The Future of Clinical Trials?

Ask patients and site staff

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Pioneering for patients

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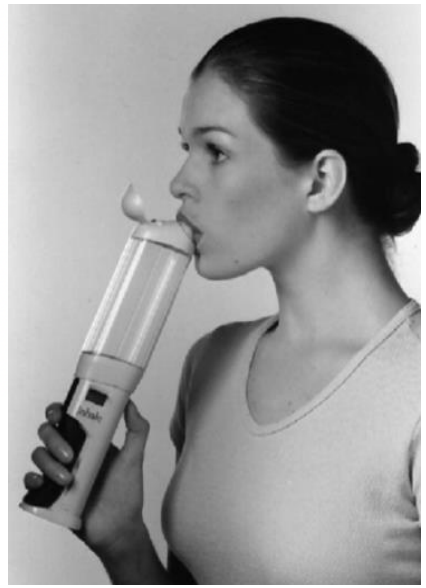
THE WALL STREET JOURNAL.

Pfizer Receives FDA Approval For Inhaled-Insulin Treatment

By Peter Loftus Dow Jones Newswires
Jan. 28, 2006 11:59 pm ET

The U.S. Food and Drug Administration approved Pfizer Inc.'s inhaled-insulin treatment for diabetics, Exubera.



Systematic patient and site engagement:
The norm before, during, and after clinical trials?

The site staff is the expert

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Patients are already the expert

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Regulators are recommending | UK

In which aspects of the research process have you actively involved (or will you involve) patients service users and/or their carers or members of the public?

Definitions:

- *Design: e.g. identifying and prioritising research topics, being involved in commissioning research, helping to design participant-facing information, or advising on the feasibility and acceptability of the research.*
- *Management: e.g. being members of project advisory, steering or monitoring groups during the time when the project is taking place.*
- *Undertaking: e.g. being co-researchers recruiting research participants, administering questionnaires, running or co-running focus groups or peer interviews, or conducting library-based research. Note: including people as research participants is not the same thing as involvement.*
- *Analysis: e.g. helping to identify and interpret themes in data and their relevance to the people living with the health condition or social care situation.*
- *Dissemination: e.g. helping to produce plain English progress reports, newsletters, or a summary of results, advising on how to share those results with participants, patients, relevant communities, and the general public, presenting at conferences or co-authoring journal articles.*

Give details of involvement, or if none please justify the absence of involvement.

For example, has the sponsor sought advice from any patient groups on the protocol design or the content of any patient facing materials?

We are under immense scrutiny on this topic – any level of involvement can improve the REC outcome.

☐Design of the research

☐Management of the research

☐Undertaking the research

☐Analysis of results

☐Dissemination of findings

☒None of the above

IRAS
INTEGRATED RESEARCH APPLICATION SYSTEM

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Regulators are recommending | US

FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making

Regulators are recommending | EU

Input towards revision of 'ICH E6 Good clinical practice guideline'

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical Trials Transformation Initiative (CTTI): ICH E6 Guideline for good clinical practice – Update on progress EMA is helping ICH to ensure that the perspectives of European **patients**, **healthcare professionals** and **clinical researchers** are taken into account in the ongoing revision of its International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E6 good clinical practice (GCP) guideline, by coordinating the stakeholder engagement process in Europe on the behalf of ICH.

The Economist INTELLIGENCE UNIT

Drugs developed using patient-centric designs were **more likely to be launched** compared to drugs developed without

Patient-centric trials took **less time to recruit** 100 participants (4 months), compared to the other innovation types (6-11 months) and all trials (7 months)

Engagement takes time, money, and resources. But it's worth it.

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Do we need operational innovation in clinical trials?

- Increased digitization?
- More home visits?
- Home medication delivery?
- eConsent?

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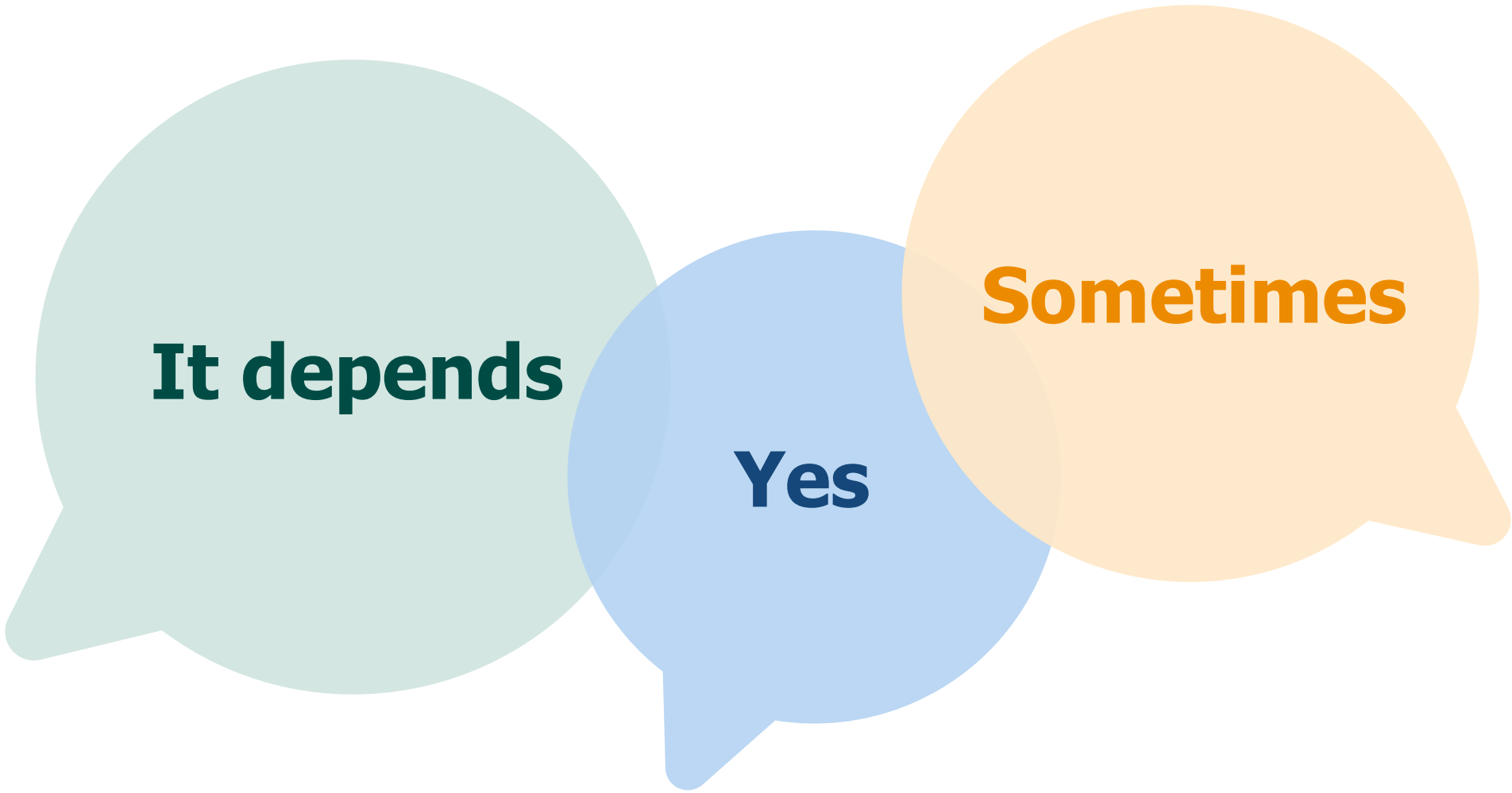
It depends
Yes
Sometimes

What do **patients** need?

What do **site staff** need?

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1. Ask the patients and site staff

Systematically

Early

Implement recommendations

2. Prepare for innovation

Tools tested by patients and site staff

Implement when needed by patients and/or site staff

3. Create simple and clear information

Follow Health Literacy principles

Co-create documents with patients

Test materials with patients

Whatever you do for me but without me, you do against me.

Mahatma Gandhi, 1869-1948

Let’s connect!

Heidi Müller

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