

**MEDICALTECHNOLOGIES INFORMATION PROFORMA**

\*Please use this proforma for medical devices, regenerative technologies, biologics, intervention/procedures, diagnostics, traditional and complementary medicines.

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| --- | --- | --- | --- |
| **Company detail** | | **Contact Person Detail** | |
| **Date:** |  | **Name:** |  |
| **Company name:** |  | **Position in company:** |  |
| **Address:** |  | **Email:** |  |
| **Telephone:** |  |

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| **Technology description** | | **Confidential Information**  **Tick (√) where applicable** |
| Name of the device/product  Please list any brand name/s, synonyms |  |  |
| Who are the commercial developer/s &/or distributors (if different)? |  |  |
| Patient group &/or indication  Please include stage of disease and targeted patient sub-groups (including sex, age-range etc) |  |  |
| Brief description of the device (2 paragraphs)  i.e. what it is and how it works |  |  |
| What is the intended use of the device?  e.g. prevention, treatment, rehabilitation |  |  |
| What is innovative about the device? |  |  |
| What advantages does the device have over current options?  e.g. ease of use compared to current options, non or less invasive, fewer adverse effects, shorter length of stay in hospital, fewer infections |  |  |
| Is the device already available for a different patient group? |  |  |
| **Stage of development, availability and launch plans** | | **Confidential Information**  **Tick (√) where applicable** |
| Date of CE mark/ FDA/TGA approval |  |  |
| If not yet CE marked or FDA/TGA approved, when is this anticipated?  e.g. Q3 2014 |  |  |
| **Date of actual or planned launches:** | |  |
| Malaysia – research use |  |  |
| Malaysia – clinical use: private |  |  |
| Malaysia – clinical use: government facilities |  |  |
| Is it available or launch in other countries? |  |  |
| **Research evidence** | |  |
| **Published clinical trials**  Please list references of relevant publications and abstracts from conferences |  |  |
| **Unpublished completed clinical trial**  Please provide brief details &/or web links/trial names/codes for any unpublished completed trials |  |  |
| **Ongoing clinical trials**  Please provide brief details &/or web links/trial names/codes for any unpublished completed trials |  |  |
| **Possible impact** | |  |
| Likely impact of this technology in terms of **patient benefits** (please quantify where possible), e.g. increased effectiveness in meeting outcomes, safety etc |  |  |
| Likely impact of this technology in terms of **system benefits** to the health service (please quantify which possible), e.g. price, net cost savings, training needs etc. |  |  |