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Siemens Healthcare Diagnostics

MDR Reporting – Challenges for the IVD Industry

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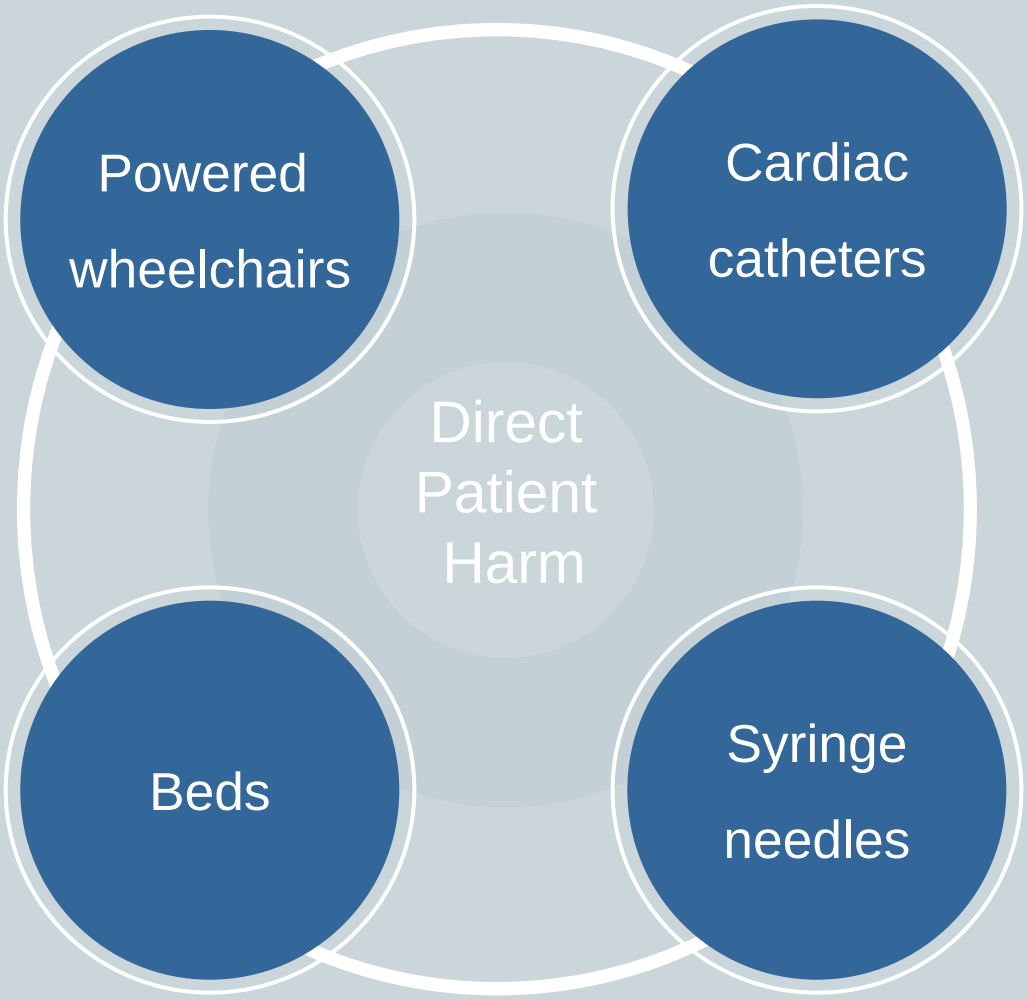
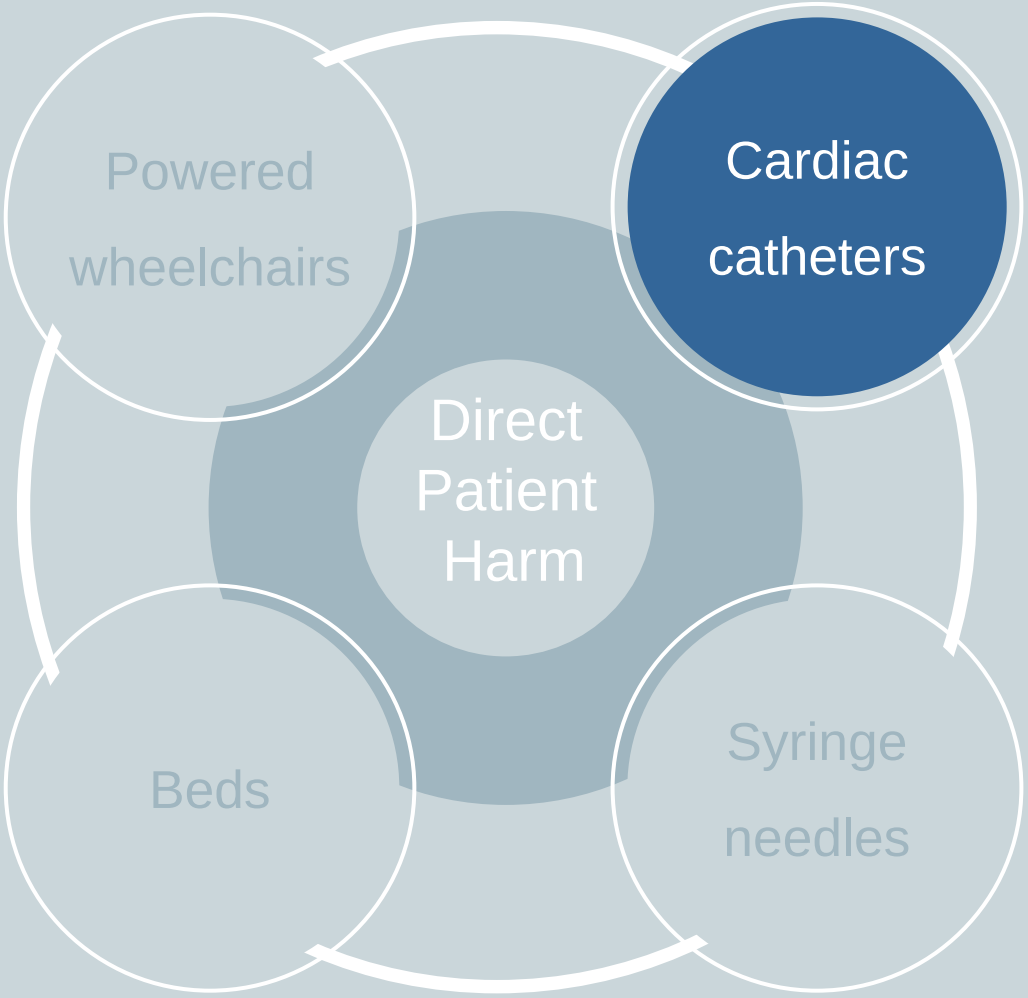
Quality Engineer

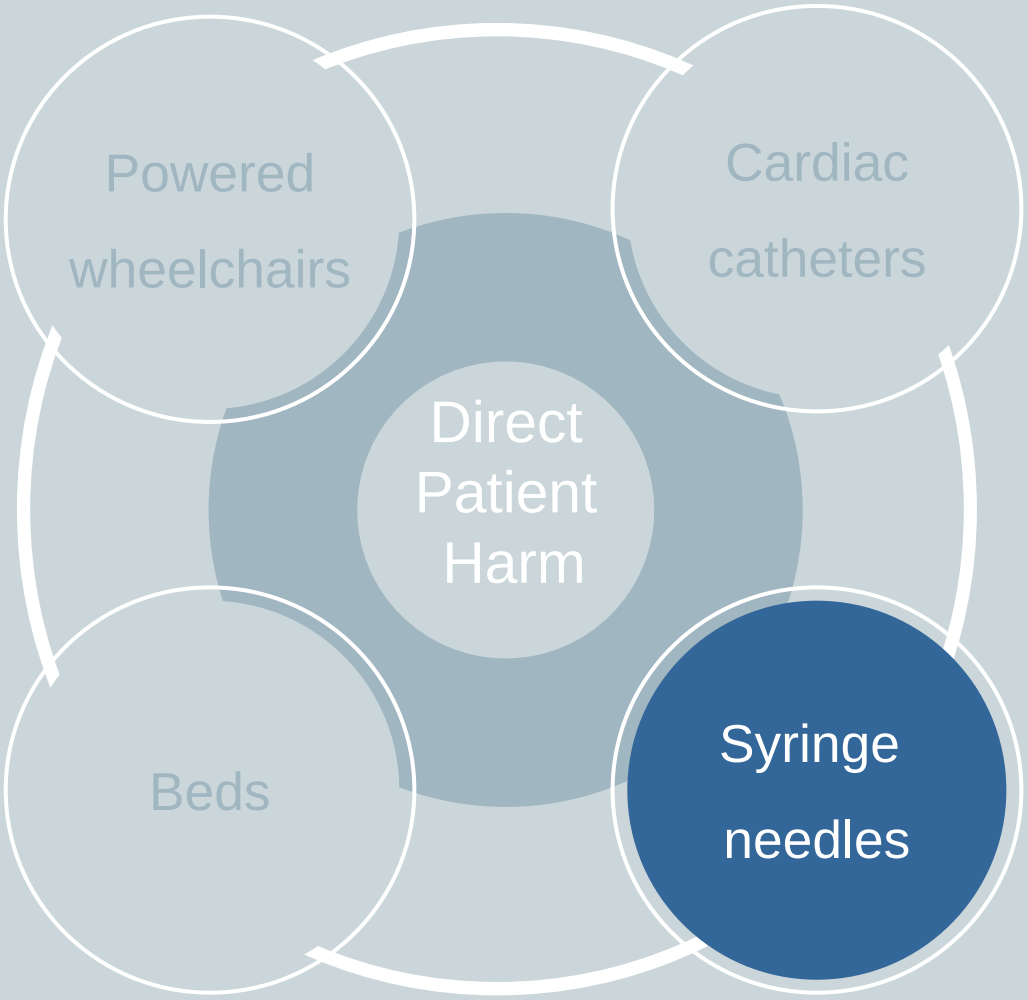
Adverse events in Medical Devices



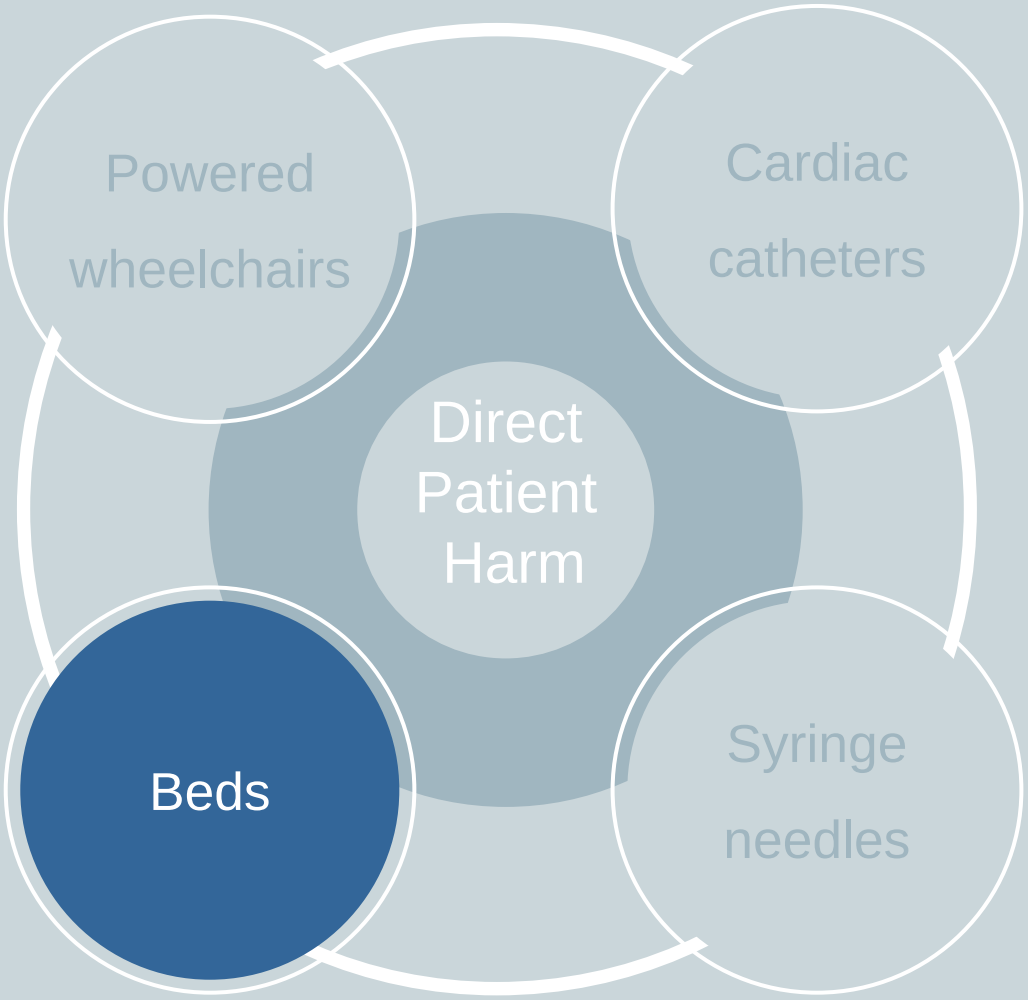
Adverse events in Medical Devices



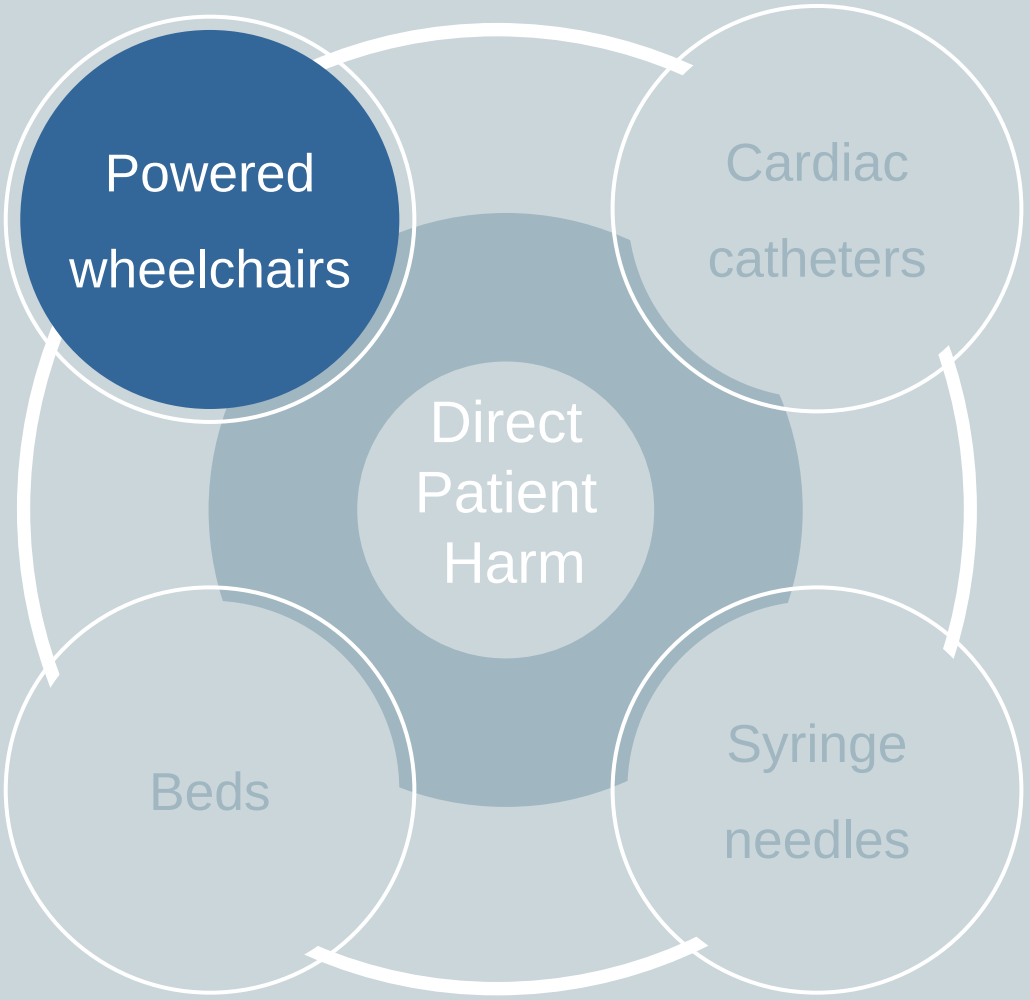
Adverse events in Medical Devices



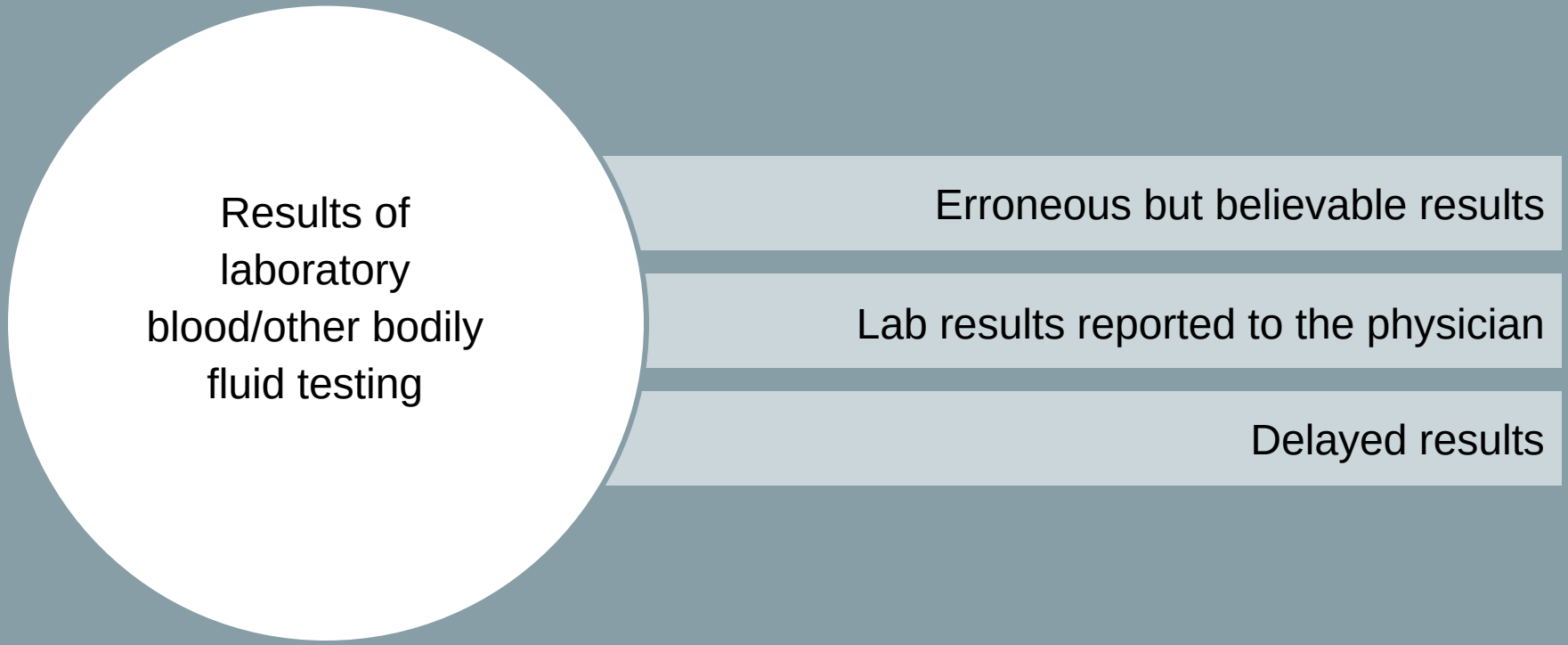
Adverse events in Medical Devices



Adverse events in Medical Devices



Differences in the IVD Industry



Adverse events in the IVD Industry

Adverse events	Examples
•Issues that **would be likely <u>to cause or contribute</u>** to a death or serious injury if the malfunction were to recur. • Erroneous but believable results • Change to treatment or medication • Need for clinical significance of erroneous result	•Low glucose – treatment not harmful – candy, OJ • High glucose – insulin • False positive HCG – mental anguish, delayed x-ray, delayed surgery or treatment • False negative HCG – missed ectopic pregnancy • Incorrect TDM results – changes in medication dosages

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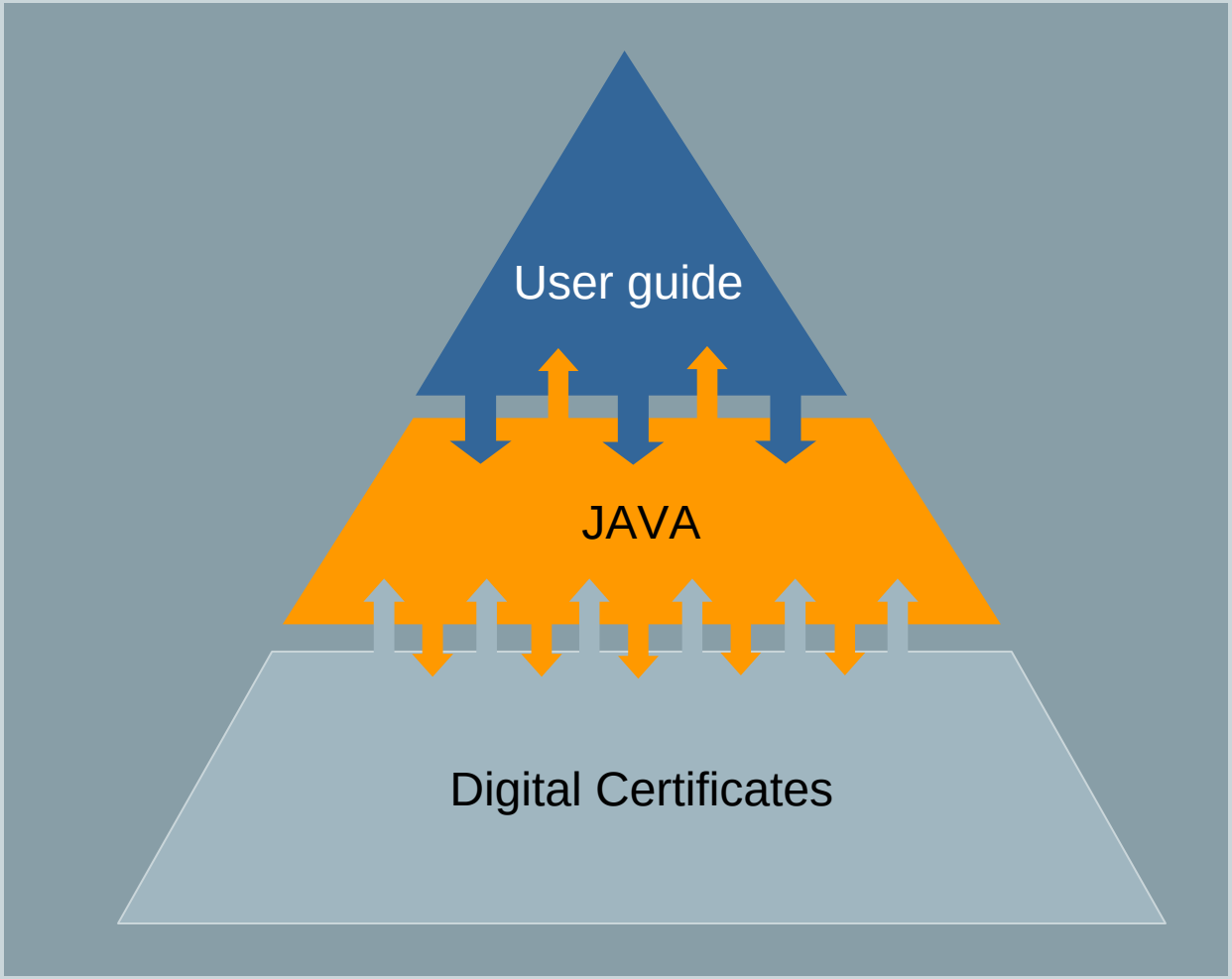
Clinical Significances – Erroneous but believable results

Assay/group	*MDR*	*Potential Clinical Impact*	*No MDR*
Bilirubin Critical Value: Newborn Lower – N/A Upper - >15mg/dL Ref Value 0-3 months: >15mg/dL 4-6 months: >20 mg/dL	Falsely low, potential under treatment for infant	Missed diagnosis and treatment of neonate	Falsely high > 3mg/dL, greater likelihood for overtreatment in infants – low risk Falsely low or high for adults
BUN	Falsely low	Missed or underestimated kidney diseases, fail to identify ineffective dialysis	Falsely high – causes further investigation
Ca (Use IFU range)	Falsely high or low …..if difference between discrepant and true value is >2mg/dL or 0.5 mmol but <4mg/dL	Incorrect or missed diagnosis/intervention in response to electrolyte imbalance and/or hypo-hyper conditions	If it is Falsely high, greater likelihood to cause investigation

Causes of erroneous but believable results

Electronic MDR filing – Getting started



User guide – getting started

Weblink: http://www.accessdata.fda.gov/esg/userguide/

JAVA - Challenges

Weblink: http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm

Digital Certificates

Weblink: http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital_Certificates.htm

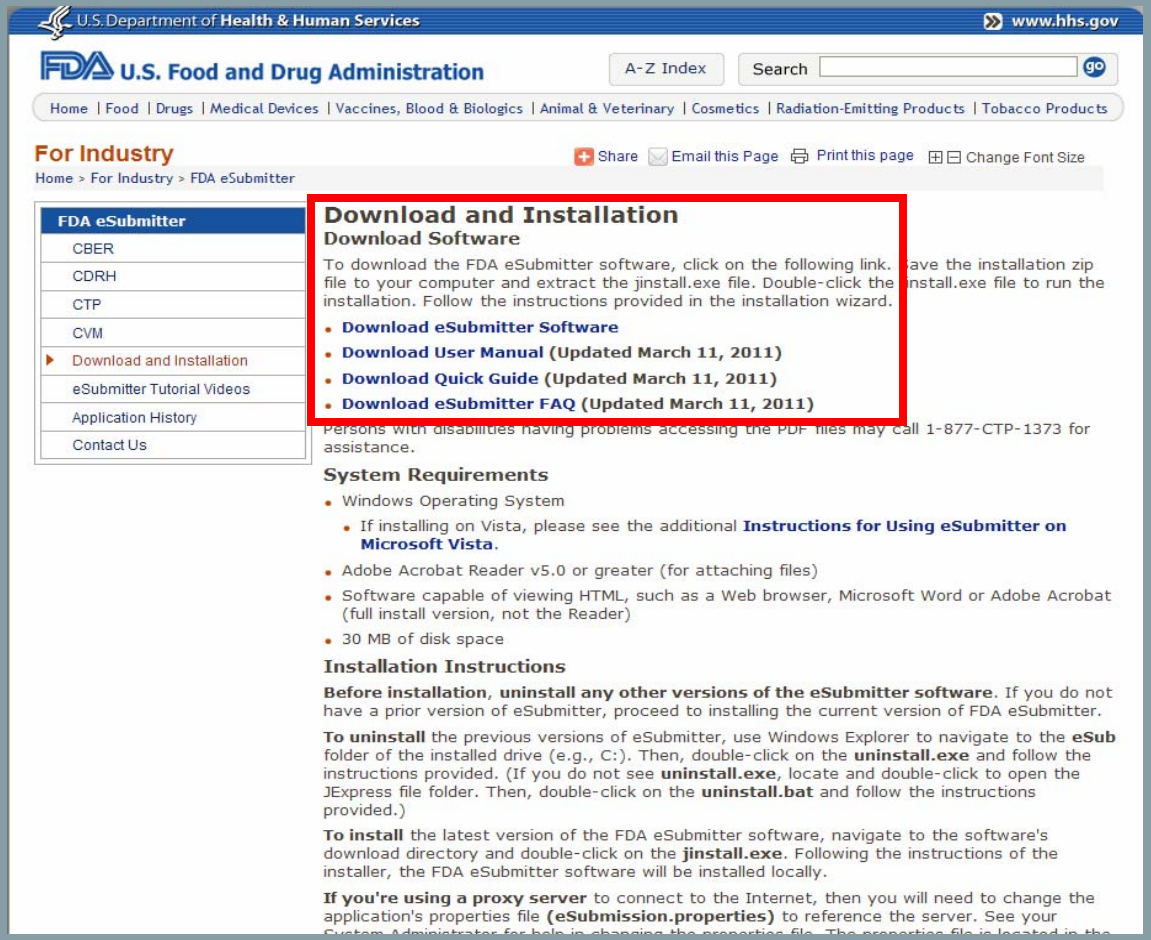
Electronic MDR filing – Getting started

eSubmitter

- Select “download Application

Weblink: http://www.fda.gov/ForIndustry/FDAesubmitter/ucm108165.htm

Electronic MDR filing – Getting started



eSubmitter

- Select “Download eSubmitter Software”
- Request a test account
- Request a production account

Thank you!