contract and gender:

	Permanent	**Temporary**
Male	150	21
Female	464	59
	Full-time	**Part-time**
Male	156	15
Female	432	91

Collective bargaining agreements

TFS operates in different countries, in some of them, a bargaining agreement is in place, and therefore employees are covered by its content. This is the case in Spain, France and Italy. They represent 47% of TFS staff.

Vendors

In case services are requested which are not part of the TFS services (for example laboratories, imaging, investigational drugs storage and distribution, monitoring in countries where TFS has no office) TFS might use TFS-approved vendors to perform applicable parts of the work.

Furthermore, external suppliers are used for IT equipment and infrastructure, companies that provide services related to offices and its equipment and travel arrangements.

Finance

In 2017 the net sales was €85M including professional fees and reimbursable expenses

Consolidated balance sheet was €30M. Equity accounts for €7M. Total debt with financial institutions at €7M.

TFS works with an average of 500 orders on a yearly basis.

Location of TFS Headquarters and operations and entities included in TFS consolidated financial statements can be found in Appendix 1.

During 2017 no significant changes to TFS locations/operations, finance structure and vendors have taken place.

4. TFS and Sustainability

In 2015 TFS became part of the Ratos group. As a result, corporate responsibility and sustainability are a reporting topic for TFS with 2016 as the first reporting year.
The 2017 report is the second TFS sustainability report.

Regarding the 2017 report, the following can be noted:

- No re-statements of information provided in previous reports have to be made.
- The 2017 report is more elaborate than the 2016 report and is based on the GRI standards.
- There are no significant changes in the list of material topics; topic boundaries have been added.
- The reporting period for the 2017 report is 1 January - 31 December 2017.
- The reporting cycle is annually.
- The previous (2016) report was issued on 20th March 2017.
- The TFS Global Management Team is responsible for producing the report and for the information within.
- The contact point for questions regarding the report or its content is TFS Quality Assurance Department; Theo van Delft, Senior QA Manager.
- This report has been prepared in accordance with the GRI Standards: Core option.
- PricewaterhouseCoopers AB (PwC) have issued an auditor's opinion in accordance with the Swedish Annual accounts act.
- To ensure compliance to GRI standards external support from consultancy (on sustainability and responsibility) company Enact has been used.
- The GRI Content Index can be found in Appendix 2.

External initiatives and memberships

We want to help create a better world, by forming partnerships with global organisations, like the UN, we can increase the impact of our efforts. In 2017, we continued to strengthen our global partnerships.

- TFS's Code of Conduct is based on the United Nations (UN) Global Compact's 10 principles.
- TFS is a supporting partner to Plan International's initiative 'Because I am a Girl' and to clearly demonstrate our support of Plan's work to strengthen girls' rights and to achieve lasting improvements in the quality of life of children in developing countries!
- TFS respects the UN Universal Declaration of Human Rights
- TFS follow the UN Guiding Principles on Business and Human Rights

TFS, separate local offices or individual employees are members of national and international associations.

TFS is a member of association of CROs: ACRO; EUCROF
Local offices are members of national associations:

- TFS Spain: AECIC & AMIFE
- TFS Italy: AICRO
- TFS France: AFCRO
- TFS Netherlands: ACRON
- TFS Sweden: Apoteksocieteten
- TFS Finland: Lääketeollisuus
- TFS Germany: BMVA

Individuals can be member of professional associations like for example RQA, ACRP, ACDM, EMWA.

The 2017 sustainability report

TFS is an integrated part of society. To conduct our operations and make contributions to successful clinical trials requires different types of input. Our work with sustainability is an integral part of our operations and helps us achieve our goals.

To preserve and create value, TFS conducts structured sustainability initiatives. When we define our sustainability priorities, we start with intelligence gathering (internal stakeholders, literature search, developments in peer companies/benchmarking), analysis (both the business opportunities and the risks) and a process that weighs the priorities and relevant issues for the different stakeholders.

TFS stakeholders include the employees, management group and TFS board, owners, customers, vendors and subcontractors and the authorities. The list of stakeholders is compiled by a range of professionals within TFS who are recruited for their knowledge and experience in this area.

Communication with our stakeholders is conducted via a range of methods and platforms.

The Business Development Team liaise directly with our customers and are supported by the marketing department that uses social media platforms such as LinkedIn and Twitter. A customer database is managed via the software package, Salesforce, and via this, emails and other e-communications are sent out to customers.

The TFS business and contracts department liaises with TFS vendors and a vendor database is managed in Salesforce. On an annual basis TFS project managers are requested to provide input on vendors. During the performance of clinical studies the TFS project managers are collaborating closely with vendors.

Communication with authorities is mainly focused on compliance with regulations.

Furthermore, the TFS customers have been involved through specific interviews. The results of these interviews have been included in the final materiality assessment.

One of the customers involved, summarized what most of the customers expressed regarding the importance and focus on sustainability issues: "Provide high quality services to customers, maintaining high quality employees that meet the mission and goals of TFS. This can be done by treating employees well."

Additional outcome of the customer involvement was that most of people interviewed mentioned they are not well informed about TFS sustainability efforts. Communication to customers on TFS material sustainability issues and activities should be further developed.

The TFS employees have been involved through the employee survey. See focus area A; Equal opportunities and focus area D; Talent Development.

In the below table the sustainable topics per stakeholder are presented.

Stakeholders	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 customers	• 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
Authorities	• Compliance with regulations

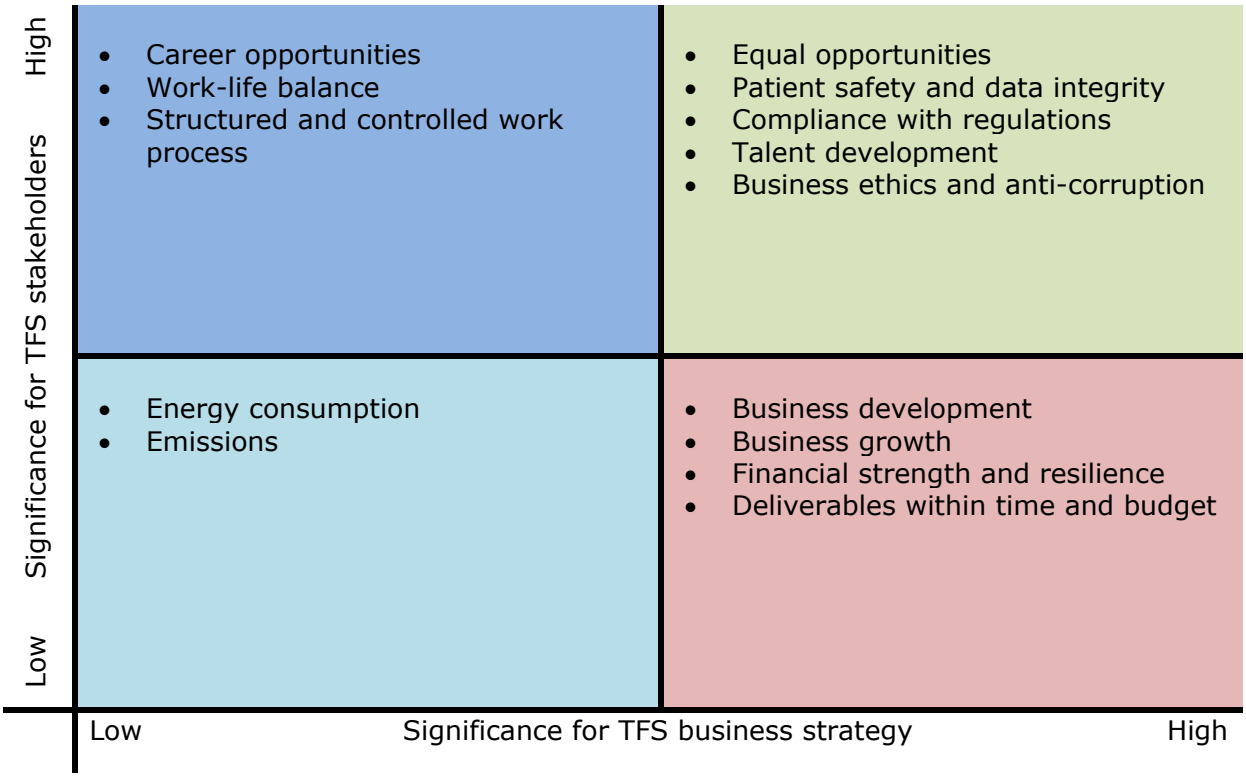
5. Materiality-analysis, areas of focus and stakeholders

An analysis of the company's role and impact on the society and its stakeholders is key for TFS. The materiality-matrix is a presentation of the most material sustainability issues, how they relate to the business and operations of TFS.

Materiality is determined on stakeholder significance and TFS business strategy significance.

Sustainability topics have been discussed and approved by TFS Board.

Materiality-matrix



Risks

We recognise the connection between enterprise risk management and sustainability management. During 2017 TFS performed a risk analysis. We conducted an assessment to connect our sustainability material issues to risks identified.

In 2018, we will explore further integration.

Below we have summarized the risks 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 also likely to affect employee engagement, 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 U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) 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
- Missing a whistle-blowing system. Unable to anonymously report issues, with the potential negative impact of discovering ethical or corruption issues too late.

Environment:

- Poor environmental efficiency;
  - energy inefficient offices
  - pollution due to travelling
- Chapter 2; precautionary principle includes more information on the management of environmental risks.

More information regarding how TFS manages these risks is discussed per material topic in Chapter 6 of the report.

6. TFS focus areas and agenda for sustainability

TFS's sustainability issues have been prioritised (materiality analysis).

TFS work as a reliable partner for clinical trials is our top priority. The 5 key/material issues for TFS that concern TFS sustainability efforts are given below.

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

6.1. Focus area A: Equal opportunities

6.1.1. Materiality of the focus area.

TFS places great importance on equal opportunities and diversity.

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

TFS staff is TFS' most important resource. Although the work is guided and regulated by policies and procedure, TFS staff have to complete the work. The professionalism, qualifications and dedication of TFS staff ensure that the agreed and required results can be achieved.

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 would not only have legal implications but also likely to affect employee engagement, staff motivation and damage our company name.

Impact may occur mainly as a result of TFS activities.

6.1.2. The TFS management approach

TFS has the ambition to attain equality and to be non-discriminatory. TFS shall act to prevent all forms of discrimination and harassment, by applying equality to all people, regardless of gender, age, ethnic origin, religion, functional handicap, or sexual nature. Employment and promotion and other related matters shall be assessed only with the employee's qualification as a basis and with no regard to the above-mentioned factors.

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

The global TFS Human Resources department have issued the Global Ethics and Diversity Policy and Action Plan in which TFS ambition and plans are explained.

In this policy, TFS expresses its ambition to offer all individuals equal opportunities regardless of skin colour, ethnicity, nationality, religion, gender, age, sexual orientation or other distinguishing characteristics. TFS is working actively for equality between men and women, by offering the same possibilities to men and women regarding employment, education, promotion, salary and development in their work and by facilitating for both male and female employees to enable them to combine employment with parenthood.

TFS works with 'Job evaluation' (in our case through Hay levelling). This process consists of ranking jobs/positions in a logical, transparent and neutral way on a pre-determined scale and connects jobs with salary ranges. We use this to compare salary levels for different positions internally as well as for external benchmarking. An additional impact of job evaluation is that it helps TFS to ensure that similar possibilities are offered in terms of roles or career paths regardless of gender, nationality or other distinguishing characteristics.

6.1.3. Evaluation of the TFS management approach.

Several instruments are used to evaluate equal opportunities at TFS.

First and foremost our approach can be evaluated by analysing the actual diversity in our workforce, further specified in 6.1.4. GRI Disclosure 405-1.

TFS regularly conducts surveys amongst all employees to get a better understanding of employee satisfaction and engagement at TFS. Our anonymous employee survey helps us to capture our staff opinion on topics such as Work environment, Benefits, Work tasks, Communication & Information, Training and Management. The survey provides a forum for open feedback, herewith involving employees in the development process by giving them a direct voice to TFS management. The survey results are published within the organization after which follow up and action planning is being done on different levels in the organization (team, function, global).

The employee survey does not currently feature a question that enables us to measure explicitly to what extent our employees feel they get equal opportunities. It is therefore TFS' ambition to add a specific measurement on this topic in the upcoming employee survey.

The employee survey includes however one parameter that can be used to partly highlight our results regarding equal opportunities. In the survey section regarding well-being at the workplace, staff are asked to what extent they feel bullying or discrimination is happening in the workplace. The 2017 survey revealed that 94% of our staff worldwide are not aware of any discrimination happening in the workplace. We have zero tolerance towards all forms of discrimination and harassment and make active efforts to completely eliminate discrimination and harassment from the workplace.

The Human Resources department monitors the equality of salaries and opportunities in connection to the job titles, responsibilities and achievements. The yearly Salary review process helps to keep a continued oversight. Assistance is provided to each TFS function to balance the salaries where necessary and escalate when abnormalities are found.

6.1.4. 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 (TLG)	Gender	Male	11	91,67%
		Female	1	8,33%
	Age	Under 30 years	0	0
		From 30 - 50 years old	6	50%
		Over 50 years old	6	50%
	Other indicators of diversity where relevant (such as minority or vulnerable groups).		n/a	
Rest of employees	Gender	Male	160	23,46%
		Female	522	76,54%
	Age	Under 30 years	54	7,91%
		From 30 - 50 years old	500	73,31%
		Over 50 years old	128	18,78%
	Other indicators of diversity where relevant (such as minority or vulnerable groups).		n/a	

In the 2016 report the following figures on Gender Equality Percentage of women in TFS were reported:

- Board of Directors: 20%
- Global Management Team: 20%
- Senior Management: 46%
- All employees: 77%

The % within the all employees group is similar in 2017. However, due to a different presentation of the management figures no comparison between 2016 and 2017 can be made.

The figures show that in our overall workforce the absolute majority of staff (over 75%) are female.

Our highest governance body (TLG) balances in the opposite direction with one female representative out of 12. It is TFS ambition to change this figure and have more female representation within the top governance bodies.

This disclosure illustrates that the age group under 30 years is underrepresented in our workforce compared to the other categories. It is TFS ambition to investigate this further and where needed develop an action plan.

6.2. Focus area B: Patient safety and data integrity

and

6.3. Focus area C: Compliance with regulations

6.2 / 3.1. Materiality of the focus areas.

Values, principles, standards and norms of behaviour

The conduct of clinical trials is regulated by international and national laws and regulations, which are designed to protect the rights and integrity of participants in clinical trials and define the manner in which clinical trials are designed, managed and reported.

Patient safety and data integrity are top priorities and we are committed to ensuring compliance with all legal and regulatory requirements.

Since patient safety and data integrity are the basis for the regulatory requirements the focus areas Patient safety and data integrity and Compliance with regulations are not separated in the report since the two are inter-twined.

Since patient safety and data integrity as well as compliance with regulations are core for TFS and its' business, serious non-compliances may be catastrophic for TFS and have enormous impact. This impact is not acceptable for TFS, TFS' clients and authorities.

It should be noted that an impact may occur as a result of TFS activities or may be caused by TFS collaborators like for example TFS vendors and staff at investigational sites involved in a clinical trial.

Ethical research

TFS are committed to conduct clinical trials in line with the highest ethical, medical and scientific standards, in accordance with the ethical standards defined in the Declaration of Helsinki, and that are consistent with International Council on Harmonisation (ICH) E6 (R2) Good Clinical Practices (GCP) guidelines and other similar guidelines as well as applicable regulatory requirement(s). This includes both interventional and non-interventional studies, and studies that use data from previous clinical trials.

Quality

As a company working in the CRO industry, TFS are required to conform to International, national and local legislation and regulations by authorities such as the European Medicines Agency (EMA), U.S. Food and Drug Administration (FDA), as well as to International Conference on Harmonisation (ICH) guidelines that govern Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) and Good Pharmacovigilance Practice (GVP) and ISO guidelines regarding Medical Devices. We also have to comply with local regulations by numerous agencies such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK.

6.2 / 3.2. The TFS management approach

To ensure that TFS operates in accordance with the requirements, we have developed and continuously improve our Quality Management System (QMS) (including policies and procedures). The TFS QMS is compliant with the aforementioned requirements.

The QMS is available for all employees on the TFS Intranet.

All TFS employees are trained on applicable parts of the QMS according to their role and responsibilities.

TFS Quality Assurance maintains the e-learning system (TFS Academy) for training. It is the primary responsibility of every TFS employee and their line manager to fulfil the training requirements.

TFS Quality Assurance is responsible for ensuring that appropriate Controlled Documents in the QMS are written and updated as and when necessary. TFS QA also maintains the QMS on the TFS Intranet.

Responsibilities related to approval and release:

- After approval by the SOP Committee, SOPs are forwarded to the EVP Quality Assurance and the Functional Head of the area concerned or the CEO, if applicable, for final signed approval and release.
- After approval by TFS QA, Policies will be forwarded to the CEO and EVP Quality Assurance for final approval and release.

As part of the TFS QMS there are several grievance mechanisms included: SOP on issue management and escalation; SOP on suspected misconduct and fraud; CAPA SOP. In these procedures the process to report, address and resolve grievances is described as well as how the mechanisms are managed.

TFS is also using an external whistleblowing system.

All grievance mechanisms are available for all TFS employees.

TFS department of Drug safety focusses on safety issues and monitors and reports on safety in clinical studies. To achieve this, the QMS includes dedicated safety SOPs.

The collection of reliable, accurate and secure data is the basis for many procedures including quality control checks and reviews. The processes for different departments are complementary and together strive for reliable, accurate and secure data.

6.2 / 3.3. Evaluation of the TFS management approach.

Compliance with regulations is assessed/evaluated on an ongoing basis:

- TFS Quality Assurance performs audits according to an audit schedule; audits are performed on TFS systems and projects and on TFS vendors.
- TFS Quality Assurance can perform additional or for cause audits when deemed necessary.
- On a regular basis TFS is inspected by national regulatory authorities and audited by external parties.

Based on the outcome, TFS instigates a process to resolve issues and/or to adapt or improve TFS SOPs and policies to resolve the issue and prevent future occurrences.

For 2018, TFS are developing a system to collect appropriate metrics which will be presented as a Quality Indicator dashboard. This information can be used by management to identify any areas of concern which require remediation.

6.2 / 3.4. Qualitative indicator

TFS uses a qualitative indicator for patient safety & data integrity and for Compliance with regulations. TFS' approach is described in the sections entitled TFS management approach and Evaluation of TFS management approach.

6.4. Focus area D: Talent development

6.4.1. Materiality of the focus area.

As already mentioned in Focus area A, staff is the most important resource for TFS.

The education, qualification, training and development of TFS staff is hugely important to achieve our company goals and to meet agreed client deliverables. The conduct of clinical trials is a strictly regulated business environment where qualification of staff directly impacts business success.

ICH E6 (R2) GCP guidelines require that appropriately qualified individuals are used at all stages of a trial and that they are adequately trained. 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.

6.4.2. The TFS management approach

In order for TFS to ensure that staff 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 for all functions
- A Standard Operating Procedure (SOP) defines the TFS policy for training and development of TFS staff and describes the procedures for completing and documenting this training.
- Annual review of competency
- Overview of required training for the positions within TFS
- TFS Academy; an eLearning system as well as a system to provide an overview of upcoming courses, training records and for storing CVs
- Annual performance dialogue to discuss development goals and targets.
- Offering training opportunities that build general and functional competence.

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

TFS Line Managers are responsible for:

- Ensuring and documenting that their staff are appropriately qualified and trained, including GCP training.
- Ensuring that their staff are trained in, and familiar with, relevant TFS SOPs.
- Preparing an individual induction and training programme for all new employees in their department. Ensuring that sufficient time and opportunity is available for staff training.
- Conducting a performance dialogue on a regularly basis (at least once per year).

TFS Project Leaders are responsible for:

- Ensuring that all members of their study team have received adequate training, including both TFS and Sponsor-specific SOP training and GCP training.
- Obtaining documentation of study specific training performed/undertaken from all members of the study team.
- Ensuring that employees update their CVs and Training Records as soon as information changes, for example after participating in a training course.

6.4.3. Evaluation of the TFS management approach.

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

During TFS internal audits, qualification and training is one of the audited topics.

Also during external audits and inspections this topic is reviewed and records are requested.

Audit findings need to be resolved and if deemed necessary, a preventative action may be required to prevent future occurrences.

On an individual basis, improvement processes may be initiated to allow the TFS employee to develop skills to the standard required for that role.

The annual review of competency and the performance dialogue provides the Line Manager with input on the individual's needs.

During the annual performance dialogue, training/development is one of the items to be assessed/discussed in order for TFS staff to deliver on their objectives and in accordance with the regulatory requirements.

TFS regularly conducts surveys amongst all employees to get a better understanding of employee satisfaction and engagement at TFS. The anonymous employee survey helps to capture our staff opinion on topics such as Work environment, Benefits, Work tasks, Communication & Information, Training and Management. The survey provides a forum for open feedback, herewith involving employees in the development process by giving them a direct voice to TFS management. The survey results are published within the organization after which follow up and action planning is done across the organization (team, function, global).

The TFS employee survey includes a complete section on Training. In the 2016 and 2017 surveys it has been indicated by TFS staff that improvements can be made to the training provided at TFS. Training has become one of the prioritized improvement areas at TFS and investments have been made to improve functional and general training and competence development. During 2017, several new training and development initiatives have been launched and more are planned during 2018, amongst others through a relaunch of the online training portal.

6.4.4. 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.

In the below table the results for this GRI disclosure are presented.

Percentage of employees receiving regular performance and career development reviews	100%

Since the percentage is 100% no distinction has been made in percentage of total employees by gender and by employee category.

6.5. Focus area E: Business ethics and anti-corruption

6.5.1. Materiality of the focus area.

The ethical principles guiding our work have their origin in the Declaration of Helsinki, as well as International Council on Harmonization (ICH) E6 (R2) Good Clinical Practices (GCP) and other similar guidelines.

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

Non-ethical or corrupt behaviour will harm the performance of clinical trials and the clinical data 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 behaviour can be enormous on TFS activities and deliverables since it is not acceptable to TFS, TFS' clients and regulatory authorities.

It should be noted that an 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.

6.5.2. The TFS management approach.

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

TFS have implemented procedures and policies to achieve this.

Ethical research:
As mentioned above, TFS are committed to conduct clinical trials in accordance with the ethical standards defined in the Declaration of Helsinki.

Furthermore, the global TFS Human Resources department have issued the Global Ethics and Diversity Policy and Action Plan in which TFS' aims and plans are explained. It is TFS' ambition to attain equality and to be non-discriminatory.

Anti-bribery and anti-corruption:
The term 'corruption' refers to abuse of a position of trust for one's own or the company's gain, for example through the use of bribes. A bribe is a gift or other benefit that might influence another person, as part of their employment or duties, to show improper favour to the giver.

TFS has zero tolerance for all forms of corruption and makes active efforts to ensure that it does not occur within the TFS Group.

TFS have an Anti-Bribery & Corruption Policy (ABAC) in place and all employees are required to perform the training course and have the obligation to comply with this ABAC policy.

Responsibilities for all TFS employees regarding ABAC are described in the ABAC policy.

Code of Conduct:
During 2016, TFS developed and released a Code of Conduct. In March 2017, 75% of TFS staff have been trained in TFS Code of Conduct.

Goal for 2017 was that all staff have to complete the training and work according to the Code of Conduct. By the end of December 2017, 96% of TFS staff has completed the TFS Code of Conduct training.

Whistle blowing:
TFS is in the process of establishing a whistle-blowing function.

In 2017 a decision was made regarding which whistle-blowing system would be chosen. An external whistleblowing function: WhistleB was chosen.

The implementation of WhistleB will be finalised in 2018.

6.5.3. Evaluation of the TFS management approach.

Business ethics and anti-corruption is currently monitored:

- During TFS internal audits, business ethics and anti-corruption are included.
- Also during external audits and inspections this topic is reviewed.
- When the whistle-blowing system is implemented an external party will be involved

Audit findings will be resolved and if deemed necessary a preventative action may be required to prevent future occurrences.

For 2018, TFS are developing a system to collect appropriate metrics which will be presented as a Quality Indicator dashboard. This information can be used by management to identify any areas of concern which require remediation.

As mentioned in 6.5.4 the anti-corruption training will now be required for all TFS staff.

It has to be discussed if TFS will also include vendors and subcontractors in the anti-corruption process and training.

6.5.4. 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.

In the table below the results for this GRI disclosure are presented.

Total number and percentage of TFS employees who have completed the TFS anti-corruption training.	
Of 708 TFS employees (November 2017) 550 have completed the TFS anti-corruption training.	78%
157 of the 708 employees are part of the TFS People group and until December 2017 there was no requirement for them to do the TFS anti-corruption training. Of the 551 TFS employees who are required to do the training, 550 employees have completed (December 2017)the TFS anti-corruption training.	99.8%

GRI 205-2 requires the following specific information to be reported:

a. Total number and percentage of governance body members that the organization's anti-corruption policies and procedures have been communicated to, broken down by region.

b. Total number and percentage of employees that the organization's anti-corruption policies and procedures have been communicated to, broken down by employee category and region.

c. Total number and percentage of business partners that the organization's anti-corruption policies and procedures have been communicated to, broken down by type of business partner and region. Describe if the organization's anti-corruption policies and procedures have been communicated to any other persons or organizations.

d. Total number and percentage of governance body members that have received training on anti-corruption, broken down by region.

e. Total number and percentage of employees that have received training on anti-corruption, broken down by employee category and region.

The training and eLearning system TFS uses (TFS Academy) cannot support this requirement since these data are not specified in the system.

Since TFS requires all staff to complete the anti-corruption training, TFS do not see the need to change their system.

TFS do not require their business partners to complete the TFS anti-corruption training. During the vendor and subcontractor assessment, the TFS vendors and subcontractors are asked if they have an anti-bribery and anti-corruption policy or SOP. The requirement to be trained remains with the vendor and subcontractor.

It has now decided (December 2017) that also the TFS People employees are required to perform the anti-corruption training.

Appendix 1: Location of TFS Headquarters and operations and entities included in TFS consolidated financial statements

TFS name	Legal Entity Name	Function	Address	VAT Numbers
TFS International	TFS Trial Form Support International AB	Headquarters	Scheelevägen 8B, Byggnad 1601 223 63 LUND Sweden	556513-1660
TFS Financial Service	TFS International Financial Services AB	Parent company of TFS Clinical Services (no operations)	Scheelevägen 8B, Byggnad 1601 223 63 LUND Sweden	559038-8228
TFS Clinical Services	TFS International Clinical Development Services AB	Holding company for all operating affiliates (no operations)	Scheelevägen 8B, Byggnad 1601 223 63 LUND Sweden	559039-6452
TFS Sweden	TFS Trial Form Support AB	Clinical operations	Scheelevägen 8B, Byggnad 1601 223 63 LUND Sweden	556652-7735
TFS Denmark	TFS Trial Form Support Aps	Clinical operations	Gyngmose Parkvej 50, 2860 Soborg	10064627
TFS Finland	TFS Trial Form Support OY	Clinical operations	Jaakonkatu 2 01620 Vantaa, Finland	1776835-8
TFS Norway	TFS Trial Form Support AS	Clinical operations	Hegdehaugsveien 24 0352 Oslo, Norway	992422351
TFS Spain	TFS Trial Form Support, S.L.	Clinical operations	Consell de Cent 334-336, 4a planta ES-08009 Barcelona, Spain	B-60 569 175
TFS Portugal	TFS Trial Form Support, Portugal	Clinical operations (non-operative). Branch from Spain	Rua Quinta dos Loios, 7 Lazarim 2825-156 Caparica; Portugal	980349273
TFS Italy	TFS Trial Form Support S.r.l.	Clinical operations	Viale dei Parioli,12 00197 Rome, Italy	377720100
TFS France	TFS Trial Form Support SAS	Clinical operations	7c place du Dôme, 3ème étage Immeuble Elysées la Défense 92056 Paris la Défense cedex, France	752 032 094
TFS Netherlands	TFS Trial Form Support BV	Clinical operations	Hogeweg 35-h, 5301 LJ Zaltbommel, The Netherlands	NL806417638B01

TFS name	Legal Entity Name	Function	Address	VAT Numbers
TFS Great Britain	TFS Trial Form Support Ltd	Clinical operations	Brook House, 54A Cowley Mill Road,Uxbridge Middlesex UB8 2QE, United Kingdom	5397155
TFS Germany	TFS Trial Form Support GmbH	Clinical operations	Business Center Bavaria, Radlkoferstrasse 2, 81373 München,Deutschland	143/185/91203
Sciderm	SCIderm GmbH	Clinical operations	Drehbahn 1 — 3, 20354 Hamburg Deutschland	HRB 93824
TFS Hungary	TFS Trial Form Support Kft	Clinical operations	Angyal u 5 HU-2000 Szentendre, Hungary	1309124457
TFS Poland	TFS Trial Form Support Sp. z o.o.	Clinical operations	ul.Iłżecka 26 E, 02-135 Warsaw, Poland	330798
TFS Czech Republic	TFS Trial Form Support s.r.o.	Clinical operations	Klimentska 1216/46 110 02 Prague 1, Czech Republic (also responsible for studies in Slovakia)	27876756
TFS Estonia	TFS Trial Form Support OÜ	Clinical operations (non-operative)	J. Kunderi 8A Tallinn 10121, Estonia	11208436
TFS Lithuania	TFS Trial Form Support OU filialas	Clinical operations (non-operative). Branch from Estonia	Didžioji g. 25 LT 01-128 Vilnius, Lithuania	302467938
TFS Latvia	TFS Trial Form Support OU Latvijas filiāle	Clinical operations (non-operative. Branch from Estonia	Antonijas iela 24-5 LV-1010 Riga, Latvia	40103265469
TFS US - Holding	TFS Holdings US, Inc	Holding with US (no operations)	212 Carnegie Center, Suite 208 Princeton, New Jersey, 08540 USA	N/A
TFS US	TFS Trial Form Support, Inc	Clinical operations	212 Carnegie Center, Suite 208 Princeton, New Jersey, 08540 USA	N/A

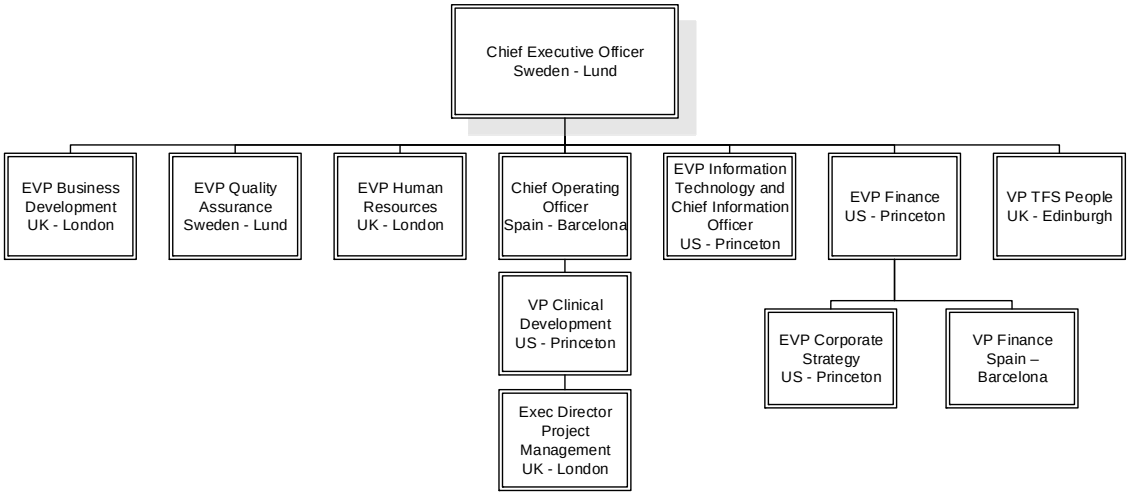
Appendix 2: GRI Content Index.

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**
Organizational Profile			
102-1	Name of the Organisation	5-7, 24-25	
102-2	Activities, brands, products and services	3, 5, 6, 24-25	
102-3	Location of headquarters	24	
102-4	Location of operations	6, 24-25	
102-5	Ownership and legal form	6-7, 24-25	
102-6	Markets served	3, 5, 6, 24-25	
102-7	Scale of the organization	6-7, 24-25	
102-8	Information on employees and other workers	6-7	TFS do not report numbers per country due to confidentiality reasons
102-9	Supply chain	6-7	
102-10	Significant changes to the organisation and its supply chain	7	
102-11	Precautionary Principle or approach	5	
102-12	External initiatives	3, 4, 8, 17, 20-21	
102-13	Membership of associations	8-9	
Strategy			
102-14	Statement from senior decision-maker	3-4	
Ethics and Integrity			
102-16	Values, principles, standards and norms of behaviour	3, 5, 16-17, 20-21	
Governance			
102-18	Governance structure	6, 30	

Stakeholder engagement			
102-40	List of stakeholder groups	9-10	
102-41	Collective bargaining agreements	7	
102-42	Identifying and selecting stakeholders	9	
102-43	Approach to stakeholder engagement	9	
102-44	Key topics and concerns raised	9-11	
Reporting practice			
102-45	Entities included in the consolidated financial statements	7, 24-25	All entities are included
102-46	Defining report content and topic Boundaries	8-11	
102-47	List of material topics	10-11	
102-48	Restatements of information	8	
102-49	Changes in reporting	8	
102-50	Reporting period	8	
102-51	Date of most recent report	1	
102-52	Reporting cycle	8	
102-53	Contact point for questions regarding the report	8	
102-54	Claims of reporting in accordance with the GRI Standards	8	
102-55	GRI content index	26-29	
102-56	External assurance	8	
Material Topics			
Number of Disclosure	**Disclosure**	**Page number (s) and/or URL(s)**	**Comments and Omissions**
Economic standards			
GRI 103: Management Approach 2016 and GRI 205: Anti-corruption 2016			
103-1	Explanation of the material topic and its Boundary	20	
103-2	The management approach and its components	20-21	

103-3	Evaluation of the management approach	21-22	
205-2	Communication and training on anti-corruption policies and procedures	22-23	Omissions: TFS does not report on 'Number and % governance body members' and 'regional breakdown' since these data are not applicable: 100% training compliance is expected. Data on 'business' partners are not available. Need for future availability will be investigated.
Social standards			
GRI 103: Management Approach 2016 and GRI 404: Training and education 2016			
103-1	Explanation of the material topic and its Boundary	18	
103-2	The management approach and its components	18-19	
103-3	Evaluation of the management approach	19-20	
404-3	Percentage of employees receiving regular performance and career development reviews	20	
GRI 103: Management Approach 2016 and GRI 405: Diversity and Equal Opportunity 2016			
103-1	Explanation of the material topic and its Boundary	13	
103-2	The management approach and its components	13-14	
103-3	Evaluation of the management approach	14	
405-1	Diversity of governance bodies and employees	15	

Company specific topics and disclosures			
GRI 103: Management Approach 2016 and Own indicator: Patient safety & data integrity			
103-1	Explanation of the material topic and its Boundary	16	
103-2	The management approach and its components	17	
103-3	Evaluation of the management approach	17-18	
Own indicator	Patient safety & data integrity	18	
GRI 103: Management Approach 2016 and Own indicator: Compliance with regulations			
103-1	Explanation of the material topic and its Boundary	16	
103-2	The management approach and its components	17	
103-3	Evaluation of the management approach	17-18	
Own indicator	Compliance with regulations	18	

Appendix 3: Organisation chart TFS Leadership Group.

TFS Leadership Group - TLG