1. Executive Summary

a. Project purpose

The effective application and analysis of data in life science industry demands that such data assets are made Findable, Accessible, Interoperable and Reusable (FAIR). These guiding principles have been articulated clearly in the seminal paper published in 2016 by Wilkinson MD et al (doi.org/10.1038/sdata.2016.18). During 2018 a design framework and exemplar metrics for FAIRness was published by Wilkinson MD et al (doi.org/10.1038/sdata.2018.118). This work has emerged mostly from academic groups which has caught the attention of the biopharmaceutical industry who are now making substantial investment in utilising the FAIR guiding principles to improve how they manage their corporate data assets.

Pistoia Alliance organised numerous FAIR activities during 2018. This begun with a breakout session on FAIR during the Pistoia EU Conference in London, UK. This was followed up by a Pistoia workshop in June hosted at The Hyve in Utrecht, NL which resulted in the publication of a feature article in Drug Discovery Today by Wise et al (doi.org/10.1016/j.drudis.2019.01.008). There was a further breakout session on FAIR during the Pistoia US Conference in Boston which was followed by another workshop in December hosted by EPAM in Boston, US which generated further ideas to inform this business case.

Clearly, there is much interest in FAIR implementation by Pistoia member companies which is sufficient to warrant close scrutiny in this business case which includes the
work plan for the first phase of a full project. Funding commitments have already been made by three Pistoia member organisations (Roche, AZ/MedImmune and BMS). However, 2 or 3 more funders need to be found for realisation of the full work plan for phase 1, described here.

The major purpose of this project is to provide pre-competitive support for FAIR Implementation by Life Science industry through the development of a FAIR Toolkit, which is illustrated below.

The Pistoia FAIR Toolkit will include the definition of the needs of life science industry which will be used to develop criteria for selection of relevant FAIR resources. We will also identify one or two additional principles, corresponding metrics and use cases that are especially relevant to life science industry. A crucial approach that we will adopt is to leverage and adapt (if necessary) existing FAIR resources (abstraction and linkage) for inclusion in the FAIR Toolkit. We will begin this rapidly through using a simple prototype wiki to gather and select content, driven by the criteria. This will lead to the specification, design and implementation of a FAIR Toolkit implemented as a "one-stop shop" website. This is expected to work much like the Pistoia UXLS Toolkit (uxls.org), where the structure and html code will be adapted to support FAIR Implementation by Life Science industry by the end of 2019 as phase 1.
2. Specification and boundary drawing

a. Deliverables, milestones and timing (in scope)

1. Define the needs of life science industry by end of 2Q 2019.
2. Develop the criteria for selection of relevant FAIR resources by end of 2Q 2019.
3. Host a series of Community of Interest (CoI) webinars on FAIR (and linked) data throughout 2019.
4. Select existing FAIR resources (abstraction and linkage) for inclusion in the FAIR Toolkit as a prototype wiki by end of 3Q 2019
5. Identify any additional content such as more FAIR principles, metrics and use cases relevant to life science industry by end of 3Q 2019
6. Develop the FAIR Toolkit as a "one-stop shop" by end of 4Q 2019
7. Host a workshop event on “FAIR Implementation for Pharma working with CROs” by end of 4Q 2019.

b. Metrics of success for Phase 1

- A well-defined set of requirements for FAIR implementation by life science industry
- A set of criteria for selection of FAIR resources which align to our requirements
- A series of Community of Interest (CoI) webinars on FAIR (and linked) data
- Inclusion of a relevant set of FAIR resources relevant to life science industry
- Wiki page to prototype relevant content for inclusion in the FAIR Toolkit
- One or two additional FAIR principles and their corresponding metrics for inclusion in the FAIR Toolkit
- Inclusion of 4-6 use case examples from life science industry in the FAIR Toolkit
- Web site for version 1 of the FAIR Toolkit
- A workshop event on "FAIR Implementation for Pharma working with CROs"

c. Out of scope

While Phase 1 will leverage existing FAIR resources and adapt the UXLS.org Toolkit design and html code by a web developer, it will not include the coding of new tools.

d. Project management style

A flexible and agile project management style will be adopted, similar to the successful Ontologies Mapping project, where a similar collaborative project wiki has been adopted already.
3. Player analysis

a. Landscape of major FAIR players

The landscape of major FAIR players and the relationships between them and this project are shown in the figure below, where solid lines indicate a publicly disclosed relationship and a dashed line is more likely to be informal:

![FAIR ecosystem diagram]

The FAIR movement has grown rapidly since 2016 into a busy landscape or ecosystem of numerous major player organisations or project consortia. This has been called the Internet of FAIR Data Services (IFDS) by Barend Mons 2018 (https://doi.org/10.1162/dint_a_00002). The many relationships between the major players brings complexity as depicted as a graph in Figure 1, which shows the position of our own project in relation to the major players through our own project team members, who are often active in more than one FAIR player. It is clearly important to be well connected within this landscape where the Pistoia Alliance is in a very strong position to engage with it's members, whilst leveraging existing FAIR resources which are relevant to development of it's own distinctive role, as described in a later section.

b. Attributes of the major FAIR players

The attributes of the major FAIR players are show in the table below which includes geography and description of purpose:-
<table>
<thead>
<tr>
<th>Player</th>
<th>Link</th>
<th>Geography</th>
<th>Description of purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>FAIRsharing</td>
<td><a href="https://fairsharing.org">https://fairsharing.org</a></td>
<td>Global open</td>
<td>This is a curated, informative and educational resource on data and metadata standards, inter-related to databases and data policies.</td>
</tr>
<tr>
<td>GO FAIR</td>
<td><a href="https://www.go-fair.org">https://www.go-fair.org</a></td>
<td>Global open</td>
<td>This global open organisation follows a bottom-up open implementation strategy for the European Open Science Cloud (EOSC) as part of a broader global Internet of FAIR Data Services (IFDS).</td>
</tr>
<tr>
<td>FAIR Metrics Group</td>
<td><a href="http://fairmetrics.org">http://fairmetrics.org</a></td>
<td>Europe open</td>
<td>This group took-on the challenge of designing a framework for evaluating “FAIRness“. With a mechanism in-place to design metrics, we now open the process of generating metrics to community participation.</td>
</tr>
<tr>
<td>Dutch Techcentre for Life Sciences</td>
<td><a href="https://www.dtls.nl">https://www.dtls.nl</a></td>
<td>Holland public-private</td>
<td>This is a public-private partnership of more than 50 Dutch life science organisations. It acts as a network of professionals that jointly improve the Dutch life science research infrastructure, with a focus on accessible high-end technologies, FAIR data treatment, and expert training.</td>
</tr>
<tr>
<td>FAIRplus IMI project</td>
<td><a href="https://fairplus-project.eu">https://fairplus-project.eu</a></td>
<td>Europe public-private</td>
<td>This IMI/EFPIA funded project aims to develop tools and guidelines for making life science data FAIR (Findable, Accessible, Interoperable, Reusable). The project has 22 partners from academia and industry, and runs from January 2019 to June 2022.</td>
</tr>
<tr>
<td>FAIR4Health project</td>
<td><a href="https://www.fair4health.eu">https://www.fair4health.eu</a></td>
<td>Europe open</td>
<td>This Horizon 2020 funded project encourages the reuse of research data generated by publicly funded research projects in health.</td>
</tr>
<tr>
<td>---------------------</td>
<td>-----------------------------</td>
<td>-------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Data Commons Pilot for NIH</td>
<td><a href="https://commonfund.nih.gov/commons">https://commonfund.nih.gov/commons</a></td>
<td>USA open</td>
<td>This pilot aims to accelerate new biomedical discoveries by developing and testing a cloud-based platform where investigators can store, share, access, and interact with digital objects (data, software, etc.) generated from biomedical and behavioural research.</td>
</tr>
<tr>
<td>FAIRSFAIR</td>
<td><a href="https://www.fairsfair.eu">https://www.fairsfair.eu</a></td>
<td>Europe open</td>
<td>Aims to supply practical solutions for the use of the FAIR data principles throughout the research life cycle with emphasis on fostering FAIR data culture and the uptake of good practices in making data FAIR.</td>
</tr>
<tr>
<td>EOSC-hub</td>
<td><a href="https://www.eosc-hub.eu/news/services-support-fair-data">https://www.eosc-hub.eu/news/services-support-fair-data</a></td>
<td>Europe open</td>
<td>Services for the European Open Science Cloud mostly for academic users. OpenAIRE, RDA Europe, FAIRSFAIR and EOSC-hub co-host three workshops during 2019, called ‘Services to Support FAIR Data’.</td>
</tr>
<tr>
<td>OpenAIRE</td>
<td><a href="https://www.openaire.eu">https://www.openaire.eu</a></td>
<td>Europe open</td>
<td>Facilitates open science in scholarly communication. Includes guides for research data management.</td>
</tr>
<tr>
<td>Research Data Alliance (RDA)</td>
<td><a href="https://rd-alliance.org">https://rd-alliance.org</a></td>
<td>Global open</td>
<td>Building the social and technical bridges to enable open sharing and re-use of data.</td>
</tr>
</tbody>
</table>

The FAIR movement begun largely in European universities with a workshop which culminated in the seminal 2016 paper by Wilkinson et al. This explains why the major players shown in Table 1 are based in Western Europe. FAIRsharing.org begun as Sharing.org serving as a catalogue of open standards, databases and policies which has embraced the FAIR movement to such an extent that it's name now reflects this. It is seen an overarching resource by Global, Open FAIR which is a labyrinthine and
c. Distinctive value for this project

This project will develop the concept of a FAIR Toolkit in to a "one stop shop" or hub for existing FAIR resources which have been selected as being relevant to the needs of life science industry for implementation of the FAIR guiding principles for data management and stewardship. The FAIR Toolkit will leverage existing tools and methods which have been selected by criteria determined by the requirements of the project team. We will also define FAIR principles relevant to data quality which is crucial for effective application of AI and ML by industry. Existing FAIR training and education resources will also be leveraged and adapted for usage by industry for inclusion in the FAIR Toolkit. Culture change methodologies relevant to effective FAIR implementation will also be part of the toolkit. Final elements of the toolkit will be selected case studies contributed by the project team and in particular, we will include tangible examples of cost benefit in the enterprise setting. Another distinctive feature is that this project will focus on a data provider group, chosen by the funders, such as contract research organisations.

d. Compete or collaborate?

Our strategy is to collaborate with selected major players in the FAIR landscape. We have already established a collaboration with FAIRplus on use cases and with GO-FAIR through active participation in the Chemistry and Rare Diseases Implementation Networks (INs). Serena Scollen (FAIRplus PI) and Katharina Lauer (FAIRplus Industry Liaison) have joined the project team (both at ELIXIR hub; now a Pistoia member) along with other partners of FAIRplus such as Kees van Bochove (The Hyve) and Nick Lynch (Open PHACTS). The project team also includes Ian Harrow (Project Manager) who is a member of the GO FAIR Rare Diseases IN and Carmen Nitsche who is a member of the GO FAIR Chemistry IN. This demonstrates how the project is well connected within the FAIR landscape which is expected to grow as the Internet of FAIR Data and Services.
e. Alignment with member business

The IFDS is emerging already as an ecosystem of academic centres, especially in Europe and North America. In addition, content and technical service providers are actively embracing the FAIR guiding principles to bring a commercial dimension. Many of these companies are members of the Pistoia Alliance, for example, Elsevier, OSTHUS, SciBite and OntoForce, to name a few who are also members of the project team. These companies are supporting this precompetitive project because it is an opportunity for the community of life science industry to form a single voice to agree on common data management needs and practices in an informed and coherent manner. This is evident from the feature article published recently by Wise et al 2019 entitled "Implementation and relevance of FAIR data principles in biopharmaceutical R&D" ([doi.org/10.1016/j.drudis.2019.01.008](https://doi.org/10.1016/j.drudis.2019.01.008)).

4. Market assessment

a. Community/market sectors and potential size

The emerging IFDS has the potential to power a market of professional products and services for data analytics. This is expected by Barend Mons and others to be much the same as the scalable growth of the world wide web. Since it's invention by Sir Tim Berners-Lee in 1992, we have all witnessed the dramatic growth of global businesses, such as Google, Amazon and Facebook which has been powered by the world wide web and business focussed practice in data management. The life science sector is coming to recognise the power of digital transformation which is why it is important to recognise the true value of data as a corporate asset. For example, in a recent article in [Forbes by the CEO of Novartis](https://www.forbes.com) who wanted to implement machine learning technology but this has been impeded by dirty datasets. Implementation of the FAIR guiding principles promises to deliver much cleaner data. The traditional biopharmaceutical sector can learn from the proven success of Google, Amazon and Facebook with the application of powerful data mining and analytics to understand the patterns of customer spending and preference behaviours on their web sites. This business return has taken nearly two decades to mature to yield publicly quoted companies on the stock market.

The IFDS of commercial providers have the opportunity to facilitate the digital transformation of traditional pharma and also, to partner with the new breed of micro drug discovery companies, such as Benevolent AI and Exscientia, who also embrace FAIR data to feed their hungry algorithms through cycles of machine learning and validation. The potential size of the IFDS as a commercial market opportunity is currently unknown, but it should be seen as being coupled to application and support for more effective data analytics and digital transformation. This market is forecast to reach a huge US$462 Billion by 2024 with a compound annual growth rate of 18% (source: [MarketWatch Aug 2018](https://www.marketwatch.com)).
5. Cost benefit analysis

a. Benefits to stakeholders

i. To business processes

- Improved reproducibility of preclinical laboratory experiments
- Improved reproducibility of clinical trials
- Improved outcomes in patient care
- Better collaborative and competitive intelligence
- Better mergers, acquisitions and partnerships

ii. To management

- Scalable, better quality and faster data analytics
- Collaborative intelligence data for partnering
- Complementary data assets for partnering
- Competitive intelligence data to understand the market
- Manage external data from mergers and acquisitions
- Manage sharing of data with external partners

iii. To end-users

- A catalogue to find data sets and understand their context
- Managed access to data sets using open protocol standards
- More integration of internal and public data sets
- Better query using vocabularies and ontologies
- More reusability of data sets to extend their life
- Greater reproducibility from context and provenance
- Less time required to clean the data for automated analysis
- Better scaling of quality data analysis from machine readability

b. Strategic time frames

i. Short term (Phase 1 by end of 2019)

- Develop the FAIR Toolkit for Life Science industry for launch as a maintained web site.
- A definition of the FAIR data needs of Life Science industry to drive the content of the toolkit.
- Build a network of collaborations in the FAIR landscape as part of the Community of Interest.
- A workshop event to attract CROs will be organised to output actionable plans for phase 2.
o Develop themes such as engagement with content and healthcare providers for phase 2.
o A proposal to extend the project into phase 2 for 2020.

ii. Long term (Vision for Phase 2 during 2020)

o Develop and maintain the FAIR Toolkit for Life Science industry.
o Implement the three FAIR data themes developed during phase 1.
o Organise two workshops based on the FAIR data themes.
o Continue to network with collaborators in the FAIR landscape as part of the Community of Interest.

c. Cost estimates

i. Manpower

The estimated costs for the skills required for full implementation of phase 1 are summarised in the following table:-

<table>
<thead>
<tr>
<th>Skills required</th>
<th>Estimated Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Management (2 days per week)</td>
<td>$30,000</td>
</tr>
<tr>
<td>Web developer to adapt uxls.org (25 days max.)</td>
<td>$20,000</td>
</tr>
<tr>
<td>Subject matter expertise (from Project Team)</td>
<td>In kind</td>
</tr>
<tr>
<td>Pistoia Business Development support</td>
<td>As needed</td>
</tr>
<tr>
<td>Community of Interest (CoI) collaboration</td>
<td>Sharing</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$50,000</strong></td>
</tr>
</tbody>
</table>

ii. Publicity and Outreach

The estimated costs for publicity and outreach are summarised in the following table:-

<table>
<thead>
<tr>
<th>Publicity and Outreach</th>
<th>Estimated cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article publication</td>
<td>$5,000</td>
</tr>
<tr>
<td>Workshop organisation</td>
<td>$5,000</td>
</tr>
<tr>
<td>Conference outreach</td>
<td>$5,000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$15,000</strong></td>
</tr>
</tbody>
</table>
iii. Other costs

No other costs are expected.

iv. Funding contributions for full implementation of the workplan for phase 1

Three Pistoia member organisations (Roche, AZ/MedImmune and BMS) initially committed $10K each which has already enabled us to publish the Discovery Today shorty feature as an open source publication and start the project in 2019. During 1Q 2019 the project team has been assembled, meeting every 2 weeks. They are supported by a project manager (Ian Harrow) who makes heavy use of the project wiki and Google drive for collaborative work, such as the business case and candidate content for the FAIR Toolkit. Most recently (16 May 2019), further funding has been provided by Bayer ($11K) and Roche ($30K) bringing the total to $71,000 which enables operation as a fully formed project.

The total budget for manpower, publicity and outreach of $65K compares well with the funds raised to date ($71K minus 10% Pistoia incidental costs). This is sufficient to realise the work plans of phase 1 as described in this document. Further funding contributions would be most welcome because this would enable us to increase the scope and quality of our deliverables at greater pace.

6. Risks and uncertainty

a. Key risks and mitigation

The key risks early in phase 1 are shown below, along with the mitigating actions to manage the risk:

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigating actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distinctive value has been hard to realise</td>
<td>Get feedback from the funders, project team and CoI and make changes to increase distinctive value and it's visibility.</td>
</tr>
<tr>
<td>Too slow to react to change</td>
<td>Identify early signals of change and implement a tactical plan to remedy.</td>
</tr>
<tr>
<td>Insufficient usage by the FAIR Toolkit users</td>
<td>More userability testing to improve the user experience.</td>
</tr>
</tbody>
</table>

b. Sources of uncertainty

- Will the Pistoia member organisations see sufficient value in working together to overcome common barriers for FAIR implementation? Can we translate this potential value into engagement with this project through funding and in kind contributions?
o How will the complexity of the FAIR landscape change as the IFDS grows over the next few years? Will the maturing IFDS bring clarity and consolidation or more complexity and fragmentation?

7. Sustainability plan

a. Phase 2 vision

Phase 1 will develop at least three themes to seed phase 2. These will develop FAIR activities and resources to promote more effective FAIR implementation throughout the whole data supply chain for biopharma business. This will involve engagement with Pistoia member organisations whose business is to generate data for their pharma customers such as contract research organisations (CROs), content providers, technology service provider and healthcare systems such as academic hospitals. This will see the IFDS grow and mature to support the whole Life Science industry eco system on a holistic and proactive basis rather than bilateral and reactive manner.

b. Scenarios for sustainability

i. Commercial potential?

The Internet of FAIR Data Services (IFDS) has the potential to grow into a market of commercial products and professional services offered to consumer organisations. An early example is Phortos Consultants (http://www.phortosconsultants.com) which specialises in professional FAIR consulting, FAIR training and FAIR services. Phortos say that they partner with another company called Euretos (http://www.euretos.com) which offers an AI (Artificial Platform) used by pre-clinical researchers for in-silico discovery & validation of targets and biomarkers. This platform is available by direct access for a subscription fee which is supported by a professional consulting service. Another early example is Research Data Consulting at San Diego Supercomputer Centre (https://www.sdsc.edu/services/ci/research_data_consulting.html) which offers three tiers of FAIR data consulting service as the first GO-FAIR office in the US.

In addition to such explicit FAIR data consulting services there are technology and content providers are also actively embracing FAIR data as an integral part of their products and services. Examples are Elsevier RELX (https://www.relx.com), The Hyve (https://theonew.nl), Osthus (https://www.osthus.com), OntoForce (https://www.ontoforce.com), SciBite (https://www.scibite.com) and Linguamatics (https://www.linguamatics.com). These are all Pistoia member organisations and most are already engaged in this project.
Given this dynamic context and the promising growth of the IFDS as a potential new market (or a new part of the bigger digital transformation market) it could be argued that in the next 3-5 year timeframe this project has the potential for commercial spin-off either as an independent entity or as part of an existing enterprise, which is explored further below.

ii. Foundation?

In a 3-5 year timeframe this project has the potential to transition into or become part of a not for profit enterprise such as a foundation which offers products and services in the digital transformation market.

iii. Pistoia sustainability?

Future sustainability for a FAIR project by Pistoia is likely to comprise of a phased project which is managed over a 3 year period. It will most likely depend on attracting funds from the Pistoia member organisations whilst it develops as a distinctive and productive project. Beyond this period, it will need to transition to being a Pistoia funded project to becoming a self-sustaining entity which is independent or part of larger enterprise.

iv. Merger with an external project?

Numerous external FAIR projects or entities have been described already as players in the FAIR landscape. At this time, we believe that there are distinctive opportunities of for a Pistoia project focussed on FAIR Implementation by Life Science industry through rapid development of a FAIR Toolkit and relevant case studies for FAIR implementation within industry. We consider that it is important that this project remains distinctive with this focus, whilst building collaborative relationships with related external projects such as FAIRplus and GO-FAIR.

v. Donate to an external organisation?

Donation of the outputs from this Pistoia project to an external organisation could be one of the paths to a sustainable future in a 3-5 year timeframe.

c. Process for end of project

This will be a managed process to ensure that outputs from the Pistoia project are published and preserved as appropriate digital artefacts, guided by the FAIR principles! These digital artefacts (data and metadata) will be transferred to an appropriate entity for independent sustainability at the end of the project life cycle.
8. Communications plan

a. Tactics to build and maintain visibility

Building and maintaining strong visibility will be an ongoing set of tactics to expose what we are doing through the project Community of Interest (CoI), blog posts on the Pistoia web site, timely snippets through the social media channels (Twitter and LinkedIn). We will also continue to seek opportunities to contribute to relevant workshops and conferences so that we remain highly visible and distinctive so that this Pistoia project is regarded as a strong contributor to the FAIR landscape and the emerging IFDS.

b. Strategy for outreach and publicity

The long-term strategy will comprise of collaboration with major players, such as FAIRplus and GO-FAIR, especially on use cases and contribution of project outputs to scientific conferences, workshops and peer reviewed, open source publications.

9. Consultation and work plan

a. Consultation with Pistoia member organisations and wider community

This project has emerged from much consultation with Pistoia member organisations and the wider community which has clearly demonstrated both need and interest. Three Pistoia member organisations have already committed funds as described already.

Consultation begun formally with a breakout session on FAIR at the Pistoia 2018 EU conference in London which invited numerous experts to present on FAIR from the different perspectives of academia, SMEs and Pharma. This was followed up by a workshop on FAIR hosted by The Hyve in Utrecht in June 2018 and the output (Report in Google drive) from this resulted in a feature article being published in Drug Discovery Today (doi.org/10.1016/j.drudis.2019.01.008). Another breakout session on FAIR at the Pistoia 2018 US conference in Boston focussed on ideas to drive a FAIR project which was followed up by a second FAIR workshop was hosted by EPAM in December 2018. This considered the FAIR metrics for pharma and the seeds for the business case. The full report (on Public Google drive) is a compilation from four World Cafe breakout sessions and below summarises the output from session 4:-

Breakout session 4: on FAIR for Pharma considered “What is the business case for a Pistoia FAIR project?”
Red whiteboard led by Tom Plasterer listed numerous aspects including competition, partners and internal projects. For example, GO-FAIR, FAIRplus and other relevant standards and institutes. Big high-level resources include big academic institutes (NCBI, EMBL-EBI & ELIXIR), NIH Data Commons pilot, big commercial FAIR players, pharma focused AI companies, content providers and CROs.

Black whiteboard led by Andreas Matern described how it is important to start from Reuse and ask “what are we trying to accomplish?”. Important to emphasize the business value of precompetitive approaches for FAIR metrics in pharma. Who are the stakeholders? Pharma? Vendors? Start with pharma R&D. Less data wrangling and more effective machine learning.

Blue whiteboard led by Daniel Clarke listed numerous aspects of business value. For example: What metrics are most relevant to pharma? What does FAIR really mean? Lack of resources (money and people). Lack of measurable ROI. Risk of NOT being FAIR?

Green whiteboard led by Ted Slater focused on communications to the business; getting the message out (internally to the business rather than IT) and sustaining the FAIRification effort. More important to address cultural need for change rather than the technical issues. Prioritise to FAIRify low hanging fruit data sets which combine high business value, doability and speed to show the benefits of success (=ROI).

Following on from this, a FAIR project team was formed at the beginning of 2019 which has developed the concept of a FAIR Toolkit, as described in this business case, which was presented to the Pistoia 2019 EU conference in London at a breakout session. The talk received strong interest and support from the audience (Pistoia members Google drive).

b. Work plan for Phase 1

The preliminary work plan is presented in the table below:

<table>
<thead>
<tr>
<th>Deliverable milestone</th>
<th>By whom</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Define the requirements of life science industry for FAIR implementation</td>
<td>Project team</td>
<td>by end 2Q 2019</td>
</tr>
<tr>
<td>2. Agree on criteria for selection of relevant FAIR resources</td>
<td>Project team</td>
<td>by end 2Q 2019</td>
</tr>
<tr>
<td>3. Host a series of Community of Interest (CoI) webinars on FAIR (and linked) data</td>
<td>Project manager</td>
<td>throughout 2019</td>
</tr>
<tr>
<td>4. Select existing FAIR resources for inclusion in the FAIR Toolkit</td>
<td>Project team</td>
<td>by end 3Q 2019</td>
</tr>
</tbody>
</table>
5. Develop additional content such as a data quality principle, metrics, methods and use cases for the FAIR Toolkit | Project team | by end 3Q 2019

6. Implement the FAIR Toolkit as a "one-stop shop" web site | Web developer | by end 4Q 2019

7. Host a workshop event on “FAIR Implementation for Pharma working with CROs” | Project Team | by end 4Q 2019

The timeline for the deliverable milestones for phase 1 is presented below:-

1. Define requirements
2. Agree on criteria for selection
3. A series of webinars
4. Select existing resources
5. Develop additional content
6. Implement web site
7. A workshop event