**Business Plan: The Institute for Regulatory Science**

1. **Introduction**

South Africa’s quadruple burden of disease – HIV/AIDS and related illnesses notably TB, Maternal and Child morbidity and mortality, Non-communicable diseases, violence, injuries and trauma – looms as a major obstacle to the realization of the National Development Plan 2030 goal of a safe, prosperous and healthy South Africa. Major public investments complemented by donor resources have led to significant improvements in AIDS mortality, TB detection and treatment and in reducing maternal and childhood deaths. However, sustaining these gains will require continued investment in order to build a durable and responsive health system, staffed by a skilled and motivated workforce with reliable access to safe and effective health products and technologies.

Notwithstanding these health benefits, the positive impact of the health products industry is also evident in the trade and investment (DTI) and science and technology sectors (DST). The South African pharmaceutical market is the largest in Sub-Saharan Africa and valued at between R42 - 48 billion (USD 3.5 – 4.0 billion) in 2014[[1]](#footnote-1). This market is forecast to grow by a compound annual growth rate of 6 - 9%, to reach an estimated value of R60 – 84 billion (USD 5 – 7 billion) by 2018.[[2]](#footnote-2), [[3]](#footnote-3), [[4]](#footnote-4)

The market for medical devices is valued at R14.4 billion (USD 1.2 billion) in 2013 and is expected to grow annually by 6 %, reaching R20.6 billion by 2018[[5]](#footnote-5). Similarly, the Clinical Research industry was valued at R 3,4 billion (250 million Euros) in 2013.[[6]](#footnote-6)

Despite gloomy overall economic predictions, market sentiment in all three areas remains positive, based largely on the promise of market opportunities in the National Health Insurance rollout, the implementation of public-private partnerships and the ability to contest for low risk, high volume public tenders. Anticipation of improved efficiencies through the transition to the South African Health Products Authority (SAPHRA) has also featured prominently.

Regulation of health products in South Africa is the responsibility of the Medicines Control Council (MCC) in terms of the Medicines and Related Substances Control Act 101 of 1965, as amended. The Council is appointed by the Minister of Health and consists of 24 members drawn from academia, non-government organisations (NGO’s) and government and appointed for a period of five years.

The MCC is assisted in its deliberations by recommendations from several expert committees. Currently there are nine such committees, seven of which perform a specific function with respect to either the registration of a medicine, clinical trial or post-marketing surveillance of medicinal products. Although complementary and African traditional medicines are currently not regulated, a separate committee for each of these alternative therapies has been established. The work of Council and the Committees is supported by the Department of Health Cluster: Medicines Regulatory Affairs (MRA) See Figure 1.

**Figure 1: Overview of the Medicines Control Council, Committees and MRA**



This model of part-time external evaluators supported by a Department of Health secretariat (MRA) seems to have worked reasonably well until the mid to late 1990’s, at which time the system began to show strain. The mid 2000’s brought huge increases in the number of applications for the registration (mainly generics), that was not matched by an equivalent increase in regulatory capacity. On the contrary, high staff turnover and difficulty in attracting qualified staff to the MRA, despite improved remuneration under the Occupational Specific Dispensation (OSD), has further eroded this capacity base.

A further drawback of this model relates to the logistical challenges it poses; there are delays due to the non availability of evaluators, the couriering of hard copy dossiers, the return of the completed evaluations and the recompilation of all completed elements into the final dossier before it can be considered by Council.

Finally, many applications for registration are of poor quality or incomplete and place a significant burden on an already overwhelmed system. This impact is greatest where these applications relate to priority products, with knock on delays across the system as a whole. As a result of these and other factors, in particular the continuing surge of new applications, the backlog for registration has lengthened considerably. While these delays are understandable, they come at a significant cost to the applicant, the health funder and the end user. However, the reputational costs to the MCC have arguably been even higher.

Beginning with the draft South African Medicines and Medical Devices Regulatory Authority (SAMMDRA) Bill and related KPMG report in 1998, a succession of task teams have looked into these problems over the ensuing decade, with this collective work culminating in the South African Health Products Regulatory Authority (SAPHRA) business case[[7]](#footnote-7) and the draft SAPHRA bill currently under consideration in parliament.

In February 2014, the Minister of Health, Dr Aaron Motsoaledi announced the proposed establishment of the Institute for Regulatory Science (IRS), in order to address the lack of training courses in regulatory science in South Africa and to respond to the “staggering” number of drugs awaiting regulatory approval[[8]](#footnote-8). Pursuant to this announcement, an EU funded task team (ECORYS Health Consortium) undertook an extensive review and consultation process in March 2014, to explore the feasibility of establishing the Institute as well as its possible structure, functions etc.[[9]](#footnote-9)

A project team was recruited in March 2015, to oversee the establishment of the IRS, with the following brief and deliverables:

***“Institute of Regulatory Science (IRS):*** *The Institute is being established to build human resource capacity for the regulation of health products both within South Africa and the SADC region. The Institute will function as a hub to integrate, coordinate, and identify appropriate training programmes for regulatory sciences provided by academic institutions and other partners as well as to develop internal courses targeting specific regulatory needs. The model proposed is a ‘virtual’ institution and programmes offered by the Institute will be modular in content and will be offered as online courses to encourage e-learning with contact time in between. An experiential aspect will also be incorporated to promote practical skills and to support mentoring”.*

Deliverables:

* Support the establishment of an interim Board to oversee the implementation of the Institute and act as interim secretariat to the Board.
* Clarify sources of revenue from Government, Industry and Development Partners
* Set up financial management systems for the project team and the IRS as part of its business and operational plan;
* Lead the development of a Business Plan for establishing the IRS as recommended by the interim Board.
* Develop an organogram for the future IRS, job descriptions for the CEO and other senior positions, and undertake recruitment and induction in collaboration with the NDoH and the interim Board.
* Set-up and facilitate priority training courses in line with the objectives of the Institute.

**While this Business Plan draws heavily upon the earlier work of the ECORYS Health Consortium and the SAPHRA Business case referred to above, the narrower focus defined in the terms of reference dictates that it responds to the most critical needs; (a) boosting regulatory capacity, especially in the area of generic medicines, (b) developing systems that will progressively build the required competencies beginning with the scores of new recruits due to join the MRA in the short term and (c) improving the quality of new applications at source, through the up-skilling of regulatory pharmacists in industry. These elements are further elaborated in the value propositions below.**

The processes and systems developed will subsequently be applied to other regulatory areas, (medical devices and in vitro diagnostics, complementary and alternate medicines etc) as these come on stream. On the positive side, the inspectorate directorate of the MRA appears to be well resourced, with a skilled and stable technical workforce and well established training programmes. As such, it does not feature prominently in this plan. This directorate could however, be expected to serve as an important regional training resource at some stage in the future, once the remit of the IRS has expanded to include regional activities.

1. **Value propositions for the Institute of Regulatory Science**

**Value proposition # 1: The IRS shall, in partnership with national and international institutions and in consultation with stakeholders, develop a series of modular courses that will address the knowledge and competencies required from entry level across the full range of the Regulatory Science spectrum. The wide consultation process underpinning the design and development of these courses will ensure that they are relevant, rigorous and recognized by the statutory Professional Councils.**

Stakeholders are unanimous in the view that new graduates are ill prepared for a career in the regulatory disciplines, largely due the poor integration of the subject matter at the undergraduate level. Pharmacy undergraduates for example, receive the required instruction, but because the content is spread across several years and instruction streams, the vital interconnections between subjects are generally not appreciated. The module content of the Fundamentals of Regulatory Science Programme (equivalent to a Post Graduate Diploma) has been specifically designed to address these short comings and will provide enrolees with a well rounded foundation in Regulatory Science and thereby serve as the gateway to onward training in their chosen career path. This program shall bear credits and once the work integrated learning requirement has been met, will yield a vocational qualification (NQF level 8), with an articulation point with the Masters degree, through the bridging facility. (See figure 2).

Once the basic knowledge has been acquired, enrolees will be offered a choice of advanced modules, tailored for specific career paths (e.g. Regulatory Authority, Industry or Clinical Research) and / or specific regulatory roles (quality, safety and efficacy). The extensive referencing of national and international learning material – The US Food and Drug Administration’s (FDA) Manual of Policies and Procedures (MAPP)[[10]](#footnote-10) and Centres of Excellence in Regulatory Science,[[11]](#footnote-11) the European Medicines Agency’s IMI-Pharmatrain,[[12]](#footnote-12) the Regulatory Affairs Professionals Society (RAPS)[[13]](#footnote-13) and The Organization for Professionals in Regulatory Affairs (TOPRA)[[14]](#footnote-14) and an ongoing process of stakeholder consultation, will ensure that the course content, learning outcomes and the desired competencies are optimally aligned. It is intended that the acquisition of advanced theoretical knowledge will be reinforced through its application to the real world work environment, by way of structured work integrated learning programmes tailored to the enrolee’s chosen career path, but incorporating vital cross disciplinary elements. (See value proposition # 2 below).

Two categories of professionals require special consideration - regulatory naïve new entrants who possess advanced degrees (e.g. MSc or PhD) in fields relevant to current or future health product regulatory areas (medical devices, in vitro diagnostics and complementary and alternative medicines) and individuals with regulatory experience who seek to upgrade their skills as a consequence of a change in career path or work responsibilities. Individuals in the former category will select courses at the fundamental and advanced levels that best prepare them for entry into the work integrated learning component in their chosen career path, while individuals in the latter category will be able to select just the courses that address their specific needs. Articulation with the academic track will similarly be available.

All course elements will be provided by academic institutions and they will either develop new modules or adapt existing modules, in accordance with established quality assurance and accreditation requirements. Wherever feasible, the modules shall be delivered online or in a digital format, should enrolees lack reliable internet access and be reinforced by dependable tutor support. The course design will be sufficiently flexible to enable the contents to be disaggregated into certificate and other short courses, including accredited continuing professional development (CPD) courses. The design will also accommodate a “step down” approach, whereby the content may be adapted to meet the training needs of ancillary staff, such as regulatory clerks, pharmacy technicians etc. The IRS will support course development and adaptation, including the conversion for e-learning, in all the areas referred to above.

Statutory bodies including the South African Pharmacy Council (SAPC), the Health Professions Council of South Africa (HPCSA) and the South African Nursing Council carry the responsibility for professional standards amongst their members, including the registration of higher qualifications. As such, they are key members within the IRS partnership and will be engaged at every level, including in leading elements of the IRS’ work.

The course outline for the Fundamental course and illustrative modules for the advanced / elective level are reflected in Figure 2. The full curriculum breakdown for the Fundamental has been widely circulated for input and additional copies are available upon request.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Advanced Courses (medicine track)** | | | | | | | | | | | |
|
| **INDUSTRY** | | | | **MCC/SAHPRA** | | | | **CLINICAL TRIALS** | | | |
| **•Drug Discovery Skills** | |  |  | **•Quantitative Benefit Risk Appraisal** | | |  | **•Translational medicine** | |  |  |
| **•Drug Discovery Pharmacology** | | |  | **•Quality Management and Inspections** | | |  | **•Advanced Clinical Pharmacology** | | |  |
| **•Drug Development Science** | | |  | **•Pharmocometrics** | |  |  | **•Manufacture of Medicine for Clinical Trials** | | | |
| **•Drug Synthesis** | |  |  | **•Evaluation of CMC** | |  |  | **•Advanced Bistatistics and Research Design** | | | |
| **•Biopharmaceutical Drug Development** | | | | **•API, FPP and Excipient Specifications** | | | | **•Advanced Ethics in clinical trials / GCP** | | | |
| **•Drug Formulation and Delivery** | | |  | **•Evaluation of Clinical Trials** | | |  | **•Risk Based monitoring** | |  |  |
| **•Advance Drug Delivery** | |  |  | **•Project Management** | |  |  | **•Medical Writing** | |  |  |
| **•Model Based Medicine Developments** | | | | **•Document Management** | | |  | **•Advanced Pharmacovigilance** | | |  |
| **•Quality by Design** | |  |  | **•Medical and Scientific Writing** | | |  | **•Health Economics and Pharmacoepidemiology** | | | |
| **•Pharmacometrics** | |  |  | **•Pharmacovigilance Systems** | | |  | **•Evidence Based Medicine** | | |  |
| **•Advanced Pharmacokinetics** | | |  | **•Pharmacoepidemiology** | |  |  | **•Clinical Trials in Special populations** | | |  |
| **•Pharmaceutical Analysis and Quality Control** | | | | **•Global Regulatory Frameworks** | | |  |  |  |  |  |
| **•Generic and Biosimilar Medicinal Products** | | | |  |  |  |  |  |  |  |  |
| **•Medical and Technical Writing** | | |  |  |  |  |  |  |  |  |  |
| **•Validation Methods and GLP** | | |  |  |  |  |  |  |  |  |  |
| **•Pharmaceutical Producation and GMP** | | | |  |  |  |  |  |  |  |  |
| **•Risk Management** | |  |  |  |  |  |  |  |  |  |  |
| **•Documentation management** | | |  |  |  |  |  |  |  |  |  |
| **•Pharmacogenomics** | |  |  |  |  |  |  |  |  |  |  |
| **•Drug Safety throughout Drug Development** | | | |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| **Fundamentals of Regulatory Science** | | | | | | | | | | | |
|
| **Module 1** | | | | **Introduction to Regulatory Sciences** | | | | | | | |
| **Module 2** | | | | **South African Medicines Registration Framework** | | | | | | | |
| **Module 3** | | | | **Principles of Pharmaceutical Product development and Regulation** | | | | | | | |
| **Module 4** | | | | **Pre-clinical and Clinical Development** | | | | | | | |
| **Module 5** | | | | **Pharmacovigilance** | | | | | | | |
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**Table 1:** **Module outline for Fundamental and Advanced Courses**

**Value proposition # 2: The IRS will tap into the collective knowledge and experience existing in South Africa and channel this resource into structured Work Integrated Learning / Mentoring programmes, based on international best practice, guidelines and tools. Such standardization and codification is intended to usher in a step change in regulatory practice in South Africa, bringing it on par with its international comparators and able to respond to the regulatory challenges of the 21st century.**

For the purpose of illustration, the following discussion demonstrates how the evaluator skills required by the national regulator (MCC/MRA and future SAPHRA) could be developed using the work integrated learning/mentorship approach. This model could, with suitable adaptation, be applied to the health product industry and the related clinical research discipline. Indeed, a measure of cross learning aimed at providing trainee evaluators with real world insights into the products or areas that they will be expected to regulate would appear to be essential and the converse would apply to industry and clinical research trainees,.

***Evaluation is defined as a critical appraisal or assessment; a judgment of the value, worth, character, or effectiveness of something***. Implicit in this definition is the presumption that the evaluator has the necessary underlying knowledge, which when applied to a robust evaluation framework, delivers a scientifically rigorous expert opinion, in a format that is widely accepted and understood. Like other acquired skills, evaluation is learnt by “doing,” usually under the watchful eye of a mentor, with clear waypoints marking the progression to proficiency, as demonstrated in the system used by the EMA (see Annex 1).

The MCC/MRA model of external evaluation and high staff turnover have tended to cap the expertise within the MRA at a level short of full proficiency, a situation that will need to be rectified in the transition to SAPHRA. The time required for new entrants to reach functionality, has generally been at least two years, with pharmacy graduates tending to fare best. However, the progression to functionality within clinically oriented work streams has been much slower, with outcomes that remain uneven. This suggests that a greater effort should be made to recruit and cater for the needs of graduates with a clinical background (MBChB and B.Nursing).

Senior MCC committee members have long fulfilled *de facto* mentor roleswithin their respective committees and the IRS will seek their guidance and leadership in developing and deploying the guidelines, standards, and tools that will comprise an accredited work integrated learning / mentorship programme and determining the required outputs (e.g. the compilation of a portfolio of completed evaluations). The portfolio requirement will be structured to demonstrate the competencies typically elucidated through the research component of a Masters programme. Achieving proficiency in evaluation will be viewed as a journey rather than a destination and active steps will be taken to retain such expertise through IRS brokered opportunities for further professional development through, fellowships, twinning arrangements, participation in cutting edge research and courses etc.

This programme will find immediate applicability. Several supervisory staff within the MRA are on the threshold of being fully fledged evaluators and already function as mentors to their own team members. These staff and the new Committee members, represent the natural first entrants into this learning programme. Given the calibre of these staff, the up-skilling process should be a swift and this building of internal regulatory capacity will mark the beginning of the transition from currently overwhelmed MCC/MRA model. The practice of using external evaluators is nevertheless likely to continue for the foreseeable future, especially for complex evaluations, including those pertaining to new chemical entities (NCE).

**The twin track approach underpinning these value propositions provides the flexibility in learning required to address the different needs and circumstances of a diverse group of potential enrolees and their employers. It explicitly recognizes the statutory role of the university system and seeks to harness the expertise embedded therein for the benefit of a much wider audience. Since both tracks will utilize the same quality assured course material and accredited experiential / work integrated learning platforms, it is expected that both tracks will yield high calibre professionals with equivalent skills. Similar leveraging of vocational education has occurred in multiple professional areas, including taxation[[15]](#footnote-15), banking[[16]](#footnote-16) and financial markets[[17]](#footnote-17) and in each instance, this has advanced the major policy objective of achieving rationalization and synergy in the post school system.[[18]](#footnote-18) Indeed, the overall delivery model proposed for the IRS closely mirrors that currently under implementation by the National School of Government.[[19]](#footnote-19)**

**Value Proposition # 3:** **The IRS will monitor the wider regulatory environment and serve as a think-tank for emerging issues in regulatory science. This will provide a platform for stakeholder engagement and facilitate the formulation of strategic responses that best serve the public interest.**

The IRS’ role in benchmarking, integrating, facilitating and coordinating post graduate training in regulatory science, must be complemented by a forward looking component that will identify and respond to emerging issues that are likely to impact on stakeholders and by extension, on the work of the IRS as a whole. The diverse and participatory institutional make up and governance of the IRS, make it ideally suited to fill this “thought leadership” role. However, some issues may require the engagement of individual stakeholders through for example, IRS hosted seminars and roundtables. Key issues may include, the drive towards regulatory convergence, combating antimicrobial resistance and developing new antibiotics, adapting to new technologies, pharmacogenomics, and the pursuit of a robust and universally accepted process / tool for assessing benefit and risk.[[20]](#footnote-20), [[21]](#footnote-21), [[22]](#footnote-22), [[23]](#footnote-23)

Figure 2 summarizes the detail in the preceding narrative in a graphic form. At the macro-level, this framework contextualizes the value added and linkages of the IRS in 4 linked domains namely, **the acquisition of theoretical knowledge, work integrated learning, strategy** and **policy.** It also identifies the key partners / stakeholders for each domain and reflects a progressive order of expected results, located at the level of **outputs, outcomes** and **impact** respectively. Finally, the framework is intended to illustrate the flexibility inherent to the IRS design, whereby changes generated at the policy level may be translated into the appropriate downstream actions, or conversely, the identification of key emerging issues may trigger actions upstream, downstream or indeed in both directions.

At a more detailed level, the framework illustrates the twin track approach (**vocational** and **academic**) for the acquisition of knowledge and expertise, aimed at providing the maximum flexibility and choice for enrolees and employers.

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Outputs

Outcomes

Impact

**Figure 2**

1. **Organization, legal status and governance arrangements**

* **The Institute for Regulatory Science will be a public – private partnership, with the mandate to build regulatory capacity in both sectors and thus contribute to the delivery of a public good – access to safe and effective health products.**

* **Its legal status shall be that of a public benefit not for profit trust.**

* **Governance shall be exercised through a Board of Trustees representing the major stakeholder constituencies and appointed by the Master of the High Court. The Board shall be led by a Chair appointed by the Minister of Health.**

* **The work of the IRS will be carried out by a secretariat under the day to day management and leadership of the CEO / Executive Director. The CEO / Executive Director shall be appointed by the Minister of Health, on the recommendation of the Board and report to her / him through the Board.**

**The rationale for these choices is elaborated below.**

The online search for models to guide the development of the Institute for Regulatory Science, yielded few results that are directly applicable to the South African situation. A wide range of North American and European academic institutions offer courses in Regulatory Affairs/Science, many with specific focus on the needs of the Pharmaceutical Industry. Some of these courses carry the specific endorsement of the regulator through formal partnership arrangements such as the FDA’s Centers of Excellence in Regulatory Science (CERSI),[[24]](#footnote-24) and the EU supported IMI – Pharmatrain[[25]](#footnote-25) collaborative network. The internal training needs of the FDA and EMA are largely met in-house, though given the more complex regulatory arrangements in Europe, the EMA is seeking raise the standard within national regulatory authorities, through the launching of the EU training network Centre in March 2014.[[26]](#footnote-26)

The Centre on Regulatory Excellence (CoRE), was established at the Duke University - National University of Singapore Graduate Medical School in June 2014, with support from the Ministry of Health and the Economic Development Board of Singapore. Given that CoRE’s mandate and positioning is similar to that of the IRS, a study visit was undertaken by the IRS project manager in May 2015 to Singapore and included in depth discussions with the senior management and staff at the Health Sciences Authority (HSA), the health product regulator for Singapore.

CoRE’s establishment within a single academic institution represents a model that has already been deemed unsuitable for the South African context (see ref 22 below). However, elements of its organizational structure and operational have proved useful for the evolving IRS model.

CoRE’s initial activities are focused on a convenor and thought leadership role within the policy space and targets the middle to top levels within the region’s regulatory authorities and industry. This is accomplished through the hosting of seminars and roundtables and in the case of the IRS, these functions are subsumed within value proposition # 3. With funding from the Asian Development Bank (ADB) and the Asia Pacific Economic Cooperation (APEC), an initial regional training (on multi regional clinical trials) has been done and work initiated on a gap analysis of regulatory capacity in the ASEAN region. However, in the absence of an entry level post graduate training platform, it remains unclear what role CoRE may play in addressing the identified gaps and it would appear that the IRS thinking is perhaps more advanced in this respect. Discussions within the HSA yielded valuable insights on the training of evaluators, the use of assessment reports generated by reference agencies, Singapore’s experience as part of the Consortium on Benefit Risk Assessments (COBRA) and the regulation of other health products (medical devices, IVD’s and CAMS).

The ECORYS report presented four options for the organizational structure of the IRS[[27]](#footnote-27) and while expressing a preference for option 4, the review team concluded that the local dynamics required that this decision be left to the NDoH leadership. The NDoH was said to favour a combination of options 3 & 4 and this is indeed the model emerging from the IRS project team’s exploratory efforts.

In the established tradition that form should follow function, several key principles will guide the emergence of an IRS that is fit for purpose:

1. The IRS will address a national need by facilitating the acquisition of skills and expertise required within the public and private sectors, requiring the engagement of and yielding benefits to sectors beyond health sector and government. (see Figure 2). These benefits that could be extended to the broader Southern African region at a later stage.
2. To execute this mandate, the IRS needs to be positioned close to the regulator (MCC/SAPHRA), in order to understand and respond to its needs in a rapidly changing regulatory environment. The more established international regulatory agencies have already traversed much of this ground and there is much that they can offer to achieve the step change that South Africa is currently seeking. However, much of this assistance will only be accessible through state-state linkages and this provides additional support for an IRS identity that is readily discernible as being linked to the State.
3. By a similar token, the IRS will have an equal obligation to be respond to the needs of stakeholders beyond the regulator and this will in turn, require a degree of accessibility and shared governance not typically associated with government entities.

*Given this broad mandate and the dual persona that this mandate imposes on the IRS, it is readily evident that the IRS will need to be a public-private partnership, able to serve both sets of needs and equally able to draw upon the strengths and resources of each sector.*

1. The set-up and running costs of the IRS should, in principle, be primarily met through short and long term commitments from its major intended beneficiaries of its work, specifically SAPHRA/DoH and the Pharmaceutical and Health Products Industries. Significant additional financial resources may be forthcoming from other sources e.g. other government departments, statutory bodies, international donors and private foundations, some of whom might be reluctant to directly fund a state entity. In return, contributors would expect to exercise some oversight of their investments, usually through participation in the governance arrangements, avenues that are not usually open in state entities.

*In the view of the IRS project team, in order to deliver on its mandate, the IRS (a) must be able to transact in its own name e.g. receive funds from multiple sources and make disbursements (b) its governance setup must be amenable to multi-stakeholder representation and (c) its institutional setup should by design, ensure that it is able to meet the high standards expected from institutions charged with delivering a public good. The South African legal system provides for these needs to be met through the incorporation of a not for profit company or trust, the relative merits of which are summarized in Annex 2.* ***The preferred option is the establishment of a Non-Profit Trust, due to a greater degree of flexibility, favourable tax treatment for donors and simpler legal and administrative requirements.***

In line with its establishment as a non profit trust, the IRS shall be governed by a Board of Trustees, appointed by the Master of the High Court, in line with the terms of reference defined in the Trust Deed. It is expected that trustees will represent the major stakeholders and will function under the leadership of a Chairperson, appointed by the Minister of Health. The responsibilities of the Board of Trustees shall be similarly defined in the Trust Deed and will likely centre around the strategic direction and fiduciary oversight. Should the need arise, the work of the Board may be facilitated through the creation of Committees e.g. for Budget and Finance, Programmes and Strategy.

The IRS will be headed by the Executive Director, appointed by the Minister of Health on the recommendation of the Board of Trustees. The Executive Director shall be responsible for the running of the Institute and answerable to the Board of Trustees.

The mandate of the IRS and the decisions of the Board shall be implemented through two units; Administration and Finances and Programs each headed by a Director and comprising a small complement of technical and support staff. These proposed governance and management arrangements are reflected in Figure 3.

**Figure 3**



1. Exchange rate USD 1.00 = R12.00; Euro 1.00 = R13.50 [↑](#footnote-ref-1)
2. <http://www.gbiresearch.com/report-store/market-reports/archive/emerging-pharmaceutical-market-south-africa-proposed-introduction-of-new-drug-regulatory-agency-(sahpra)-to-accelerate-drug-r>. Accessed 22 Mar 1015 [↑](#footnote-ref-2)
3. <http://store.bmiresearch.com/south-africa-pharmaceuticals-healthcare-report.html>. Accessed 22 Mar 2015 [↑](#footnote-ref-3)
4. [https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report-south-africa.pdf.](https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report-south-africa.pdf.%20)  Accessed 22 Mar 2015 [↑](#footnote-ref-4)
5. <http://www.espicom.com/south-africa-medical-device-market.html> Accessed 23 Mar 2015

   [↑](#footnote-ref-5)
6. <http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Clinical_Trials_Industry_South_Africa_2013_v3.pdf> [↑](#footnote-ref-6)
7. SAPHRA Business Case, Ministry of Health, Pretoria, July 2012 [↑](#footnote-ref-7)
8. http://www.sanews.gov.za/south-africa/govt-establish-institute-regulatory-science [↑](#footnote-ref-8)
9. Proposal for the development of a South African Institute for Regulatory Sciences, ECORYS Health Consortium, Rotterdam, April 2014 [↑](#footnote-ref-9)
10. http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/manualofpoliciesprocedures/default.htm [↑](#footnote-ref-10)
11. http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm301667.htm [↑](#footnote-ref-11)
12. http://www.imi.europa.eu/content/pharmatrain [↑](#footnote-ref-12)
13. http://www.raps.org/education-training/online-learning/online-university/ [↑](#footnote-ref-13)
14. ttp://www.topra.org/TOPRA/TOPRA\_Member/courses/Progression\_pathways.aspx?WebsiteKey=ee1ef362-412e-4402-9d9e-43f5e7447f19&hkey=a15c4dd7-386b-47f7-a083-8eb6775ac4a4&New\_ContentCollectionOrganizerCommon=5#New\_ContentCollectionOrganizerCommon [↑](#footnote-ref-14)
15. <http://www.thesait.org.za/?page=Tax_Qualifications> [↑](#footnote-ref-15)
16. http://www.iob.co.za/our-services/iob-professional-recognition-framework [↑](#footnote-ref-16)
17. <http://sais.co.za/docs/Financial%20Markets%20Practitioner%20Curriculum%20Document%20to%20QCTO%2019%20April%202013.pdf> [↑](#footnote-ref-17)
18. **Policy framework on differentiation in the South African post school system,** DHET, July 2014. [↑](#footnote-ref-18)
19. http://www.thensg.gov.za/pebble.asp?relid=3437 [↑](#footnote-ref-19)
20. **Regulatory and methodological standards to improve benefit-risk evaluation of medicines.** Workshop report http://www.ema.europa.eu/docs/en\_GB/document\_library/Report/2014/04/WC500165803.pdf [↑](#footnote-ref-20)
21. **Building the Benefit-Risk toolbox, Workshop synopsis**, Walker S, McAuslane N, Liberti L, Connelly P. http://cirsci.org/system/files/private/CIRS\_June\_2012\_Workshop\_Synopsis.pdf [↑](#footnote-ref-21)
22. **Structured Appoach to Benefit-Risk Assessment in Drug Regulatory Decision Making.** http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM329758.pdf [↑](#footnote-ref-22)
23. Strategy for communicating benefit-risk decisions: a comparison of regulatory agencies' publicly available documents. James Leong Wai Yeen, Sam Salek and Stuart Walker. http://journal.frontiersin.org/article/10.3389/fphar.2014.00269/full [↑](#footnote-ref-23)
24. http://www.fda.gov/scienceresearch/specialtopics/regulatoryscience/ucm301667.htm [↑](#footnote-ref-24)
25. http://www.imi.europa.eu/content/pharmatrain [↑](#footnote-ref-25)
26. http://www.hma.eu/otsg.html [↑](#footnote-ref-26)
27. **Option One**: It is possible to consider a physical facility (institute) which functions as a facultywithin one university structure.

    **Option Two**: Alternatively an “academy” (institute) could beoutside the university structure.

    **Option Three**: There could be collaboration between academic institutions (universities) which allhave joint ownership of the institute.

    **Option Four**: It could be a virtual platform (institute or centre), registered as a not-for-profit (NPO) organisation with the ability following accreditation, to award degrees for satisfactory completion of study undertaken.” [↑](#footnote-ref-27)