INTERNATIONAL DEVICES & DIAGNOSTICS MONITOR

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IN THIS ISSUE

FDA Issues Final Guidance On Expedited Access Program

Clinical evidence on devices designated under the U.S. FDA's Expedited Access Program may include intermediate and surrogate endpoints, as long as the endpoints to predict a clear benefit to the patient, the agency says.

Companies should consider using these earlier endpoints if the traditional endpoint is rare or may be delayed, measurement of the endpoint is invasive or costly or the treatment effect is small enough that reaching a traditional endpoint would require an impractically large trial, the FDA says in final guidance on its EAP initiative released Thursday.

The guidance stresses that EAP devices may be approved based on a successful intermediate endpoint even if the result doesn't lead to lower mortality. Sponsors whose devices are approved based on less than full-scale clinical trials will be required to gather additional data in a postmarket study. Postmarket data collection requirements will be set on a case-by-case basis and guided by separate guidance on balancing premarket and postmarket data requirements, also released Thursday (*see story, page 2*).

Frequent Meetings With FDA Staff

The EAP, first proposed in April 2014 draft guidance, is meant to give sponsors of PMA and de novo devices that serve unmet needs in treating life-threatening or debilitating diseases a way to speed innovative technologies to patients.

Like the Center for Devices and Radiological Health's Innovation Pathway for new technologies, the EAP relies heavily on early and frequent meetings between sponsors and FDA staff. It also requires sponsors to prepare a data development plan, including a description of clinical and nonclinical data the firm proposes to collect and a timeline for developing and marketing the device. The idea is to allow more data on device performance to be collected postmarket while maintaining a reasonable assurance of safety and effectiveness, CDRH Director Jeffrey Shuren says.

The EAP also allows the FDA to accept more uncertainty regarding how a device's potential benefits outweigh its risks and

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Expedited Access, *from Page 1*

whether this warrants earlier access. Decisions about allowing early access, however, should take into account the risk level of the device and the likelihood that postmarket surveillance will detect serious risks, the guidance says. There should also be strong indications that postmarket data collection will be completed in a timely manner, the FDA adds.

Examples of products that may qualify for EAP designation include a continuous glucose monitor that could replace blood glucose testing, a transcatheter heart valve that is delivered transcutaneously and an in vitro test for earlier diagnosis of preeclampsia, the guidance says.

Janet Trunzo, senior executive vice president for technology and regulatory affairs at AdvaMed, says the trade group welcomes the EAP and has proposed adding onto the EAP with an easier path to Medicare coverage for new technologies.

The EAP takes effect April 15. View the final guidance at www.fdanews.com/04-13-15-expedited.pdf. — Elizabeth Orr

FDA to Balance Premarket, Postmarket Data Requests

The U.S. FDA plans to apply its least burdensome principle in deciding when to insist on premarket data in a PMA and when to allow the sponsor to gather additional clinical data postmarket.

Federal law requires the agency to request just enough data to assure a device's safety and effectiveness and no more, meaning postmarket information may be used to reduce the amount of premarket data. This includes quality systems compliance, MDR reporting and postapproval studies, according to final guidance released Thursday.

The key to deciding how much premarket versus postmarket data is okay is the product's impact on public health, the FDA says. For example, the agency may agree to accept more postmarket data to hasten approval of devices that address unmet medical needs or if it pertains to uncommon or minor risks. The agency also needs less premarket information to approve devices using technology that's already well understood, the guidance says.

The balance could also tip in favor of more postmarket data if the device addresses an urgent public health need, such as a diagnostic to detect a spreading epidemic, or when the data is intended to confirm mitigation of known risks, the FDA says. Another reason for collecting postmarket data would be to gather information about a patient population beyond that addressed in the premarket study, the agency adds.

The guidance, *Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval*, was issued alongside one explaining the FDA's new Expedited Access Program for devices filling unmet needs. It is expected to help agency staff balance premarket and postmarket information requests for devices on the EAP pathway (*see story, page 1*).

View the guidance document at www.fdanews.com/04-13-15-balancing.pdf. — Elizabeth Orr

Stringent New Device Regulations Take Effect in Czech Republic

Devicemakers doing business in the Czech Republic face a steeper regulatory burden than before, thanks to regulations that took effect April 1.

The law, which was adopted last fall, goes beyond EU regulations to introduce rules applying to every stage of the medical device lifecycle, says Tomáš Čihula, who leads Kinsellar's life sciences and healthcare practice in Prague.

"There is no question that it will take all concerned stakeholders some time before they become comfortable with the challenges of the new legislation" such as more paperwork and

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heavier demands on the State Institute for Drug Control, or SÚKL, Čihula says.

Among other changes, the new law sets out the Czech Republic's first legally binding regulations on clinical trials, including comprehensive provisions on performance evaluations and strict requirements for how evaluations should be conducted and reported.

The law also introduces a new Register of Medical Devices for manufacturers, importers, distributors and companies that service and repair medical devices. Previously, only manufacturers had to register these activities. The agency in charge of registering devices was also changed, from the Ministry of Health to SÚKL.

Higher Fines Imposed

The new law also requires devicemakers, importers and distributors to archive product safety documentation for five years and subject products to regular validation testing.

New sanctions have been introduced as well, including harsher penalties for violations relating to device safety and performance. The maximum penalty for an administrative breach increased from US $38,900 to $77,800.

More changes lie ahead, as clauses on device advertising and pricing were discussed but ultimately left out of the final law, Čihula says. In addition, a National Information System for Medical Devices is set to launch on April 1, 2018, and will provide information on devices to users, patients and healthcare providers.

On the plus side, Čihula says the law ends a confusing situation in which seven different entities shared oversight of devicemakers. Now most oversight will be handled by SÚKL, with the Ministry of Health covering the appeals process.

View the law, in Czech, at www.fdanews.com/04-13-15-czech.pdf. — Elizabeth Orr

U.S. FDA Warns Devicemaker Over Leasing 510(k) Clearances

An otherwise routine U.S. FDA warning letter includes a firm warning against leasing 510(k)s.

The FDA's Florida district office issued the nine-observation warning letter to Craftmatic Industries on Feb. 17. The letter says Craftmatic's staff told investigators that the company was leasing its 510(k) to other companies to manufacture and distribute their own therapeutic adjustable beds.

While a 510(k) may be bought, sold or transferred, multiple companies may not make the same device under the same 510(k), the FDA states emphatically. Instead, a company wishing to license a 510(k) for a device still in production must obtain its own 510(k) clearance. This ensures that devices on the market exactly match the device described in the 510(k), the agency says.

This contrasts with a company selling its products to distributors for marketing under the original 510(k, because only one product is being manufactured, the agency adds.

Issue Rarely Addressed

Attorney Alan Minsk with Arnall Golden Gregory says the issue has come up before, but has rarely been clarified by the FDA.

This is the first time he's seen a policy statement in writing, Minsk says, and while the letter was issued by a district office, he believes it was intended for the entire industry as CDRH typically signs off on district warning letters.

In addition to the 510(k) leasing, the warning letter recounts quality-related violations (*IDDM*, April 7). Craftmatic could not be reached for comment.

View the warning letter at www.fdanews.com/04-13-15-craftmatic.pdf. — Elizabeth Orr

MHRA Tells Hospitals to Report Poor IFUs as Adverse Events

Devicemakers whose instructions for use are flawed or poorly written could see them flagged by the UK's Medicines and Healthcare products Regulatory Agency as adverse events.

Potential difficulties could result from improper placement of instructions, unclear and imprecise language, print size inappropriate for the visually impaired or poorly translated or outdated instructions, the agency says in recently published guidance. Such concerns qualify as adverse events, the agency adds.

The guidance focuses on reusable devices for diagnosis, monitoring, improved function and emergency services. In vitro diagnostic medical devices are not included.

The guidance, which is directed at facilities and providers, stresses that manufacturers are ultimately responsible for how their products are used and will be held accountable for IFUs that don't consider the user's knowledge and training.

The guidance offers examples of situations that may occur with poor IFUs and training. In one instance, the MHRA received reports of incorrectly assembled respiratory therapy devices where an expiratory pathway wasn't provided, ultimately resulting in lung injury.

In another case, after a "cut and push" technique was used to remove an endoscopic gastrostomy tube through the skin, a remnant lodged in the patient's small bowel, resulting in death. The manufacturer's instructions recommended only endoscopic removal of the PEG tube. The agency advised that when endoscopic removal wasn't feasible, appropriate risk assessment and patient follow-up should be done.

Manufacturers should provide all necessary information on storage, pre-use checks,

(See **MHRA**, *Page 5)*

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MHRA, *from Page 4*

maintenance and cleaning of devices, the MHRA says. Special instructions may also be required to cover systems where devices are used with other devices — such as connecting a blood analyzer to a computer for automatic updating of patient data.

Read the guidance at www.fdanews.com/04-09-15-MHRA.pdf. — Charlotte Astor

Medtronic Settles Lawsuit With U.S. Government for $4.4 million

Medtronic will pay $4.4 million to settle a lawsuit accusing the company of illegally selling Asian-made devices to the U.S. military, Minnesota U.S. Attorney Andrew Luger announced.

The suit alleged that the company violated the False Claims Act by relabeling devices made in China and Malaysia as manufactured in Memphis, Tenn., and selling them to the U.S. Veterans Affairs and Defense departments between 2007 and 2014. The devicemaker's spinal division is in Memphis.

Federal law requires that devices sold to the military be manufactured in the U.S. or by specified international trading partners.

The devices at issue include anchoring sleeves that secure cardiac leads to patients, spinal surgery instruments and a handheld patient assistant used with a cardiac device.

The settlement allows Medtronic to resolve the case without admitting guilt. — Charlotte Astor

Malaysian Draft Guidance Outlines Proposed Postmarket Audit Approach

Devicemakers up for routine postmarket surveillance audits in Malaysia will get at least two weeks' notice, the country's Medical Device Authority says.

A draft guidance, released last week, explains postmarket audits Malaysia is putting in place as part of ongoing efforts to implement its 2012 medical device regulations (*IDDM*, March 27). The MDA may audit devicemakers either as part of proactive surveillance or for cause. Specific reasons to initiate an audit include:

- Concerns raised by vigilance issues;
- Changes in legislation;
- Complaints about marketed products;
- Sampling across a specific technology or sector;
- Receipt of information from internal or external sources; or
- Requests from other regulatory authorities.

The list is not exhaustive, but meant as an outline of how postmarket surveillance audits are chosen, the MDA says. Issues that pose a public health concern are grounds for an immediate audit without prior notice, the authority adds.

After the MDA tells a manufacturer that it plans to audit its facilities, the authority will send a letter specifying the agreed-upon date and time and a list of areas the audit will cover. The regulator may also request some information before the audit, such as a brief company profile, a list of manufactured products or a high-level manufacturing flow chart.

Auditors will be looking for two types of noncompliance, major and minor. Major noncompliances are where failure to follow requirements poses a significant risk to public health or individual safety, while minor noncompliances pose a significantly lower risk. Inspections may also result in observations, which are concerns that do not require corrective action, the guidance says. Investigators will discuss observations and processes to fix them with the manufacturer.

On the day of the audit, an investigator will host a brief opening meeting to outline the audit plan and explain potential types of noncompliance. Concerns will be discussed with the manufacturer as they arise during the audit and a close-out meeting will be held to go over the findings. The manufacturer and investigator will set terms for a corrective action plan, if needed.

(See **Malaysia**, *Page 7)*

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Malaysia, *from Page 5*

Following the audit, the MDA will issue a letter to the devicemaker once the corrective action plan generates a satisfactory response. If the authority doesn't receive a satisfactory response, or if the devicemaker has breached the regulations, the MDA may take further enforcement action, the guidance says.

The guidance is still awaiting government sign-off, but should be finalized by the end of the year, says Zamane bin Abdul Rahman, chief executive of the MDA. It will take effect in 2016.

View the guidance at www.fdanews.com/04-13-15-malaysia.pdf. — Elizabeth Orr

Devicemakers Should Prepare Now for eMDR Submissions

Devicemakers should submit new electronic Medical Device Reports several days before the deadline or risk being considered late under U.S. FDA requirements that take effect Aug. 14.

The extra time is necessary because the date of receipt will depend on the FDA telling the firm that the form was successfully loaded into the Center for Devices and Radiological Health's database, says Deborah Kacera, a regulatory and industry strategist with Pilgrim Solutions.

The new system requires three electronic acknowledgements. The first contains the regulatory date that the FDA received the eMDR and lets the sender know if the form was received on time. The second informs the sender that the report passed through the electronic gateway and is on its way to the CDRH server, and the third tells the sender that the file has been accepted.

"If acknowledgement three comes back and says the submission failed, it will tell you what failed," Kacera says. The sender must correct the failure, which may include a format or code issue, and resubmit the eMDR, restarting the process and requiring three new acknowledgements, she adds. Once approved, the file moves to the Manufacturer and User Facility Device Experience, or MAUDE, database.

Kacera, who spoke in a recent FDAnews webinar, also reviewed the steps devicemakers must take before posting an eMDR. The first is to generate an electronic file and send it to the FDA's electronic submission gateway.

Next, companies need to submit a Non-Repudiation Letter affirming that the signer's digital signature is equivalent to a handwritten signature. U.S. agents or consultants sending eMDRs for customers will need an authorization letter in addition to the Non-Repudiation Letter, Kacera says. A digital certificate that defines the sender as the company's submitter must be sent to the FDA as well.

To assist companies, the FDA has free downloadable software that generates an eMDR file, she notes. When the required documents and software are in place, firms must do basic connectivity tests with the ESG. The agency will provide tests so that devicemakers can track submissions through the process to the MAUDE database.

Kacera recommends that during testing, companies create a "mock go-live" and attempt to submit eMDRs. Find it out ahead of time if the eMDR was done properly, she says, "because once you've gone live, you can't go back." — Charlotte Astor

IMDRF Proposed Document Sets QMS Standards for Device Software

The International Medical Device Regulators Forum has issued a proposed document explaining how to use quality management systems to regulate software as a medical device.

According to the document developed by IMDRF's SaMD Working Group, effective QMS should include:

- A governance structure that provides leadership, accountability, and sufficient resources to ensure SaMD safety, effectiveness and performance;
- A scalable set of quality processes that apply across the SaMD lifecycle; and

(See **Software**, *Page 8)*

Software, *from Page 7*

- A set of key lifecycle activities scalable to the type of SaMD and the size of the organization.

The governance structure should include periodic internal audits of the QMS process, the document says. In addition, management should review verification results to ensure the QMS is suitable, adequate and effective, adjusting it as necessary. The managers should also ensure any staffers working on SaMD projects are properly trained. Maintenance of networks and other work-from-home tools may become more important as offices become more virtual, the guidance says.

The group recommends that SaMD manufacturers monitor potential patient risks throughout the software development process. This should include consideration of user-based risks, such as whether the software could be used by elderly patients, as well as device-based risks, such as whether the software could be used safely on a small smartphone screen. Firms should also consider whether the SaMD will be safe if used in a noisy or distracting environment and what cybersecurity risks the software presents.

In terms of control, IMDRF suggests SaMD developers "align document complexity with organizational maturity" — that is, a small company may not need recordkeeping procedures that are as elaborate as those used by a larger company.

The working group suggests manufacturers design their QMS policy to comply with international standards ISO 13485:2003 on medical devices and ISO 12207:2008 on software development.

View the proposed document at www.fdanews.com/04-13-15-software.pdf. — Elizabeth Orr

Swiss Bring Device Regs in Line With EU Focus on Patient Safety

Switzerland is changing its medical device act, effective April 15, to bring it in line with EU regulations.

No change is expected for companies involved in the Swiss market as Swissmedic has already been voluntarily applying the EU rules, spokesman Peter Balzli says.

By renegotiating its mutual recognition agreement with the EU, Switzerland aims to cooperate more in market surveillance, says Erik Vollebregt, with Axon law firm in the Netherlands. The move is not surprising and creates a means for the country to keep up reforms under the European Commission's joint action plan (*IDDM*, April 3).

The plan calls for increased surveillance of devices, and Swissmedic had identified notified bodies that issued CE-certificates outside their scope, Balzli says. As a result, two of five notified bodies in Switzerland have stopped issuing CE certificates for medical devices and a third will stop in a few months, leaving just two notified bodies in Switzerland, he says.
— Jonathon Shacat

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This conference has been pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification.

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DAY ONE | MAY 13

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. - 9:45 a.m.

Pre-approval Communications

- How to meet your SEC requirements for disclosing information while not running afoul of FDA pre-approval promotion prohibitions

9:45 a.m. - 10:30 a.m.

Disease Awareness Communications

- A review of FDA's help-seeking guidance
- Keys for using disease awareness communications prior to approval. Essential information for continuing communications efforts post-approval compliantly.

10:30 a.m. - 10:45 a.m.

Break

10:45 a.m. - 11:15 a.m.

From Day of Approval through Commercial Launch

- Understanding the timeline and key dates for communications
- Minimizing the pain, while maximizing the impact of initial promotional communications

11:15 a.m. 12:00 p.m.

Essential Advertising & Promotion Regulations

- A review of all of the requirements for product promotion, including product name usage, fair balance, directions for use

12:00 p.m. – 1:00 p.m.

Lunch

1:00 p.m. - 1:45 p.m.

Format-Specific Promotional Requirements

- DTC television promotion
- Brief summary requirements for print promotion

1:45 p.m. - 2:30 p.m.

Substantial Evidence & Other Standards

- A review of the substantial evidence standard, what fails to meet that standard, and when other standards apply

2:30 p.m. - 2:45 p.m.

Break

2:45 p.m. – 4:00 p.m.

Off-Label Information

- Avoiding off-label promotion
- Scientific exchange exemption
- Responding to unsolicited requests
- Distributing off-label reprints

4:00 p.m. - 4:30 p.m.

The Promotional Review Process

- An overview of a the standard promotional review process
- Essential traits for any effective process
- Key decisions in establishing or improving performance
- Effective use of metrics for evaluating performance

4:30 p.m.

Session Wrap-Up, End of Day One

DAY TWO | MAY 14

8:30 a.m. – 9:00 a.m.

Continental Breakfast

9:00 a.m. - 9:45 a.m.

Integrating Digital Promotion

- Key considerations for evaluating the compliance of digital promotional tactics and their integration into the overall promotional mix

9:45 a.m. - 10:15 a.m.

Social Media Part 1

- Overview of the platforms, issues, and a review of the status of FDA guidance

10:15 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:30 p.m.

Social Media Guidances

- A review of the three social media guidances released in 2014: 2253 Filing, Presenting Risk Information in Space-Limited Contexts, & Correcting Misinformation on Third-party Sites

12:30 p.m. - 1:30 p.m.

Lunch

1:30 p.m. - 3:15 p.m.

Promotional Review Board Practicum

- Workshop participants will apply the lessons from the earlier part of the workshop to specific product promotions. They will work in teams to evaluate specific promotional tactics, determine what (if any) parts of the promotion are problematic, and how to provide direction to a brand marketer to make the promotions compliant.

3:15 p.m. - 3:30 p.m.

Break

3:30 p.m. - 4:15 p.m.

Continuing Regulatory Intelligence: Staying Abreast of Ad/Promo News

- Ad/Promo is an area of ongoing developments. This session will cover the most prominent sources for keeping up with these developments.

4:15 p.m. - 4:30 p.m.

Wrap-up and Adjourn Workshop

"Dale was very engaging and informative. I like the interactive portion where we reviewed actual ads."

— 2014 Workshop Attendee

WHO WILL BENEFIT?

- Advertising and marketing managers
- Social media teams
- Promotion review committee members
- Medical affairs
- Continuing education and tradeshow organizers
- Regulatory compliance officers
- PRC coordinators
- Legal counsel
- Compliance
- Executive management
- Outside ad agencies and marketing consultants

"[Dale is] an animated speaker who seems to know something about everything and has no shortage of opinions. This is potentially very dry and dull material. Dale brings out the exciting and humorous aspects especially well. It's an engaging two days."

— Michael Benedetto, Editorial Group Leader, FCB Health

"This is normally a dry topic, but with Dale it was anything but dry. Dale gave one of the best, most engaging presentations. Dale is highly knowledgeable and also very entertaining."

— Ellen Derrico, Global Head, Market Development - Life Sciences & Healthcare, QlikTech

"As a fellow regulatory professional, Dale is one of the most deeply knowledgeable experts I've heard on this complicated subject. As the pharmaceutical industry is experiencing, digital promotional tactics can trip up even experienced regulatory professionals, but Dale showed how basic principles can be applied to develop compliant promotional materials."

— Kathleen Koons, Sr Regulatory Affairs Manager, DJA Global Pharmaceuticals Inc.

Course Binder Materials:

Full slides from the PowerPoint presentations

Reference documents:

FDA Advertising & Procedural Guidances

- Help-Seeking Guidance
- DTC Broadcast Guidance & Q&A
- FDAAA Pre-Dissemination Review Requirements
- Product Name Guidance (All three versions from 1999, 2012, and 2013)
- Presenting Risk Information Guidance
- Social Media Guidances
  - Postmarketing Submissions Requirements
  - Responding to Unsolicited Requests for Off-label Information
  - Presenting Risk Information in Space-limited Contexts Correcting Third-party Misinformation
- Distributing Off-Label Reprints

Relevant Sections of Code of Federal Regulations

Form 2253

PhRMA Principles on DTC Advertising

PhRMA Principles on Interactions with Healthcare Professionals

Pre-approval Promotion Checklist

Effective Review & Approval Process Checklist

Keys to Evaluating Promotional Review Systems List of Key Resources for Continuing Education

Articles by Dale Cooke

- Developing Compliant Search Engine Marketing Campaigns (Publication Date of September 2014)!
- Industry Standards for Linking Disease Awareness Websites to Product Promotion!
- Patient Testimonial Videos: FDA Actions on Risk Information Presentation!
- Presenting Risk Information on Websites!
- Where Things Stand on FDA Guidance on Social Media (Publication Date of September 2014)

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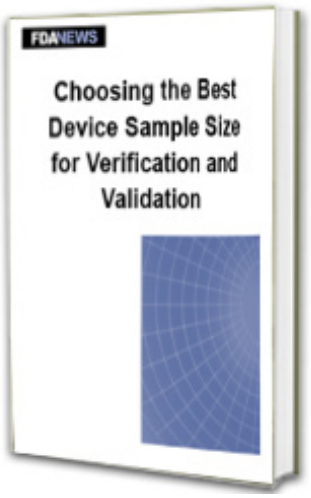

Choosing the Best Device Sample Size for Verification and Validation

If you're like many manufacturers, you understand the essence of the *21 CFR 820.30* requirement: you must run enough test samples of a product so its test results can be successfully applied to full-scale production runs. And, like many manufacturers, you've probably had trouble for years determining exactly how many units of a product you should test to satisfy the FDA.

Choosing the Best Device Sample Size for Verification and Validation will help you select the right statistical methods to make this determination. With it, you'll learn how to get the right sample size to ensure that user requirements are met in the product design. This management report will also help you understand how to:

- Examine the discrete or continuous statistical data you collect.
- Look at variability, including variation from unit to unit or from batch to batch, as well as variation in their measurement systems.
- Design verification and validation tests, particularly regarding choice of sample size.
- Fully understand the requirements for statistical techniques, including how different techniques can affect the design control process.
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Finally, you can gain a clearer understanding of how to put together a statistical methods program for design verification and validation that will satisfy FDA auditors.

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