To advance slides, press Enter, Down Arrow, or use the Scroll button on the mouse.

What is an Adverse Drug Reaction?

Presented by: Diane Turschak, Pharm.D. Candidate 2014

Goals and Objectives

- Define what constitutes an adverse drug reaction (ADR)
- Determine the difference between an allergic and non-allergic ADR
- Provide examples of an allergic and non-allergic ADR
- Demonstrate understanding of internal and external ADR reporting
- Identify ways in which ADRs can be prevented

****ASHP (American Society of Health System Pharmacists) defines a significant ADR as any unexpected, unintended, undesired, or excessive response to a drug that……..**

- Requires discontinuing the drug
- Requires changing the drug therapy
- Requires modifying the dose
- Necessitates admission to a hospital
- Prolongs stay in a health care facility
- Necessitates supportive treatment
- Significantly complicates diagnosis
- Negatively affects prognosis
- Results in temporary or permanent harm, disability, or death

Two Types of Adverse Drug Reactions

- Allergic Drug Reactions
  - A drug hypersensitivity due to an immunologic response between the pharmacologic agent and the human immune system
  - Makes up 5-10% of ADRs
  - Most common with penicillins, sulfa, and local anesthetics
  - Repeatable, therefore, the offending drug should be avoided
- Non-Allergic Drug Reaction (idiosyncratic reaction)
  - Does not involve the immune system
  - Makes up 90-95% of ADRs

Signs and Symptoms Of An Allergic Reaction

- Urticaria (hives)
- Skin Rash (blisters, vesicles, raised lesions)
- Itching of skin or eyes
- Wheezing
- Swelling of lips, tongue, or face
- Nausea and Vomiting
- Anaphylaxis
  - Trouble Breathing
  - Fainting
  - Confusion
  - Rapid Pulse
  - Decreased Blood Pressure

Non-Allergic ADRs

- All medications have a therapeutic window, which means that receiving too little of a medication is not effective and too much may cause toxicity
- Factors that help contribute to these ADRs:
  - Age
  - Gender
  - Body Size
  - Specific Body Chemistry
  - Combination Of Drugs, especially if on 4 or more drugs concurrently
  - Pre-existing Conditions such as Asthma, HIV, Renal and Liver Dysfunction

Examples of Non-Allergic ADRs

- Sedatives
  - Over-sedation
- Opioids
  - Constipation
- Anticoagulants
  - Bleeding
- Insulin and some oral hypoglycemic agents
  - Hypoglycemia
- NSAIDs
  - GI bleeding
- Corticosteroids
  - Hyperglycemia
- Antihistamines
  - Dry mouth, drowsiness
- Antibiotics
  - Diarrhea
- ACE inhibitor
  - Cough
- Drug-drug, drug-food, drug-herbal interactions
  - Alcohol may interact with other drugs, such as sedatives to cause over-sedation
  - Grapefruit juice and St. John's Wort interactions may result in decreased effectiveness of some medications

Why is it so important to learn about ADRs?

Important Points to Remember

- ADRs can occur in any patient and at any time
- The risk of ADRs may be increased by a patient's age, genetics, concurrent medications, and comorbid conditions
- ADRs may be involved with many commonly used medications, such as antibiotics, sedatives, NSAIDs, etc.
- There are other signs and symptoms of an ADR besides a rash, hives, or anaphylaxis

Important Points to Remember (Cont.)

- The population at the highest risk for ADRs are the elderly
  - 40% of individuals who are 65 years and older take ***FIVE*** or more medications!
- A recent one year study of Medicare outpatients revealed that out of the 1,523 identified ADRs, 421 were preventable

EXAMPLES?

External ADR Reporting

- Most new drugs are approved with an average of 1,500 patient exposures and the chance of some ADRs occurring is only one in 20,000 patient exposures
- Involves the teamwork of pharmacists, physicians, radiographers, nurses, and patients to report suspected ADRs

External ADR Reporting (Cont.)

- MedWatch is the U.S. Food and Drug Administration's adverse event reporting program for defective drugs and medical devices
- It was created to serve the public in ensuring safety of all marketed medical products
- It is important to report any unusual ADRs or ADRs involving newly marketed medications
  - ADRs should be reported to Pharmacy, who will then notify the FDA through MedWatch if the ADR is significant

Example One

- A recall has occurred for Duragesic 25 mcg/hr patches due to a manufacturer error. Some patches have a cut open edge, exposing patients or caregivers directly to fentanyl gel, which may lead to serious adverse reactions such as respiratory depression and possible overdose that could be fatal. *ADR reporting once again aided in making this problem known!*

Example Two

- Valproic Acid is an anticonvulsant utilized for controlling seizures. The antibiotic Doribax (doripenem) interacts with it when used concurrently.
  - This may lead to reduced levels of valproic acid in the bloodstream, which can result in loss of seizure control
- Valproic Acid also has a black box warning concerning hepatotoxicity, which is a potential adverse effect

More Examples

- Liver disease due to excessive dosages of acetaminophen
- 41,000 hospitalizations a year due to NSAID induced ulcers
- Drug Induced Parkinson's from drugs such as antipsychotics and anticonvulsants
- 32,000 hip fractures per year leading to 1,500 deaths due to drugs that cause severe dizziness, lightheadedness, or drowsiness in the elderly

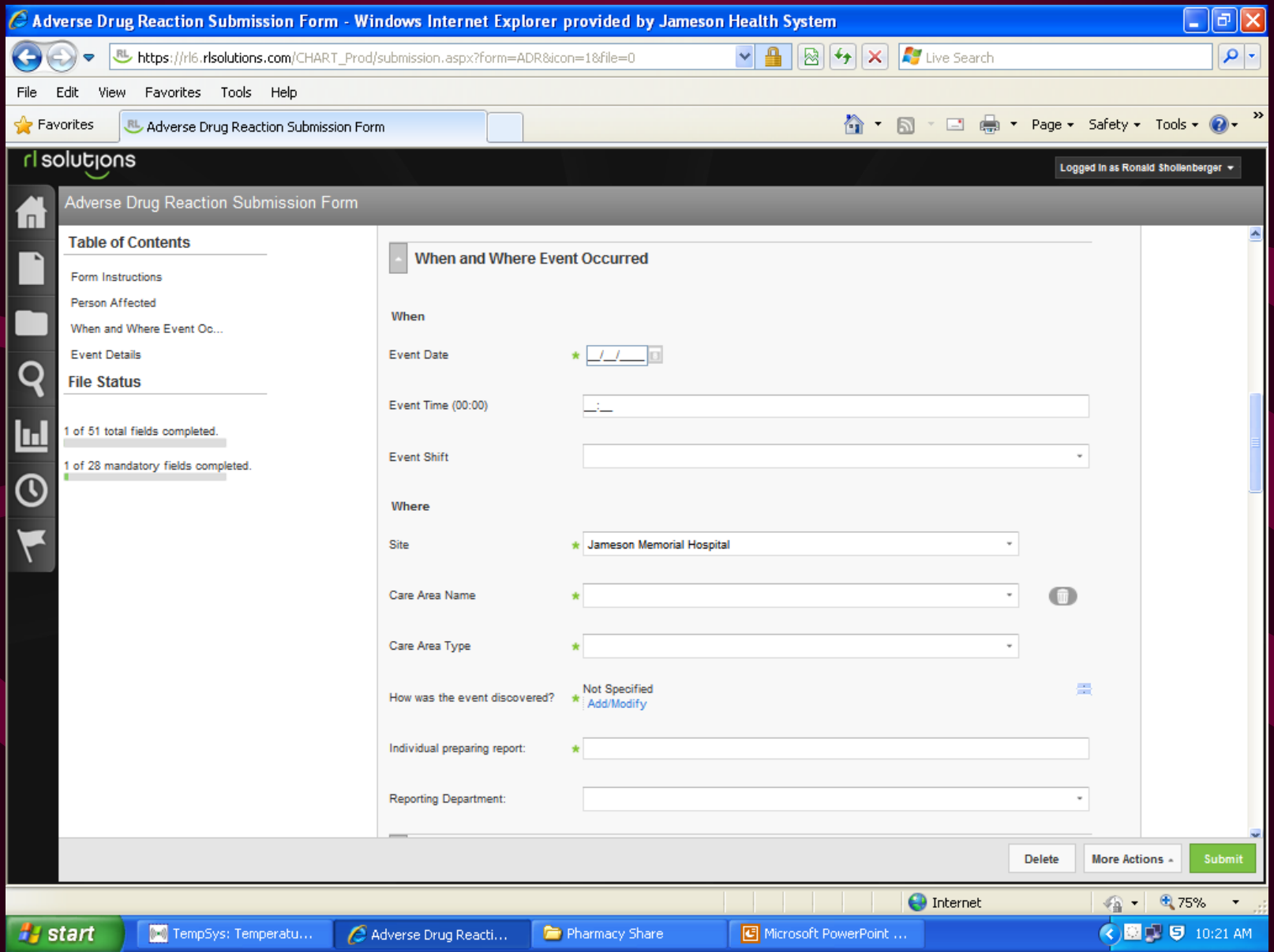
Internal ADR Reporting

- Completion of an adverse drug reaction report should be completed whenever an ADR is suspected by going to the
  - Jameson Portal Page
  - CHART
  - Adverse Drug Reaction
- You do not need to wait for the physician or pharmacy to sign off on a suspected ADR before reporting
- There are 28 mandatory fields that must be completed, which are indicated by a green asterisk

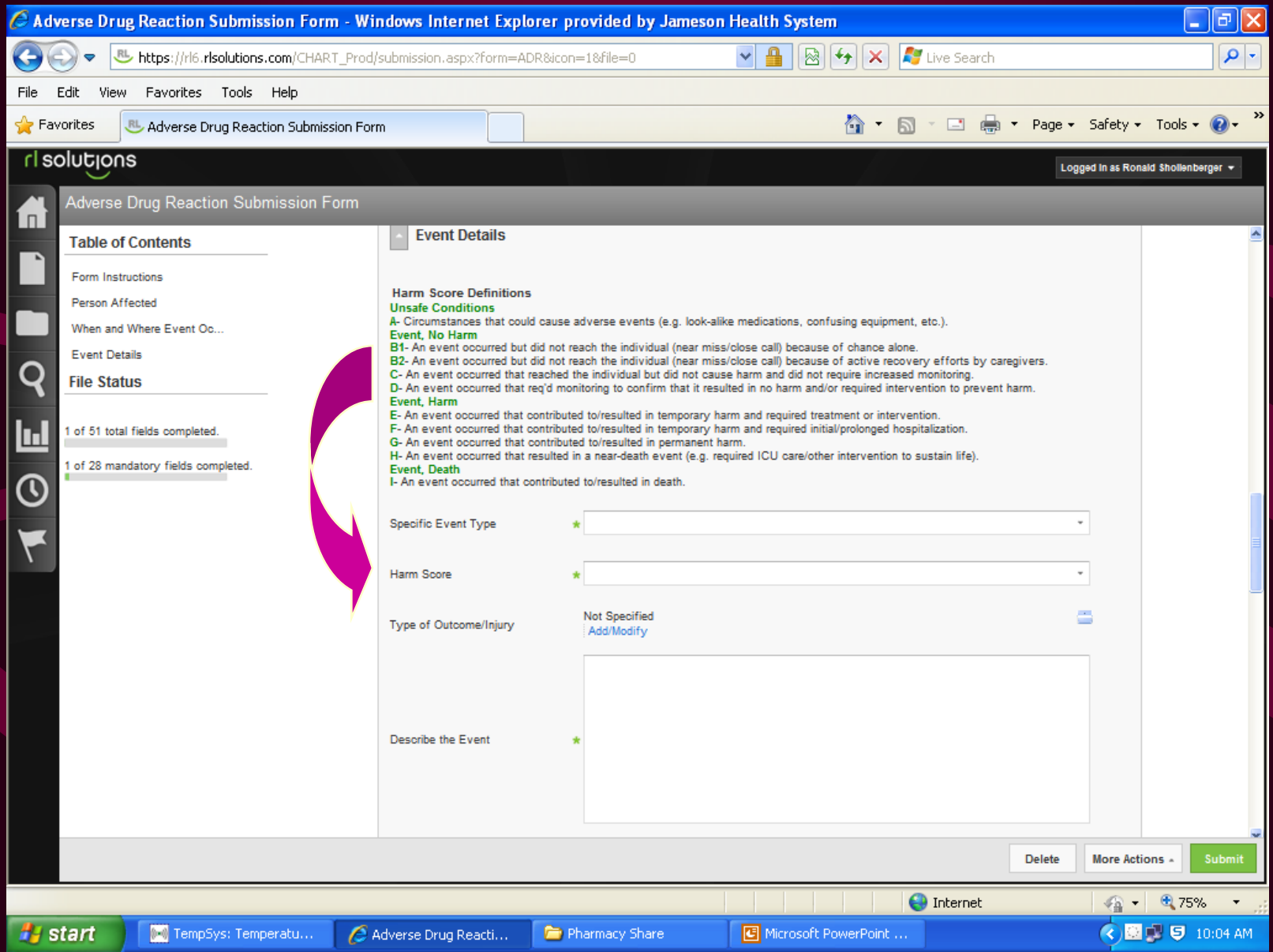
CHART – Main Screen

New File tab

When and Where Event Occurred



Event Details



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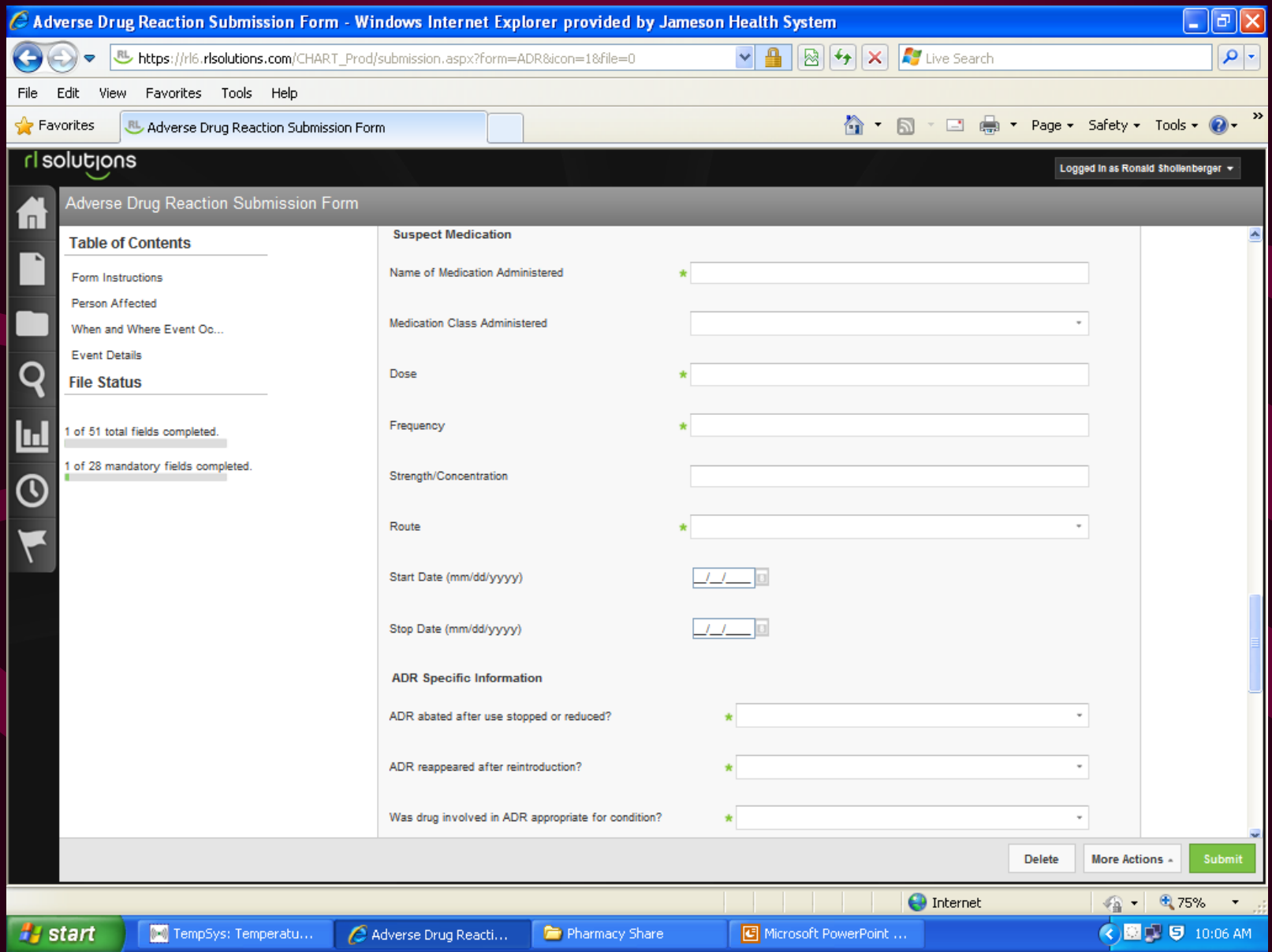

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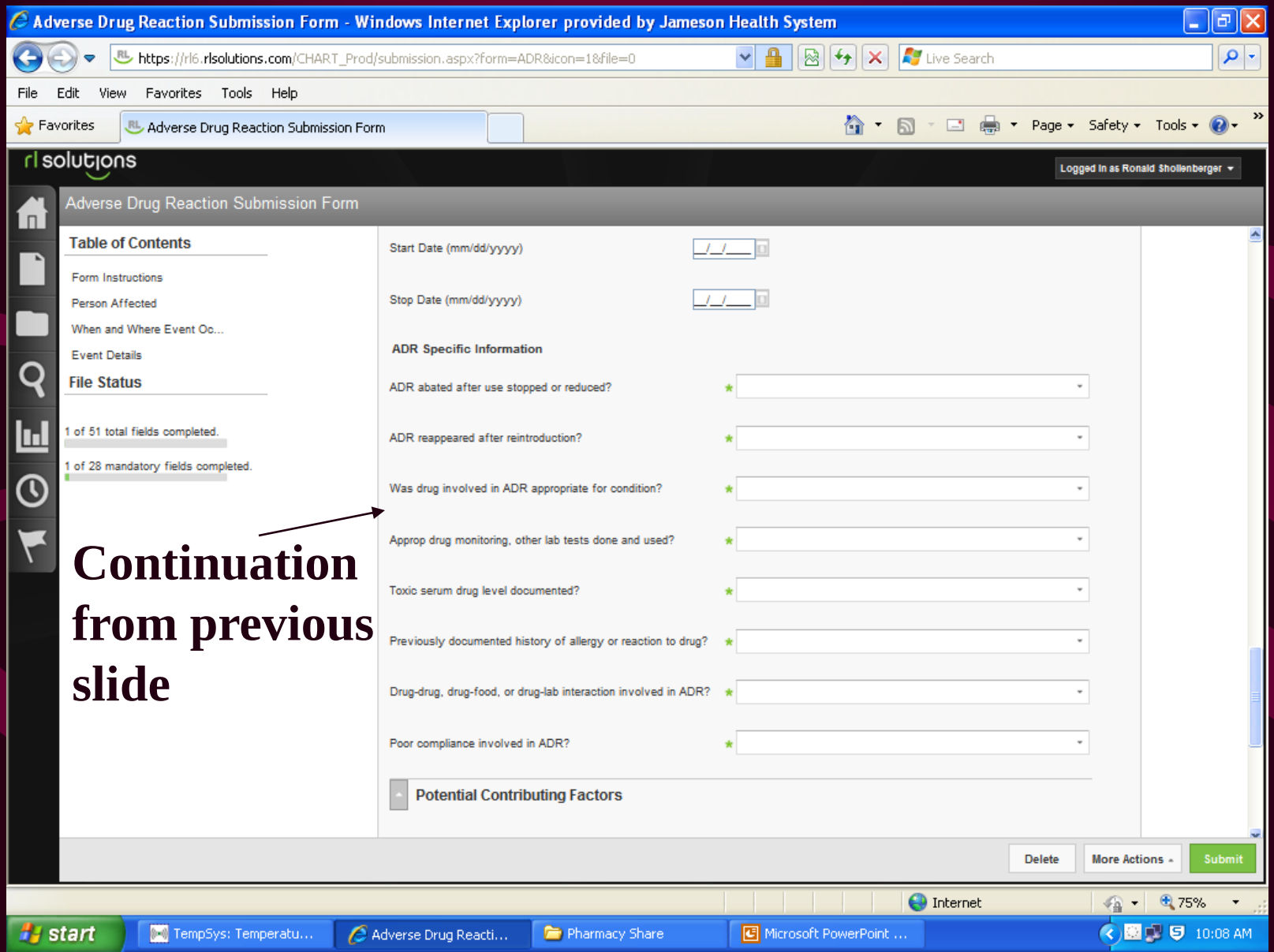
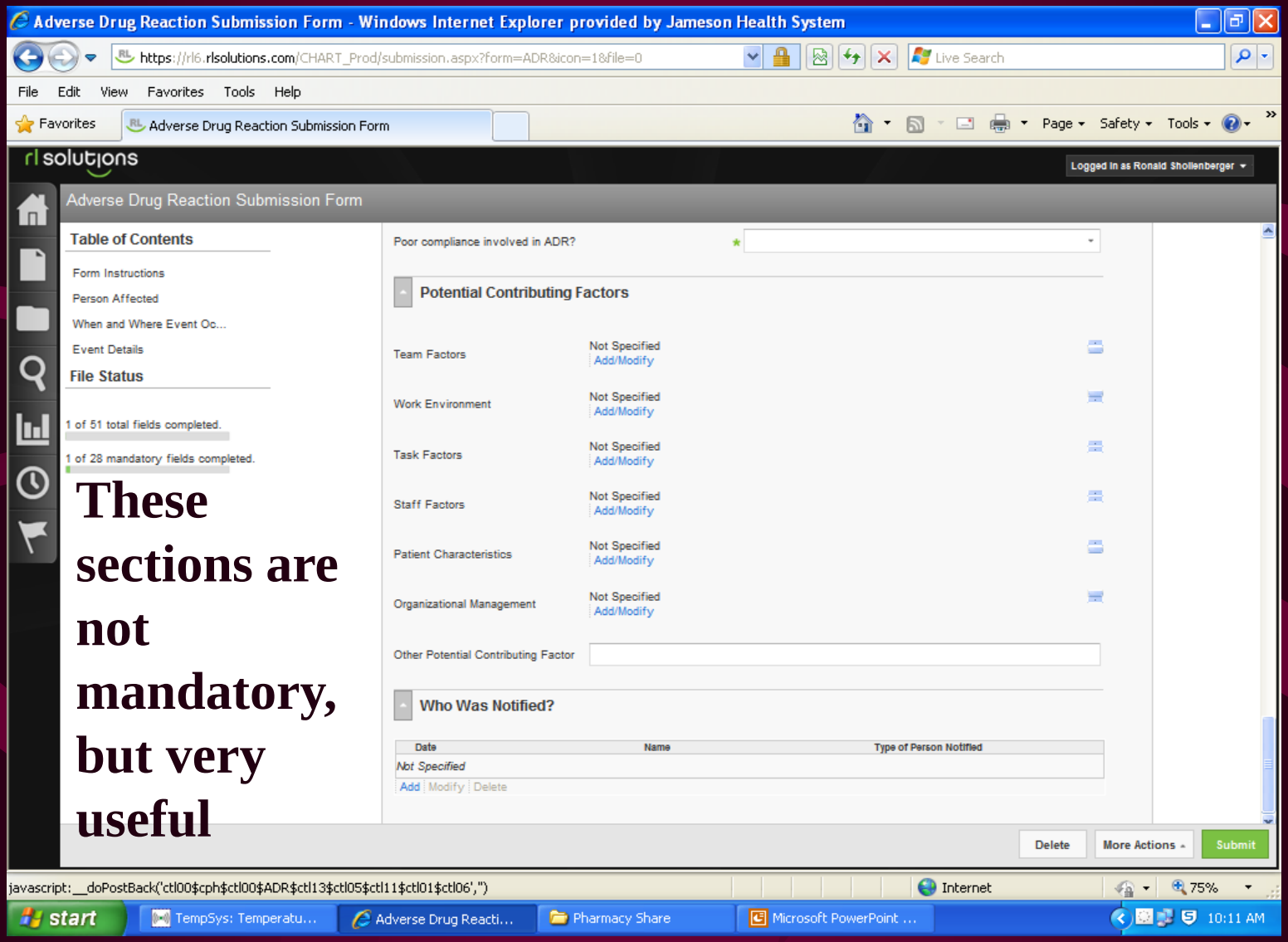


Potential Contributing Factors and Notification



How Can ADRs Be Prevented?

- Obtain A Medication History including
  - Past allergies or ADRs
  - Current medications (Rx, OTC, vitamins, herbals)
  - Recently discontinued medications (if ADR suspected)
  - Disease states
  - **MAKE EVERY ATTEMPT TO OBTAIN AS DETAILED A HISTORY AS YOU CAN!!**

How Can ADRs Be Prevented?

- Be aware of high risk patients
  - Multiple medications (2 or more)
  - Age ≥ 65 years old
  - Existing drug allergies
  - Patients taking certain medications (anticonvulsants, antibiotics, digoxin, warfarin, and amiodarone)
- Consult a pocket reference to verify unusual dosages
- Consult with pharmacists/drug info specialists
- Review appropriate IV push and infusion rates
- Check available and up-to-date computer programs
  - Micromedex
  - DynaMed

Notification to patient regarding new allergy identified during patient stay/visit to hospital.

Inpatient

- Section added under “other” on electronic discharge instructions
  - New Drug Allergy
    - During you hospital stay, your physician has determined that you may have experienced an allergic reaction to _____. Be sure to tell doctors, dentists and other caregivers about your allergies. Record this allergy information and carry it on your person or wear a medical alert bracelet that lists allergies.
    - **See screen shot next slide**

Other Instructions:
Cool mist humidifier(vaporizer) to increase air moisture

Education Forms Given To Patien
Disease Management Awareness
Pneumococcal Vaccine Teaching Sheet
Influenza Vaccine Teaching Sheet

New Drug Allergy
lasix

New Drug Allergy Explanation
During your hospital stay your physician has determined that you may have experienced an allergic reaction to lasix.
Be sure to tell doctors, dentists and other caregivers about your allergies. Record this allergy information and carry it on your person or wear a medical alert bracelet that lists allergies.

Instructions Status INPROGRS
Discharge Medication List

Adult Low Dose Aspirin (Aspirin) [81 mg tablet,delayed release (DR/EC)]: By Mouth
LAST DOSE GIVEN DATE:_____ TIME:_____

Stop taking the following Medication

No Medications qualify for this section.

Dicharge Instructions/Orders were overseen by: ABRAHAM, WILLIAM

Emergency Department

- Information provided to patient via Med Host printed discharge instructions.

Summary

- Non-allergic ADRs make up the majority of ADRs
- There are more signs and symptoms of an ADR besides a rash, hives, or anaphylaxis
- ADRs may occur with many commonly used medications, such as antibiotics, sedatives, and NSAIDs
- ADRs may be reported externally through MedWatch and internally through CHART
- ADRs may be prevented by obtaining a complete medical history as well as consulting with references or other health care professionals for verification

References

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Questions?

When done, close this window to take the test.