

# 6

## Special Planning





### **Innovations in the Management of Drugs and Medical Devices during the Pandemic**

- Accelerate COVID-19 vaccines launch and continuously support emergency epidemic prevention needs
- Accelerate support for emergency public health policy needs and fostering R&D capacity for epidemic prevention test
- Ensure the supply of safe and effective medical devices for epidemic prevention



### **A New Era of Smart Medical Device Management**

- Establish Smart Medical Device Office
- Accelerate the product launch of domestically manufactured smart medical devices
- Construct a comprehensive regulatory environment for smart medical devices
- Help cross-sector business operators, reviewers, and inspectors enhance their knowledge about smart medical devices regulations
- Establish AI/ML Medical Devices Information & Matchmaking Platforms



### **National Award for Research and Development of Pharmaceutical Technology**

- Expand reputation of operators internationally
- Demonstrate the R&D capacity of Taiwan's medical and biotechnology industry
- Promote Medical and Biotechnology Innovation Excellence and Global Presence

Section 1 Breakthroughs and Innovations in the Management of Drugs and Medical Devices during the Pandemic

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# 06

## Special Planning

In 2021, under the impact of COVID-19 pandemic and emerging technologies, TFDA was facing new challenges. TFDA flexibly addressed these challenges through the combination of emerging technologies in different fields and the cooperation between domestic and foreign experts and industry operators. In addition to solving the urgent epidemic problems from the administrative aspects, TFDA also lay the foundation for the development of AI/ML-based medical devices from the legal and technical aspects.

At the same time, in order to support the outstanding pharmaceutical and medical device manufacturers and business operators in Taiwan, TFDA actively promotes the consultation mechanism, improves relevant laws and regulations, and continues to held Pharmaceutical Technology & Research Development Award to encourage the industry to invest in the research and development of innovative products and related production technologies so as to keep promoting the development of domestic pharmaceutical and medical device technologies.

### ■ Section 1

#### Breakthroughs and Innovations in the Management of Drugs and Medical Devices during the Pandemic

##### ■ Introduction of the Policy

The COVID-19 pandemic is still ravaging the world. To ensure the quality, safety and supply of drugs and related medical devices during the pandemic, TFDA assisted to accelerate the development and production speed of domestic COVID-19 vaccines, and also shortened the mass production time of domestic vaccines to market. In addition, TFDA expedited the lot releases in response to the urgent demand for the vaccines, and improved the smooth supply of the pandemic prevention drugs supply chains to support the capacity of domestic COVID-19 testing technology, thus to strengthen the resilience of Taiwan's emergency response system.



## ▪ Implementation Strategy

### **I. Accelerate the review of COVID-19 vaccine and drug under EUA for import or manufacture, and provide guidance for domestic vaccine development**

Vaccines and drugs are powerful tools to prevent the spread of infectious diseases. To fulfill the needs to the public health, besides importing vaccines and drugs, developing the earlier availability of domestic vaccines was also an important prevention strategy. Through the measures such as active project counseling mechanism, flexible regulatory adaptations, and rapid review efficiency, TFDA expedited the import and manufacture of COVID-19 vaccines and drugs under EUA during the COVID-19 pandemic.

### **II. Ensure that vaccine manufacturing and storage comply with international standards**

TFDA dispatched auditors with biologic products inspection expertise to the domestic COVID-19 vaccine manufacturers, including bulk solution production (cell amplification culture and protein purification) and pharmaceutical product production (formulation and filling) then subsequently conducted GMP inspections in accordance with PIC/S GMP regulations to ensure

the quality of vaccine manufacturing. In addition, TFDA also provided the list of pharmaceutical companies with cold chain permits and conducted GDP inspections, to allow the Centers for Disease Control to plan the cold chain storage and transportation operations after vaccine procurement.

### **III. Accelerate the vaccine test mechanism and continue to support the supply of national reference standards**

TFDA established and published the immunogenicity test method for COVID-19 vaccines, also produced the first generation SARS-CoV-2 neutralizing antibody national standard to support domestic manufacturers in evaluating the vaccine efficacy. In response to the domestic epidemic and vaccine demand, task teams were set up to handle the lot releases of the domestic and imported COVID-19 vaccines. A rapid alternative method for sterility testing of the vaccines was established to speed up the vaccine lot release process. Since the outbreak of the pandemic, TFDA has continued to supply SARS-CoV-2 nucleic acid standards and respiratory virus panels in order to ensure the objectivity and credibility of COVID-19 testing and improve the testing capacity of national epidemic prevention.



#### **IV. Real-time information on the supply and demand of medical devices for prevention of outbreaks and strengthen quality control**

By establishing a contact point for dealers of epidemic prevention medical devices, TFDA can collect real-time information regarding the supply and demand of relevant medical devices. At the same time, following Article 35 of the *Medical Devices Act*, TFDA has started to approve specific medical devices to be manufactured or imported with special approval, and a consultation team has been set up to provide consultation services to support domestic manufacturers as they develop SARS-CoV-2 antigen test reagents. As the COVID-19 virus continues to mutate, TFDA has revised its guidance for manufacturing specific medical devices as a special case and TFDA will continue to monitor the performance of SARS-CoV-2 antigen test reagents manufactured with special approval. In addition, TFDA has also strengthened border control and quality monitoring of medical masks.

##### **▪ Achievements and Benefits**

#### **I. Acceleration of COVID-19 vaccines launch and continuous support of emergency epidemic prevention needs**

(I) In order to accelerate the early launch of domestic vaccines and ensure the vaccine quality, efficacy and safety, TFDA and the Center for Drug Evaluation (CDE) formed a project

consulting and counseling team, which held weekly meetings with domestic vaccine manufacturers, and provided timely professional regulatory and technical consultations. In the meantime, TFDA adopted a rolling review mechanism to significantly accelerate the review time for applications of clinical trials and EUA manufacturing. Since the beginning of the pandemic, the consulting and counseling team has held up to 111 consultation meetings with domestic vaccine manufacturers.

(II) In order to formulate the review guidance for COVID-19 vaccines and drugs, TFDA followed the progress of international regulations and also invited domestic experts and scholars to hold meetings, in order to provide professional review and consultation recommendations. A total of 24 advisory committee meetings were held between 2020 and 2021. In June 2021, TFDA announced the establishment of the COVID-19 vaccine Emergency Use Authorization (EUA) review guidelines and technical document checklists for references. Four vaccines and three drugs for COVID-19 EUA reviews were completed. In accordance with Article 48-2 of the *Pharmaceutical Affairs Act*, TFDA approved under EUA vaccines, namely Vaxzevria<sup>®</sup> (AstraZeneca), Spikevax<sup>®</sup> (Moderna), Medigen and Comirnaty<sup>®</sup> (BNT162b2), and drugs, namely Veklury<sup>®</sup> (Rem-



desivir), Molnupiravir and Paxlovid® (PF-07321332 plus ritonavir) to meet domestic emergency pandemic prevention needs.

(III) Auditors with biological product expertise were dispatched to factories for a total of 259 sessions/319 visits and conducted GMP inspections of Covid-19 vaccine bulk solution and filling manufacturers to ensure that the quality of COVID-19 vaccine used in Taiwan is in compliance with PIC/S GMP regulations. TFDA supported the domestic manufacturers in evaluating the vaccine titers and accelerating obtaining manufacturing permits, to enhance the smooth supply of the pandemic control drug supply chain. By the end of 2021, TFDA has completed 114 batches (41,129,376 doses) release for imported or domestic manufactured COVID-19 vaccines.

## **II. Accelerate support for emergency public health policy needs and fostering R&D capacity for epidemic prevention test**

TFDA has been producing and supplying SARS-CoV-2 nucleic acid reference standards and reference materials since 2020, and has been accredited with the Symbol of National Quality (SNQ) certification, thus indicating that the service quality of the national reference standards is well recognized. By the end of 2021, a total of 374 bottles of reference standards have

been supplied to 31 units, to assist the industry to obtain EUA for manufacturing of the test reagents, thus effectively fostering domestic industry in pandemic prevention.

## **III. Ensure the supply of safe and effective medical devices for epidemic prevention**

TFDA has initiated fast track services to review and approve applications more flexibly. By the end of 2021, 334 applications for approval for manufacturing and importing medical devices have been approved, including test reagents, computer-aided diagnosis in chest X-ray images, electronic stethoscopes and respirators, to enhance Taiwan's capacity to cope with the pandemic. In response to the increasing demand for COVID-19 self-test reagents, TFDA announced the "Requirements of performance evaluation for manufacturing SARS-CoV-2 nucleic acid or antigen self-test reagents as a special case" and "Guidance for the public to use COVID-19 self-test kits", to accelerate the approval of 5 applications to manufacture and 19 applications to import COVID-19 self-test kits. A specific area was designated on the official website of TFDA for relevant inquiries. TFDA has also revised and announced 6 guidance documents for manufacturing medical devices as a special case, and inspected the testing performance of 9 COVID-19 antigen testing reagents against Omicron variant. Also, to ensure the safety and the quality of medical masks, TFDA

completed 100 quality monitoring of medical masks available in the market and 532 inspections of packaging labels of medical masks sold in-store or online in 2021.

## ■ Section 2

### A New Era of Smart Medical Device Management

#### ■ Introduction of the Policy

With the emergence of digital technology, many companies in the information and communications technology (ICT) industry have invested in the research and development of smart medical devices. However, these companies often have to delay the time to launch their products due to insufficient knowledge about medical device regulations, a lack of communication platform for clinical practice, and a lack of talents with expertise in smart technology. To facilitate the development of the smart medical device industry in Taiwan, TFDA has established a “Smart Device Office”. The establishment of the office symbolizes the start of a new era of regulatory services that can help to accelerate the product launch of smart medical devices.

#### ■ Implementation Strategy

The “Smart Device Office” aims to provide a one-stop service with an innovative and multi-faceted consultation model to accelerate the product launch of domestically manufactured smart medical devices. The Office is committed to (1) studying the lat-

est regulatory trends; (2) formulating timely and appropriate management mechanisms and guidelines; (3) incorporating expert opinions on smart medical devices with the establishment of the “Smart Medical Device Advisory Committee”; (4) improving the review process and quality. In addition, educational training courses on smart medical devices are offered to cross-sector business operators as well as reviewers and inspectors working for TFDA to enhance cross-sector personnel’s knowledge about smart medical device regulations. Further, to facilitate communication between business operators in the ICT industry and medical institutions, the “AI/ML Medical Devices Matchmaking Platform” has been established to meet the industry’s needs to access real-time information and facilitate matchmaking.

#### ■ Achievements and Benefits

##### I. Establish the Smart Medical Device Office

On May 7, 2021, TFDA held the grand opening ceremony of the AI/ML Medical Device Office to inform the public of the establishment of the Office. In total, 768 people participated in the event (309 on-site) (Figure 6-1) showing that many people have high expectations and hope that the Office can facilitate the development of the domestic smart medical device industry.



Figure 6-1

**Opening Ceremony of AI/ML Medical Device Office on May 7, 2021**

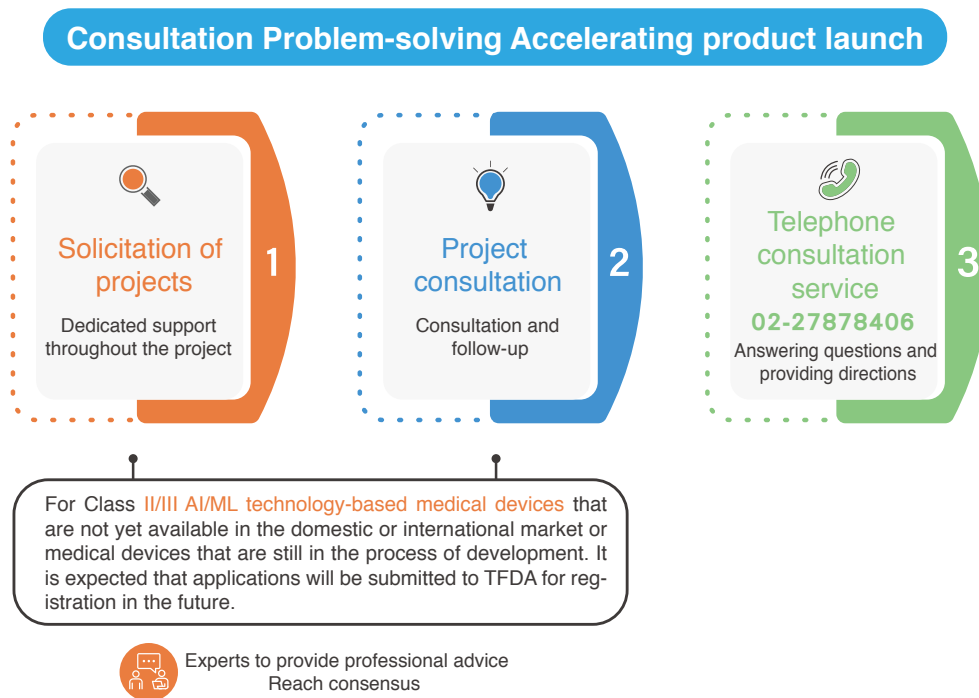
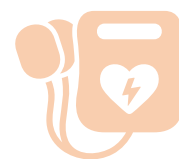


Figure 6-2

**Multi-faced Consultation Model for Smart Medical Devices**



## **II. Accelerate the launch of domestically manufactured smart medical devices**

With an innovative and multi-faceted consultation model (Figure 6-2), TFDA has used public solicitation to select 10 research and development projects that aim to develop Class II/III medical devices using AI/ML technology to actively provide consultation. One of the projects selected has successfully obtained market approval at the end of 2021. In addition, TFDA has completed 13 consultations on the quality management system for manufacturers of smart medical devices. On April 30, 2021, TFDA announced the “*Consultation Guidelines for Domestically Manufactured AI/ML Technology-based Medical Devices*”; and provided consultations for 25 applications. A consultation hotline (02-27878406) has been set up to provide timely consultation related to smart medical devices and has served 1,398 people. Since the Smart Medical Device Advisory Committee was established in 2021, the Committee has provided practical advice to 17 projects related to product development, clinical verification, and statistical analysis of smart medical devices. In total, in 2021, with the support of TFDA, 5 domestically manufactured smart medical devices have been successfully brought to the market, thus benefiting the industry development.

## **III. Construct a comprehensive regulatory environment for smart medical devices**

In 2021, TFDA published and revised 9 guidance documents, templates and FAQs related to smart medical devices (Table 6-1) to be used by operators as references to draft and prepare technical documents prior to product development and application for registration and market approval.

## **IV. Help cross-sector business operators, reviewers, and inspectors enhance their knowledge about smart medical devices**

In 2021, TFDA offered 83 regulation briefings, education and training sessions, workshops, and visits to R&D centers for cross-sector business operators and 29 sessions for reviewers and inspectors working for TFDA. Some of the courses are made available for the general public on “TFDA Digital Learning Platform for Medical Devices and Cosmetics”.

## **V. Establish AI/ML Medical Devices Information & Matchmaking Platforms**

On April 30, 2021, TFDA established the AI/ML Medical Devices Information Platform and the platform has accumulated 56,386 visits by the end of 2021. Also, the AI/ML Medical Devices Matchmaking Platform was established on August 31, 2021, and has held two matchmaking events, with 15 preliminary matches to accelerate the establishment of cross-industry alliances and to meet the demand from different fields.

**Table 6-1** Guidance Documents, Templates, and FAQs Related to Smart Medical Device

Type of Document	Publication Date	Name of the Document
Guidance Document	May 3, 2021	<i>Guidance on Medical Device Cybersecurity Applicable to Manufacturers (Revised)</i>
	July 7, 2021	<i>Guidance on Review of Registration and Market Approval of AI/ML-Based CADe SaMD</i>
	August 16, 2021	<i>Technical Guidance for Industry to Register Artificial Intelligence/Machine Learning-based Software as Medical Device (AI/ML-Based SaMD) (Revised)</i>
	December 30, 2021	<i>Guidance on Application for Post-market Changes for Software as Medical Device (SaMD)</i>
	December 30, 2021	<i>Guidance Document for Quality Management System of Manufacturers of Software as Medical Device (SaMD)</i>
Technical Document Template	December 6, 2021	Template for Cybersecurity Safety Assessment and Analysis of Medical Device
FAQs	May 7, 2021	FAQs for the Registration and Market Approval of Smart Medical Devices (Revised)
	May 7, 2021	FAQs for Submission of Applications for Registration and Market Approval for AI/ML-based Medical Devices
	December 30, 2021	FAQs on SaMD Manufacturers' Compliance with Medical Device Quality Management System Regulations

### ■ Section 3

#### National Award for Research and Development of Pharmaceutical Technology

##### ▪ Introduction of the Policy

In order to improve the pharmaceutical manufacturing standard and the quality of clinical trials, the Ministry of Health and Welfare (MOHW, former Executive Yuan Department of Health) and the Ministry of

Economic Affairs (MOEA) have jointly formulated and promulgated the “*Regulations Governing Incentive Rewards for Research and Development of Pharmaceutical Technology*” in accordance with Article 41 of the *Pharmaceutical Affairs Act* in 2000, and held the first Pharmaceutical Technology & Research Development Award (PTRD) in the following year (2001). With the evolution of times and the needs, the MOHW and the MOEA have jointly promulgated the

“*Regulations Governing Incentive Rewards for Research and Development of Innovative Medical Devices Technology*” in accordance with Article 80 of the *Medical Devices Act* in 2021, hoping to encourage more medical device manufacturers to invest in the research and development of innovative medical devices and related technologies.

▪ **Implementation Strategy**

**I. Keeping pace with the times amending related incentive award regulations**

MOHW and MOEA have amended some provisions of the “*Regulations Governing Incentive Rewards for Research and Development of Pharmaceutical Technology*” in 2004 and 2013, in order to better clarify the eligibility and the means of the incentive awards. Then in response to the introduction of the *Medical Devices Act* in 2021, issued the “*Regulations Governing Incentive Rewards for Research and Development of Innovative Medical Devices Technology*” on April 29, 2021, so as to keep the regulations up-to-date.

**II. Implement for the Pharmaceutical Technology & Research Development Award**

The Pharmaceutical Technology & Research Development Award (PTRD) is administered in accordance with the former mentioned two awards regulations, the contents include:

- (I) Expand invitation to the pharmaceutical and related production technology industry operators to participate

The promotional posters with the PTRD logo and annual slogan were produced, and were promoted through the official websites of Industrial Development Bureau, MOEA, TFDA, TFDA’s Drug and Food Safety Weekly Letter, the TFDA LINE and the Facebook fan page, and biotechnology and medical magazines to encourage related industries to submit outstanding products competing for the PTRD.

- (II) Professional review of applications

The industry will submit the award applications in accordance with the eligibility of the PTRD, and their Research and Development (R&D) products will be classified into three categories namely pharmaceuticals, medical devices, and manufacturing technology. Experts in the relevant fields are invited by TFDA to conduct rigorous reviews through preliminary, secondary reviews based on the R&D achievements, benefits, and degrees of contributions, to pick up for the Gold, Silver, and Bronze awards.

- (III) Diversified publicity and promotion of incentive award activities

A section for the PTRD on TFDA website was set up to display the call for application rules and award results from previous years. In 2021,



a dedicated website for the PTRD was set up, along with a short promotional animated video, a special 20th anniversary featured articles and a special video, providing the public the access to the 20-year track record of the incentive award.

#### (IV) Award Ceremony

PTRD has reached its 20th year in 2021, the award ceremony was held publicly to encourage all awardees, also the ceremony scopes were expanded to include the starlight interview area and the finalists honorary exhibition area. The awards were announced live to increase the level of surprise, with the Minister of MOHW presenting the trophies to the awardees who were then invited to deliver their speeches respectively.

#### ▪ Achievements and Benefits

##### I. National awards benefit industry to expand reputation internationally

The PTRD is the sole national award jointly awarded and presented by MOHW and MOEA. To show the glory of this award, the 20th award ceremony was expanded to hold on November 30, 2021, at the International Conference Hall of the National Biotechnology Research Park (Figure 6-3), with 165 people attending the ceremony, 47 exposures of press releases. The 20th award anniversary publications and videos had been promoted on a dedicated website for the PTRD and has been established to convey Taiwan's promotion and philosophy of pharmaceutical science and technology; the website has been attracting 7,736 page views and at least 1,216 visitors. By publicly recognizing products with outstanding contributions and innovative R&D, would



Figure 6-3 Group Photo of the 20th PTRD

encourage greater pharmaceutical technology research and development teams to participate in the sole national-level award to build the value of Taiwan's pharmaceutical and biotechnology brand, allowing more excellent pharmaceuticals and medical devices to be created and developed for the benefit of public health.

## **II. Demonstrate the R&D capacity of Taiwan's medical and biotechnology industry**

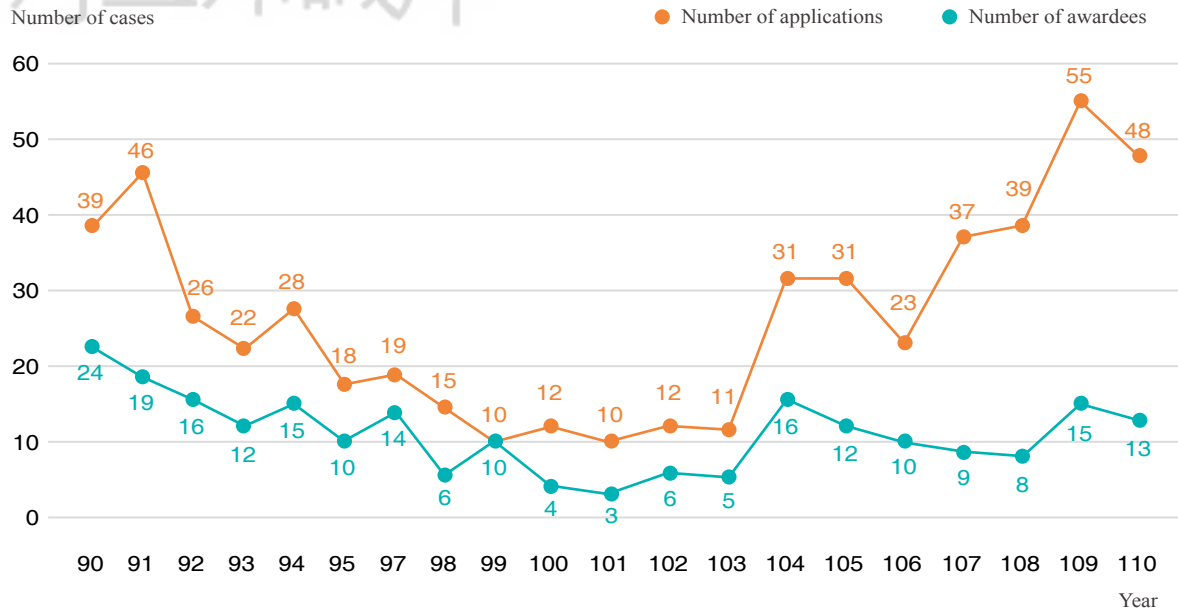
The theme of the year 2021 is "Excellent Pharmaceuticals, Leap 20", symbolizing the 20th year of the event and the upcoming 20 years. There were 13 applicants awarded with gold, silver, and bronze respectively in the 20th year, including 4 in the category of "Pharmaceuticals", 6 in the category of "Medical Devices", and 3 in the category of "Manufacturing Technology".

Among them, 3 products were recognized with "Gold Award", including "ELIX-CYTE<sup>®</sup>", a new stem cell drug for knee osteoarthritis, which can provide early relief of pain and improve joint movement; "An IVD for Rapid Detection and Surveillance of Chronic Kidney Disease: Protein-Bound Uremic Toxin ELISA Kit", which can facilitate rapid test and monitoring of chronic kidney disease for clinicians to evaluate the course of the disease and treatment; and the "Qsep Series Bio-Fragment Analyzers",

with capillary electrophoresis as the core technology, and can be used for the detection of acute epidemics, pathogenic bacteria and cancer screening, etc. These results fully demonstrated the achievements and potential of domestic medical research development.

## **III. Promote Medical and Biotechnology Innovation Excellence and Global Presence**

Despite the impact of the COVID-19 pandemic in recent years, PTRD through multiple channels of promotion and soliciting, industry participation has been eager and the number of submissions was still rising with the medical device cases also hit a record high in 2021 (Figure 6-4). From 2001 to 2021, more than 200 PTRD have been given out, the benchmarked awardees have continued to refine their products in terms of R&D, process improvement, and quality technology, to maximize the clinical benefits. They also continue to diversify the development and reach out global market, with the recognition of the PTRD, would help to strengthen the brand awareness and the company image, and create a virtuous cycle in the industry and competitive advantage of the company; hence help Taiwan's Medical Biotechnology Industry to thrive internationally.



**Figure 6-4** Number of Applications and Awardees for the PTRD Over the Years

