1 DIPLOMICS overview

Background

In its new Bio-economy Strategy, presented to the public in January 2014, the DST (Department of Science & Technology) has devised a roadmap for stakeholders in the biotech space that aims at deriving a significant contribution from the bio-economy to the country's GDP (Gross Domestic Product) by 2030.

As part of this effort the DST, together with experts from the European Strategy Forum for Research Infrastructures (ESFRI), undertook a review of South Africa's Research Infrastructure (RI) landscape in 2013. As a consequence of this a South Africa RI Roadmap (SARIR) has been prepared.

Among a number of priority RI areas, the DST listed 'omics' as an area with high-impact potential. The notion that 'omics' has the potential to advance South Africa's Bio-Economy efforts is – not least - based on the socio-economic impact the field – notably Genomics – has generated in the aftermath of the Human Genome Project (HGP) - in the US and elsewhere in the world.

The name given to the project is DIPLOMICS (Distributed Platforms for 'Omics').

Desired Research Infrastructure (RI) features[1]

- An open service to researchers within the country and outside
- A nationally governed organisation responsible for the RI
- Long term strategic plan for maintaining and upgrading
- Training both researchers and support staff in operating and maintaining the RI
- Outreach to researchers, industry, regional and national stakeholders
- Access by world class peer review
- Creating career development opportunities for all staff
- Ensuring that e-science is an integral component of the RI

[1] SARIR (South African Research Infrastructure Roadmap, 2013)

2 DIPLOMICS overview

DIPLOMICS stakeholders

Stakeholder type	Stakeholder	Sub stakeholder (not exhaustive)	Power	Legitimacy	Urgency	Impact
Innovation enablers	Bio-repository	• DST Research Infrastructure repositories • Other existing repositories, such as created through H3A or CLS		✓		Latent
	Data repository	• To be created as part of DILOMICS • Other existing repositories	✓	✓		Expectant
	DIPLOMICS	• Existing facilities • Newly created facilities	✓	✓		Expectant
	Bioinformatics	• Bioinformatics Service Platform • Bioinformatics capacity as part of DILOMICS • Bioinformatics groups at Universities	✓	✓		Expectant
	Medical & scientific researcher	• Scientists at Universities • Researchers in companies	✓	✓	✓	Definitive
Industry	Big pharma	• Merck, GSK, Sanofi, etc		✓		Latent
	Diagnostic labs	• Private labs such as Lancet, PathCare, Ampath • NHLS		✓	✓	Expectant
	Medical insurers	• Discovery Medical Aid • Others	✓	✓		Latent
	Technology suppliers	• Thermo Fisher, ABSCiex, Illumina • Whitehead Scientific, Anatech, Biocom Diagnostics	✓	✓		Expectant
	Biotech companies	• Kapa Biosystems • ReSyn Biosciences		✓	✓	Expectant
	Entrepreneurs	• Scientists keen to convert ideas into products or service offerings		✓	✓	Expectant
The public	Patients	• Public patients • Private patients		✓	✓	Expectant
	Government	• DST, DoH, DHET, DTI	✓	✓	✓	Definitive
	Funders	• Local funders: MRC, NRF, TIA, THRIP • International funders: NIH, WT, BMG Foundation • Crowd funders	✓	✓	✓	Definitive
	General public	• Tax payers • Interest groups • Advocacy groups		✓	✓	Expectant

3 DIPLOMICS overview

DIPLOMICS goals

- Make use of existing infrastructure (disparate facilities) as much as possible. This will be accomplished by way of grouping these facilities into 2 tiers (T1, T2). T1 facilities will provide capacity actively to DIPLOMICS, serve as local context point, and subscribe to common governance and operational management principles (e.g. quality, LIMS), amongst others. T2 facilities may have existing equipment but are otherwise not able to participate. They can still benefit from access to training or technology;
- Harmonise these facilities through implementation and adherence to common standards and systems (e.g. central procurement of reagents and consumables, common quality mgmt. system, LIMS (Laboratory Information Management System), CRM (Customer Relationship Management), project management/project portfolio management);
- Further stratify these facilities on the basis of workflow / assay maturity (exploratory -> validated -> certified) to (i) enhance standardisation of assays, (ii) improve understanding of omics amongst the DIPLOMICS user base (in particular regarding expectations about quantity/quality of data and assay reproducibility), (iii) user empowerment through knowledge diffusion;
- Be very strong in its operational management and stakeholder engagement capacity, to ensure that 'omics' capacity will be available, accessible and affordable (issues related to quality, cost, and turn-around must be on the top of DIPLOMICS agenda every day). In other words, DIPLOMICS will aim to produce best possible, world-class services at competitive rates (meaning that it will work so that the overall R&D costs will be low). Regarding costs, central procurement across the DIPLOMICS eco-system will be a major contributor. Regarding quality, efficient operational management will enhance turn-around and overall service delivery;
- Have the ability to render high-quality services AND to assess, validate or be involved in the development of novel technologies. Amongst others, this will be achieved by way of structuring DIPLOMICS into development and service units, as applicable. Also, this will be enhanced through entering into arrangements with technology providers to grant DIPLOMICS and its constituent user base priority access to novel technologies and applications. This is to ensure that DIPLOMICS and the research community in South Africa remains at the cutting edge of 'omics' at all times;
- Use the associated T1 facilities as local context points into the bigger DIPLOMICS eco-system. This will leverage the outreach that existing facilities have managed to build within their local community and help the facilities (and parent organisations, such as the CSIR or UWC) to maintain a certain amount of ownership and control. For example, in that way an NGS facility at a University will be able to service its constituent user base using its inherent capabilities while referring non-core work to other DIPLOMICS members;
- Constitute working groups comprised of DIPLOMICS T1 facilities, related infrastructure (e.g. biobank), users, and technology providers, as applicable. This is in the interest of enhancing stakeholder engagement, user integration and infrastructure inter-operability.

- Be associated with international networks, such as the CTLS (Core Technologies for Life Sciences, Europe) or ABRF (Association of Biomolecular Resource Facilities, US), to gain access to complementary facilities for proficiency testing, training programs, human resource exchange, and funding opportunities;
- Organise these facilities ideally into a common purpose non-profit company (NPO) to overcome partisan interests in favour of a common vision & mission. The NPO model allows users to become members, giving them voting rights at an AGM (Annual General Meeting) and power, if needed, to influence the DIPLOMICS directorship composition. This is to ensure that DIPLOMICS maintains a strong focus on user/stakeholder satisfaction and doesn't serve an internal interest only;
- Have a Scientific Advisory Committee (SAC) to conduct annual performance reviews of DIPLOMICS. This will include operational output metrics (e.g. status of certification, instrument down-time, or customer satisfaction) and outcomes metrics (such as papers published by users, patents filed, grants submitted for funding, or project deliverables achieved). In order to address socio-economic impact, DIPLOMICS will consult Battelle, a US research organisation that has worked with governments across the world in quantifying the impact made by Genomics and other high-tech science areas.
- Start working with a core group of T1 facilities who will form an initial critical mass by subscribing to the DIPLOMICS model, demonstrate feasibility of the model and start enhancing service delivery for its constituent users. It will then use this critical mass to attract further members in the NSI (National System of Innovation). Eventually it should be able to attract most, if not all, 'omics' facilities in the country to join the common cause;
- Cover in its budget mission-critical costs, such as a portion, or all, of associated facility staff salaries and service and maintenance costs of equipment;
- Initially focus heavily on creating human resource capacity by properly staffing existing facilities. A particular focus will be on Bioinformatics capacity. In addition, this will entail career development opportunities for DIPLOMICS staff through training in areas that are distinct from academic career paths (e.g. quality mgmt., lean mgmt., project mgmt.). To enhance this aspect, DIPLOMICS will have partnerships with institutions such as CPUT (Cape Peninsula University of Technology) and Business Schools to develop dedicated training programs for DIPLOMICS staff;
- Enhance 'omics' capacity through the creation of additional infrastructure, such as for higher-throughput NGS (Next Generation Sequencing). The decision for acquiring such additional equipment will be made by DIPLOMICS and deployed on the basis of a best case scenario (what, where, when). DIPLOMICS will have an adaptive recapitalisation model in view of a rapidly evolving technological landscape;
- Employ a 'sustainability' budgeting model to demonstrate how complex 'omics' equipment ought to be run (i.e. having a proper ratio of admin:lab:Bioinformatics and take into account other relevant operational expenditures). This is in the interest of creating equipment placement scenarios where

this sustainability equation doesn't work out – in other words, where a cost/benefit case cannot be established;

- Employ a 'stakeholder compact' approach to forming and supporting projects so that the value-add to a majority of stakeholders is maximised. Importantly, such compacts will include industry stakeholders, such as pathology labs, technology providers and pharma companies. This is in particular in areas where short-term impact such as in the area of Precision/Personalised Medicine can be achieved;
- Have a strategic relationship with local funders to ensure that all grant proposals requiring a DIPLOMICS component will include the budget necessary for carrying out 'omics' work. DIPLOMICS will provide supporting information such as white papers, example project plans and budget templates to empower its user base;
- Will store and make available genotypic ('omic') and phenotypic data in a properly designed and managed data-repository. This is to enhance access to reference data, to facilitate the formulation of new hypotheses and to stimulate open innovation and *in-silico* discovery and innovation. Therefore,
    - All DIPLOMICS data will be stored in a central data repository on the long-term;
    - The repository will be structured so that it can hold and manage basic research, translational (e.g. clinical trial) and diagnostic data;
    - It will contain genetic ('omics') and phenotypic data;
    - The data repository will work in alignment with the national bio-repository (part of DST infrastructure program) and DIPLOMICS, in a tripartite structure;
    - It will have a portal that provides users access to the data in a properly managed fashion;
- Associated with the data repository will be a Bioinformatics core group that will
    - be comprised of Bioinformaticians, biostatisticians, and developers/programmers, as appropriate;
    - Ensure that access to 'omics' and other data is provided in a seamless fashion;
    - Provide support in 'omics' study design, data management and data analysis to DIPLOMICS facilities and DIPLOMICS users in a service and collaborative project fashion. This will require that the members of the core are employed for service and collaborative research purposes, not to carry out their own research;
    - Work in a project-based fashion through experimental planning, project execution and downstream analysis with DIPLOMICS staff and users;
    - Ensure that group members can work as project leads or team members, as required by DIPLOMICS projects and/or users;
    - Employ quality, operational and project management principles and applications that are standardised across the DIPLOMICS eco-system and allow for efficient and effective planning, execution and performance evaluation of projects;

  - Provide remote access to analysis pipelines in accordance to user demand (either from DIPLOMICS facilities or DIPLOMICS users);
  - Replicate Bioinformatics in other geographical areas in accordance with DIPLOMICS and/or user demand, through efficient migration of systems and resources;
  - For DIPLOMICS associated (T1) facilities, deploy a sufficient number of resources to ensure basic data analysis.
- Be unique in Africa not because of the type or number of 'omics' equipment it employs but because of its operational excellence (the quality of output it produces) and stakeholder engagement capacity (the way it forms/runs multi-disciplinary, translational projects).
- Also, be unique because of its ability to support and drive projects that create value for a diversity of stakeholders, such as through aligning the interests of researchers, drug makers, doctors, patients and medical insurers in the area of Precision Medicine;
- Have a strong public engagement and outreach program to enhance understanding of topics such as genetic testing, genetic screening, human heritage, molecular crop breeding or Personalised Medicine. This will be facilitated through proper use of social media platforms, opinion pieces in print and other media, workshops, and outreach programs to public schools.
- Therefore, create impact in the short, mid and long-term.

7 DIPLOMICS overview

Stakeholder compact example[2]

Stakeholder type	Stakeholder	Description	INPUT	BENEFIT
Innovation enablers	**Bio-repository**	• Well-maintained collection of unique samples with efficiently managed access	• Biological samples of patients with cancer, representing the population diversity of SA	• Return on investment into sample collection and infrastructure development / maintenance • Has certain supply of future samples guaranteed
	Data repository	• Well-managed IT infrastructure that manages and makes biological and biomedical information available in an effective and ethical manner	• IT infrastructure and database solution that allows the integrated storage, management and exploitation of basic research, translational and diagnostic data	• Guaranteed supply of data from a diversity of sources • Can be gateway for 'Big Data' innovation in health • Potential revenue gain from data monetisation (e.g. through open innovation data exploitation models)
	DIPLOMICS	• Well run facility, accredited to industry quality standards	• Guarantees industry-standard outputs (quality, turnaround, cost volume) in basic research, translational and Dx applications (e.g. WES, WGS, targeted re-sequencing; GWAS) • Equipped to latest-stage technological standards • Ability to manage inter-disciplinary projects efficiently and effectively across the innovation-chain	• Has a certain supply of income guaranteed • Has access to knowledge in projects • Can be innovation hub through incubation and other services
	Bioinformatics	• Virtual / networked organisation with units located at the data repository, the 'omics' platform, and hot-spots of R&D across the country	• Makes human resources available in support of project needs, such as for project design and data analysis • Develops and/or manages software applications that allow user access to data as well as for data manipulation/interpretation • Trains end-users (scientists)	• Steady access to interesting data • Reputational gain
	Medical & scientific researcher	• Strong local scientific and medical expertise relevant to the disease in focus • Embarks on basic research projects (e.g. GWAS, WGS) to enhance understanding of development of key diseases in the local context	• Engages in effective collaboration with other scientists and with industry, shares knowledge and IP (e.g. in pre-competitive consortia)	• Access to data generated in collaborative research effort • Enhanced scientific outputs • Gain from industry insider knowledge • Reputational gain • Job opportunities (for graduates)
Industry	**Big pharma**	• Pharma company with active footprint in (South) Africa, considering the continent as a future growth market • Engages in effective relations with local gvt and other stakeholders	• Produces genetic profile from every sample run in a trial on the African continent • Submits data to repository and samples to bio-repository • Invests in R&D in (South) Africa, e.g. CDx development	• Tax credits or rebates • Preferential pricing for innovative new medicines • Gain in revenue from product sales in Africa • Access to unique biological information • Enhanced R&D productivity
	Diagnostic labs	• Organisation with relevant knowledge for deploying information-rich genomic medicine applications	• Provides infrastructure and resources for the wide-spread adoption of genomic medicine applications in (South) Africa • Submits data derived from routine genetic testing into public data repository • Partakes in the development of fit-for-purpose Dx/CDx applications with academia, genomic service providers and other industry stakeholders	• Knowledge gain through the active involvement in Genomic Medicine • Added competitive advantage • Revenue/profit gains
	Medical insurers	• Private or public reimbursement organisation with an interest in creating a new type of offering to its constituent membership	• Understands cost/benefit fundamentals of Genomic Medicine and provides reimbursement accordingly	• Gain in competitive advantage • Increased membership numbers or satisfaction • Revenue/profit gains
The public	**Patients**	• Disease in focus is a national priority	• Cancer incidence is already a concern and will be increasingly problematic in the future owing to life style changes • Patients put pressure on the medical establishment owing to the widespread availability of relevant information	• Improved diagnosis and medicines lead to better prevention and treatment of cancer • Improved health (better diagnosis, better treatment) and quality of life
	Government	• Master stakeholder, represented by DST, DOH and DTI	• Makes adequate research funding available (perhaps matched by intl. donor organisations) • Enables inter-ministerial and stakeholder dialogue • Creates supportive policy framework	• FDI (Foreign Direct Investment) • Access to new medicines • GDP contribution

[2] Based on discussions with a variety of oncology stakeholders; stakeholder list not exhaustive