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*Research Article*

# Constructive Technology Assessment (CTA) of Nano-Biosensor: A Malaysian Case

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**Abstract**

The latest advancements in nanotechnology, biology, advanced materials, and photonics have produced the Nano-Biosensor—an analytical device comprising a biological recognition element and a transducer in spatial proximity, whereby a recognition event triggers a measurable signal at the nano-scale level. Its future survival very much depends on carefully planned research, which needs to be critically assessed for it to be viably forecasted, monitored and controlled. However, measuring the potential impact of this technology is a double-bind problem: the technology needs to be developed and adopted widely for its impact to be measured, but by that time controlling or changing the technology is very difficult, i.e., a Collingridge dilemma. In addressing this issue, constructive technology assessment (CTA) was developed to assist in assessing the potential impact of emerging technologies. This paper presents the results of collected qualitative data through CTA interviews performed on respondents in a research institute of a local university located in the Northern part of Malaysia, who are actively involved in new nanotechnology applications development related to Nano-Biosensors. Through convenience sampling, the selected respondents had highlighted several issues, namely sensitivity issues of Nano-Biosensors, the local research spearheading the Nano-Biosensor advancement, and the potentially bright future regarding the further advancements in this field. It was concluded that the Nano-Biosensor can potentially remain in the forefront of nanotechnology development in Malaysia, since it is an enabling technology that impacts across industries and sectors at various points in the supply chain, not only in Malaysia, but also at the global stage.

**Keywords**: Constructive Technology Assessment (CTA), nano-biosensor, Malaysia, case study.

## Introduction

Nanotechnology has come a long way since it was firstly described by Feynman (1960) in his after-dinner talk describing molecular machines building with atomic precision in the early 1960s. He described a field where little has been done, but in which an enormous amount can be done in principle. This field is not quite the same as

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the other fields in physics in that it will not contribute much of fundamental physics, but it is more like solid-state physics in the sense that it might tell much of great interest about strange phenomena that occur in complex situations. Furthermore, a point that is most important is that it would have an enormous number of technical applications in other fields. He further emphasised the need to miniaturise components even further, which needs equipment capable of viewing and controlling these components at a very small scale.

Currently, Malaysia is lacking behind in this aspect because the technology is still new to the Malaysian expertise. The Ministry of Science, Technology and Innovation (MOSTI) oversees the nanotechnology development in this country, and particularly to develop policies, initiatives and strategic plans for nanotechnology. To this extent, the relatively small numbers of applications of nanotechnologies that have made it through the industrial application represent revolutionary rather than evolutionary advances (Kessler & Charles, 2007). Consequently, accurate and comprehensive management of nanotechnology at micro (organisational), semi-micro (regulatory), and macro (economy) levels are virtually impossible, especially in high-tech regulated sectors and developing economies. Therefore, there is a need of research to look into the management aspects of nanotechnology in order to efficiently and effectively manage the future directions of this technology.

In particular, technology assessment has been previously established to assist in ensuring a sustainable competitive advantage for the nanotechnology industry in general, and specifically relating to the research institutes in the Malaysian context. In order to address these issues, a technique called technology assessment (TA) has been developed to assist in evaluating these emerging technologies. Narrowing down to constructive technology assessment (CTA), CTA initiatives would attempt to broaden the design of new technology through feedback of TA activities into the actual construction of the technology, which is contrary to other forms of TA, where CTA is not directed toward influencing regulatory practices by assessing the impacts of technology, but rather, CTA wants to address social issues around the technology by influencing design practices. Due to the technical nature of Nano-Biosensor, CTA has been proposed as the core topic for this research endeavour.

## Literature Review

### *Constructive Technology Assessment (CTA)*

The term technology assessment (TA) has been defined by Braun (1998) as, "a systematic attempt to foresee the consequences of introducing a particular technology in all spheres it is likely to interact with". Thus, TA can be said to be a predictive analysis of what a technology can achieve once it is invested in and implemented. TA covers a wide aspect which touched upon various fields dealing with not just the technical aspects, but also the wider implications such as environmental and societal, as well as business and ethics.

Previous work had established that TA can be viewed under different scopes, namely at the macro, meso, and micro levels, which correlates to the size and importance of the participants involved, or who they represent (The Open University, 2014). Using examples to illustrate these different levels, technology assessment at the micro level takes place at the intra-governmental or organisational level, whereas the meso level refers to technology assessment at the national level between governmental and commercial organisations, and non-governmental organisations (NGOs).

Meanwhile, at the macro level, TA occurs at the global, international, and pan-national level. Participants of these exercises are led by governmental, commercial and NGOs with international operations, for example the Organisation for Economic Cooperation and Development (OECD), the International Monetary Fund (IMF), the European Union (EU), and the World Bank.

Since technology covers a spectrum of concepts covering all areas of the industry, performing TA activities had revealed a common need of tailoring them according to certain objectives and desired outcomes. Constructive TA (CTA) (Schot & Rip, 1997), Discursive/Argumentative TA (van Est & Brom, 2010), Participatory TA (pTA) (van Eijndhoven, 1997), Parliamentary TA (PTA) (EPTA, 2014), and Expert TA are several of the established areas of TA, especially Expert TA, whereby there are a lot of work being carried out in the health industry giving rise to the more specific Health TA (HTA) (Velasco-Garrido & Busse, 2005). A brief explanation of each type is as follows.

Initially developed in the Netherlands by Schot and Rip (1997), CTA attempts to broaden the design of new technology through feedback of TA activities into the actual construction of technology. Contrary to other forms of TA, CTA addresses social issues around technology by influencing the design practices and it is not directed toward influencing regulatory practices by assessing the impacts of technology.

Meanwhile, Discursive/Argumentative TA (van Est & Brom, 2010) was inspired by ethics, policy discourse analysis and the sociology of expectations in science and technology and thus deepens the political and normative debate about science, technology and society. Accordingly, this deals with both broader impacts of science and technology and the fundamental normative question of why developing a certain technology is legitimate and desirable.

Next, pTA consists of activities such as consensus conferences, focus groups, scenario workshops, etc., which actively, systematically, and methodologically involve various kinds of social actors—assessors and discussants—from different civil society organisations, representatives of the state systems, individual stakeholders and citizens (the general public), and technical experts (van Eijndhoven, 1997).

Thus, by combining the level and type of TA, an illustration of TA activities can be viewed in Fig 1.

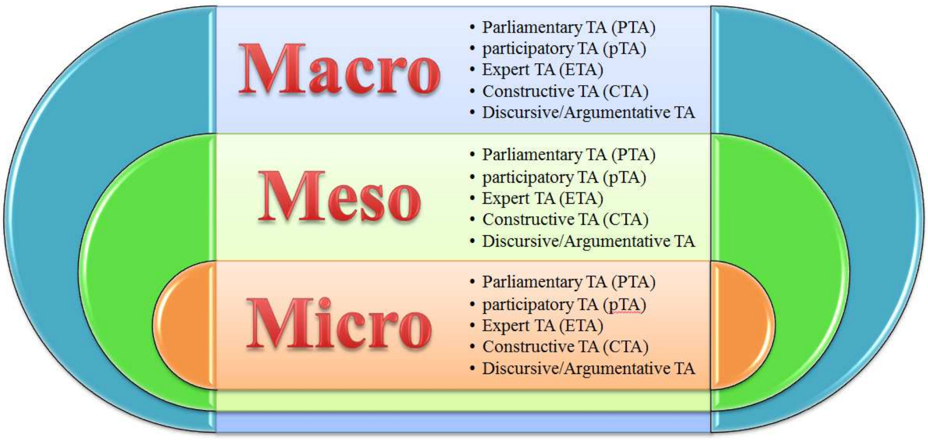


**Figure 1: Levels and Types of Technology Assessment**

Since TA has been adopted and used by the more developed nation, it is thus hypothesised that as a developing nation wanting to keep abreast with the latest technological development, Malaysia needs to explore ways of being able to manage new technology more efficiently and effectively. Therefore, this study was conducted to investigate the practice of CTA at the micro level, namely a nanotechnology research institution located in the Northern part of Malaysia.

***Technology: Nano-Biosensor***

A biosensor is defined as "an analytical device comprising two elements in spatial proximity: A biological recognition element able to interact specifically with a target [and] a transducer able to convert the recognition event into a measurable signal"

(Altschuh, 2007). This means that it is able to detect an event through a biologically based interaction which is then measured through an electric charge that is produced because of the detection, but with the Nano-Biosensor, it is done at the nano-scale.

An example of a Nano-Biosensor is shown in Fig. 2, and an explanation of which is as follows. A substrate (S) is converted into a product (P) due to a biocatalyst at point (a). This reaction is recognised by a transducer (b) which converts it into a weak electrical signal that is amplified at (c) together with a reference (R), processed for noise at (d) into a measurable form, and displayed at (e). Traditionally, the key part of this type of sensor is the transducer, which makes use of a physical change that takes part after a reaction. This may include any of the following.

The heat output (or absorbed) by the reaction (calorimetric biosensors) (Park, Cho, Moon, Yoon, Kim, Kim, & Suh, 2007).
Changes in the distribution of charges causing an electrical potential to be produced (potentiometric biosensors) (Koncki, 2007).
Movement of electrons produced in a redox reaction (amperometric biosensors) (Borgmann, Schulte, Neugebauer, & Schuhmann, 2011).
Light output during the reaction or a light absorbance difference between the reactants and products (optical biosensors) (Dey & Goswami, 2011).
Effects due to the mass of the reactants or products (piezo-electric biosensors) (Pramanik, Pingguan-Murphy, & Abu Osman, 2013).

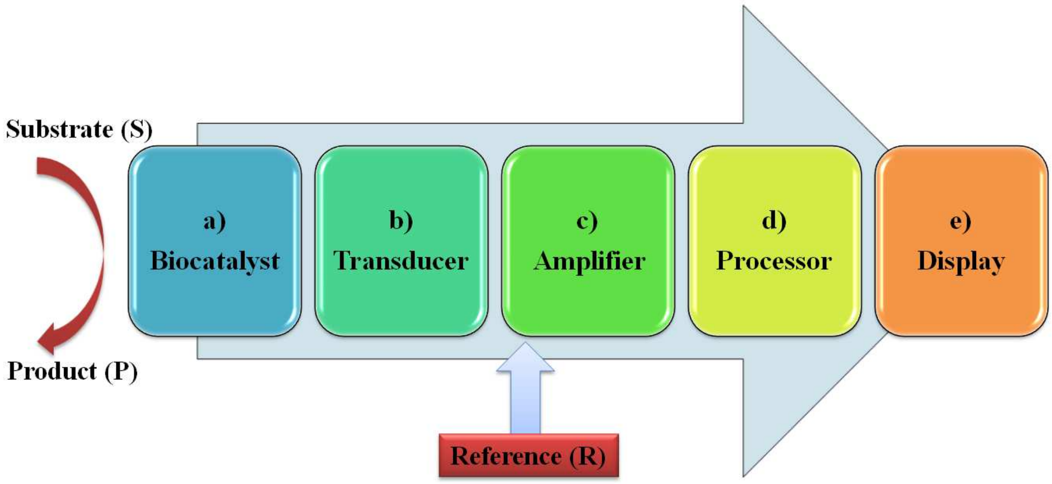


**Figure 2: Illustration of the Main Components of a Nano-Biosensor**

When observing the evolution of the biosensor, it could be seen that there are three distinct generations: the first generation biosensors where the normal product of the reaction diffuses into the transducer and causes the electrical response, second generation biosensors which involve specific 'mediators' between the reaction and the transducer in order to generate improved response, and third generation biosensors where the reaction itself causes the response and no product or mediator diffusion is directly involved.

The electrical signal from the transducer is often low and superimposed upon a relatively high and noisy (i.e. containing a high frequency signal component of an apparently random nature, due to electrical interference or generated within the electronic components of the transducer) baseline. The signal processing normally involves subtracting a 'reference' baseline signal, derived from a similar transducer without any bio-catalytic membrane, from the sample signal, amplifying the resultant signal difference and electronically filtering (smoothing) out the unwanted signal noise. Thus, the relatively slow nature of the biosensor response considerably eases the problem of electrical noise filtration. The analogue signal produced at this stage may be output directly but is usually converted to a digital signal and passed to a microprocessor stage where the data is processed, converted to concentration units and output to a display device or data store.

However, when one brings this biosensor down to the nano-scale, the properties and characteristics of elements and catalysts involved in the detection/transducer changes, which leads to more inventive use of materials in order to detect a measurable change. Such theoretical applications which are being investigated are Optical Biosensors, Nanotube Based Biosensors, Electrical Biosensors, Viral Nanosensors, Electrochemical Biosensors, Nanoshell Biosensors, and Nanowire Biosensors (Pathak, Katiyar, & Giri, 2007).

Meanwhile, one example is the nano-wire Field-Effect Transistor (FET) Nano-Biosensor, which has a nanowire for a sensing element, i.e., the semiconductor channel of the transistor. This channel is fabricated using nano-materials such as carbon nanotubes, metal oxide nanowires, or silicon nanowires, for example the Germanium nanowire field-effect transistor (Wang, Wang, Javey, Tu, Dai, Kim, McIntyre, Krishnamohan, & Saraswat, 2003). These sensor channels are very sensitive to changes in the environment due to its very high surface to volume ratio, and that a large portion of the atoms are located at the surface of the channel wire.

Because of this new level of sensitivity, there have been many areas identified for the applications of such Nano-Biosensors. Some of which include biological and environmental applications (Pathak et al., 2007; Rogers, 2006), as shown in Table 1.
One of the more pertinent field of study that nano-biosensor can assist is in the early detection of cancer. Dadmehr, Hosseini, Hosseinkhani, Ganjali, Khoobi, Behzadi, Hamedani, and Sheikhnejad (2014) had developed a novel fluorimetric nanobiosensor which helps in early cancer diagnosis. Due to its sensitivity, it can be used in rapid detection of DNA methylation based on $Fe3O4/Au$ core/shell nanoparticles. It is sensitive enough to distinguish the methylation ratio in a series of partially methylated DNA targets with identical sequences. That particular study revealed that through real sample analysis, the nano-biosensor could have viable practical application for methylation detection in human plasma sample and thus aid in early cancer cell detection.

Due to the potential value and benefits of this technology, there needs to be an effort in assessing its potential from both the international and national perspectives. Therefore, this paper presents the issues highlighted in the Malaysian context, more specifically in the Northern region of Malaysia, of a technology that is still considered to be in its infancy stage world-wide. The next section briefly describes the Nano-Biosensor developments in Malaysia.

**Table 1: Different applications of nano-biosensors**

| Biological Applications | Environmental Applications |
|---|---|
| DNA Sensors: Genetic monitoring, disease<br>Immuno-sensors: HIV, Hepatitis, other viral disease, drug testing<br>Cell-based Sensors: functional sensors, drug testing<br>Point-of-care sensors: blood, urine, electrolytes, gases, steroids, drugs, hormones, proteins, other<br>Bacteria Sensors (E-coli, streptococcus, other): food industry, medicine, environmental, other.<br>Enzyme sensors: diabetics, drug testing, other. | Agricultural monitoring<br>Detection of environmental pollution and toxicity<br>Ocean monitoring<br>Ground water screening |

***Nano-biosensors in Malaysia***

In the context of steering the direction of the nano-biosensor industry toward a more sustainable future, a roadmap was designed to guide the industry's science and research activity by highlighting a strategy that provides the broad context and high level directions from the Malaysian perspective. Roadmaps may represent the governing body's stance or position on the science of nano-biosensors, emphasising on how the industry efforts should be developed in order to best meet Malaysia's future needs. This roadmap is not one filled with detailed milestones, targets or research plan, since all of these particulars need to be decided by those with the responsibility for funding particular pieces of research in conjunction with the end-users of the research, which consequently, will build toward clarifying the overall picture that is being presented by this roadmap.

The Malaysian Government has produced a National Nanotechnology Roadmap, titled "Malaysia NNI Roadmap Report" in 2007, which was based on a study that identified five industries that would benefit from the development of nanotechnology, namely Biotechnology, Energy, Environment, Agriculture and Medicine. After a screening process of all the potential nanotechnology-based products in the industry was performed, six target products were identified as being able to bring the most impact to the above identified industries directly, and consequently the development of the country. These products include biosensors as being on the top of this list, followed by biochips, molecular farming, drug delivery system, solar and lithium-ion.

This shows how important the nano-biosensor has become in impacting other industries. Some specific identified applications of the biosensor in other industries include diagnostic kits for clinical and homes uses, real-time applications such as alert sensor and detector for pathogen infection caused by bacteria, fungi, and viruses during outbreaks and detection of contamination, and food production and agricultural diagnostic kits to aid in production. Furthermore, biosensors also assist in facilitating the usage and production of the above mentioned products, such as in molecular farming where biosensors are used in agricultural diagnostics, and in biochips and drug delivery system, where biosensors can be applied as monitoring and controlling devices.

With the governmental support put into place, the various tertiary and research institutions have responded by establishing a number of research centres that focus on the specific development of nanotechnology techniques, products and other related components, such as simulation, artificial intelligence and visualisation technologies, etc.

**Methodology**

The study was conducted with the intention to examine the CTA practices in the nanotechnology field, more specifically in the nano-biosensor sector. This study is cross-sectional whereby data were gathered once to answer the study's research questions. A cross-sectional design is adopted for this research because it is less expensive and short time consuming compared to longitudinal design (Sekaran & Bougie, 2010).

This study used qualitative approach, both interviews and documents in order to enhance the finding to be more insightful. The researcher interviewed the experts of a selected laboratory, thus asked relevant questions which were compatible with the research objectives. Hence, the interview has enhanced the result and provided clear insight about the issue and also gave this study valuable information.

Participants in the interviews were sufficient based on the nature of the study which is more on the management or managerial issues and knowledge (soft science); therefore the researcher had to exclude the answers from the "technology" aspects (hard science). The interviews were conducted with four informants from the research centre.
A qualitative approach was conducted in this study to get insight on the subject

matter. The interview protocol was used as a guideline for the researcher, which was used to all participants. In this first part, the interviews were conducted in order to gain general information about the research centre and to identify the key issues pertaining to TA in nanotechnology. The participants were first provided with information about the purpose of the study in general and how the information would be used. The ice breaking questions were asked to them to describe their work in general.

After that, the questions were specifically focused on the key objectives to be obtained by the study. Each interview lasted approximately about an hour and notes were made during the interviews. After each interview the notes were transcribed and content analysis was performed.

**Results**

The selected research centre was established in November 2008 as a converging hub for innovation, research, and expertise in Malaysia, particularly for the Northern Corridor Economic Region (NCER). It emphasises on nano-electronics engineering research activities that focus on nano-biochip, novel devices, memory devices and nano-photonic devices (a breakdown of their research groups is as shown in Table 2).

The centre aims to expand its research activities to nano-materials and nano-biotechnologies through interdisciplinary programmes and collaborations with other organisations. It comprises four distinct laboratories (Micro Fabrication Cleanroom, Nano Fabrication Cleanroom, Failure Analysis Laboratory and Nano BioChip Laboratory) with state-of-the-art scientific equipment and facilities to accommodate researchers involved in device design, fabrication, characterisation and testing. In principle, these laboratories are in sharing basis with the other institutions. Members of this centre also contribute toward the Malaysian body of intellectual property rights through a number of patents as the result of research projects performed with financial support from the government as well as the private sector.

**Table 2: Research group and related focus areas**

| **Nano Biochip Research Group** | **Novel Silicon Devices Research Group** | **Memory Devices Research Group** | **Nano Photonics Research Group** |
|---|---|---|---|
| ▪ Nano Structure Based Biosensor<br>▪ Nano Material Based Biosensor<br>▪ CMOS Based Biosensor<br>▪ Cantilever Based Biosensor | ▪ Single Electron Transistor<br>▪ Vertical Transistor<br>▪ Nano CMOS<br>▪ Silicon Based Molecular Electronic | ▪ Non-volatile Memory Device<br>▪ Volatile Memory Device | ▪ Nano Photonics Devices<br>▪ Nano Fluidics Devices<br>▪ Quantum Optical Devices |

With regard to formal CTA activities, the informants (the director - UH, a visiting professor - YD, and two researchers – RAR and HAH) indicated that they perform CTA workshops at the micro level, whereby they carry out TA activities involving their own staff members. The basis of these workshops is by looking at the current trends and development of their focus area, which is currently the nano-biosensor.

The guiding principles for their focus area selection are based on the national roadmap. They established this area of focus by identifying the insufficient selectivity and sensitivity levels of detection in various fields, for example in the detection of cancer. Through this method, it is indicative that this research centre has adopted the strategic niche management, one of three generic strategies that have been previously developed through CTA activities (Zulhumadi, Udin, & Abdullah, 2012).

The first recurring theme from the interview sessions was the issue of sensitivity of the current sensors used in the industry. The level of sensitivity of nano-biosensors is a pertinent issue in other research studies as well. This was highlighted by Anker, Hall, Lyandres, Shah, Zhao, and Duyne (2008) where the research outcome offered different methods of increasing the sensitivity of their developed nanosensor, such as by introducing a new "plasmonic structure termed 'film over nanowell' by first using reactive ion etching through an NSL sphere mask and removing the spheres to form a nanowell array, and then vapour-depositing a silver film over the nanowells".

Meanwhile, Campbell (2014) presented a new nano-biosensor for monitoring food in ensuring the safe consumption of food by the general populace. This is not different from the current situation in the research centre under study. According to one respondent "current gadget cannot meet the selectivity and sensitivity… can detect [cancer] for stage three and four which is too late … [because of] limitation of current device" (UH). Another respondent provided the objective of his/her research into sensor devices which needs to "detect early so we can provide medicine, proper remedy… [therefore these gadgets need] to detect when the disease [is] in stage one and two" (HAH), or in other words greater sensitivity in these sensors needs to be improved so as to be capable of perform earlier detection that leads to early intervention and perhaps a cure.

Next, a theme that illustrated the development of this line of research in Malaysia was mentioned several times, which was the level of maturity of the nano-biosensor technology. Through their workshops, these respondents/researchers identified nano-biosensor as being at the preliminary stage, just after the infancy stage, whereby at the device level, they are using real clinical samples (UH).

In other parts of the world, like in Japan in the advanced medical technology sector (Kimura, 2011), it was revealed that the maturity level of this technology has not reached high levels, in other words, the technology has yet to mature and considered as being still immature. In another research report by Teeuw and Vedder (2008), it was estimated that micro-chip technology with sub-10nm structures of active components will achieve 50% of maturity in 10 years from now. In that research, their definition of maturity is from the perspective of the technology being mature enough to be applied in the security domain.

Meanwhile through the CTA discussions performed by the respondents under study, it was highlighted that the future directions for the nano-biosensor market is very bright, whereby the need for such devices will instantly exist once the device is commercialised, as agreed upon by all respondents. It was interesting to note that one respondent mentioned that the progress of their current research in one of their nano-biosensor initiatives is relatively ahead of their overseas competition. This was evident with his/her remark that "[they are] still at lab scale … [and] have not reached [the stage of] using clinical research [samples]. Ours, [at the] device stage … use real clinical samples" (YD). This indeed is good news, since the Malaysian government has taken up the challenge of exploring the vast potentials of nanotechnology by launching its own National Nanotechnology Initiative on 4 July 2005 in Johor Bahru, Malaysia (Asia Pacific Nanotech Weekly, 2005). This is because of the potential untapped market nanotechnology in general, and in nano-biosensors more specifically, can improve the economy as well as the quality of life of a country.

Meanwhile, it has been estimated that "the global market for medical sensors was valued at USD 10.1 billion in 2012 and is expected to reach a value of USD 15.5 billion in 2019, growing at a CAGR of 6.3% from 2013 to 2019" (Sheela, 2013).

The respondents identified current and future projects in creating detectors for "leptospirosis, typical disease, food disease, cholera, cancer" (HAH). All of the respondents agreed that their work will have an impact on the industry and eventually society, as one of the indicated, "doctors are very supportive of this effort… [they] can care [for] critical diseases, especially cancer … [detectors] can identify rodent urine [disease] locations… early detection [of disease], halal detection kit, sugar element" (UH). So far, bio-nanosensor in particular has no known negative effects, as supported by all respondents.

## Conclusion

From the above findings, it can be surmised that CTA activities are performed by individuals within the organisation, i.e. at the micro level, but only involving experts from the same organisation. The overall national agenda is used as a guide for their discussions, namely stemming from the National Nanotechnology Initiative launched on 4 July 2005 in Johor Bahru, Malaysia (Asia Pacific Nanotech Weekly, 2005). Their adoption of strategic niche management seems to be fruitful in that they are leading the research in their respective focus areas, as when compared to their competitors overseas. Even though there were no negative effects that were identified through their CTA workshops, perhaps this matter can be further explored by engaging experts from outside the organisation, and also perhaps widen the scope from the CTA implementation at the micro level to a higher meso level or macro level, in order to get a better picture of the overall impact of their research focus areas in nanotechnology and thus gaining a clearer path to forage into the future.

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