

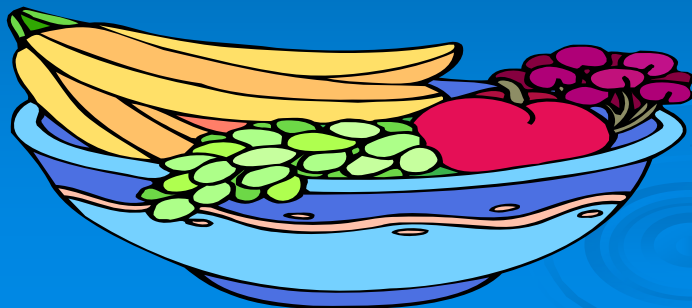
IMPLEMENTATION OF RISK MINIMIZATION ACTION PLANS

TO SUPPORT QUALITY USE OF
PHARMACEUTICALS: OPPORTUNITIES
AND CHALLENGES: A PUBLIC
WORKSHOP

The background of the slide is a solid blue color. In the lower right quadrant, there are several faint, concentric circles that resemble ripples in water, creating a subtle decorative pattern.

IMPLEMENTATION OF RISK MAPS: the LAST panel

- The “epidemiologist’s friend” OTHER
- CROSS-CUTTING ISSUES and ACTION RECOMMENDATIONS
- CHALLENGES FOR THIS AFTERNOON’S PANEL AND ...
- OPPORTUNITIES FOR US ALL!!



IMPLEMENTATION OF RISK MAPS: CROSS-CUTTING ISSUES FROM BOTH DAYS

- **CONSENSUS REMAINS:** WE APPEAR TO AGREE ON THE OBJECTIVES; BUT NOT YET THE METHODS ... AND **CONSENSUS** THAT WE MUST MOVE FORWARD TOGETHER: “IF YOU DON’T UNDERSTAND THE NEED TO MANAGE RISKS, YOU MIGHT NOT BE IN THE RIGHT INDUSTRY!”
- **STANDARDIZATION:** EACH RISKMAP IS UNIQUE; BUT THE SYSTEMS INTO WHICH THEY ARE INSERTED REQUIRE STANDARD APPROACHES ... AND SEVERAL PROMISING APPROACHES EXIST. NO MORE “WORKING WITHOUT A NET!”

IMPLEMENTATION OF RISK MAPS: CROSS-CUTTING ISSUES FROM BOTH DAYS

- **TRANSPARENCY:** ADOPTION REQUIRES ACCEPTANCE; ACCEPTANCE REQUIRES UNDERSTANDING; BUT THE SECTOR REQUIRES INTELLECTUAL PROPERTY PROTECTION AND HAS YET TO DEVELOP EFFECTIVE COMMUNICATION ... BUT PROGRESS IN COMMUNICATION AND KNOWLEDGE TRANSFER IS PROMISING

IMPLEMENTATION OF RISK MAPS: CROSS-CUTTING ISSUES

- **EMPOWERMENT:** MANAGEMENT REQUIRES CONTROL; PROFESSIONALISM REQUIRES FLEXIBILITY. REGULATION IS CENTRAL; IMPLEMENTATION IS LOCAL ... BUT WE CAN BRIDGE THIS GAP BY ENGAGEMENT.
- **RESOURCES:** SPECIALIZED PROCESSES INCREASE COSTS; THE SECTOR NEEDS COST-CONTAINMENT ... AND HUMAN RESOURCES (RISK AVERSION EPIDEMIOLOGISTS WHO “ACT LIKE SUPERMAN”!)
- **EVIDENCE:** RISK MANAGEMENT IS AN INTERVENTION; INTERVENTIONS ARE THERAPY TOO AND REQUIRE THE SAME ETHICS AND PROOFS... “WHAT IS THE QUESTION FROM THE PUBLIC HEALTH PERSPECTIVE?”
- **POLICY:** WE NEED CONTINUED CONSIDERATION OF EQUITY AND ACCESS, CLEARER CRITERIA AND THRESHOLDS (INCLUDING END-POINTS), AND UNINTENDED CONSEQUENCES AND ETHICS

CHALLENGE TO THE FINAL PANEL: ACTIONABLE STEPS

...



RiskMAPPING THE WAY FORWARD



RiskMAPPING THE WAY FORWARD

--FDA CHANGES

--INFORMATICS

--EFFECTIVENESS

--RISKMAP METHODS

--KEEPING THE TORCH
BURNING



FINAL PANEL: ACTIONABLE STEPS

ENHANCE FDA FUNCTIONS:

(I'M FROM THE OFFICE OF NP
PROBLEMS ... ER, UM ...PROGRAMS)

“GO-TO” PERSON

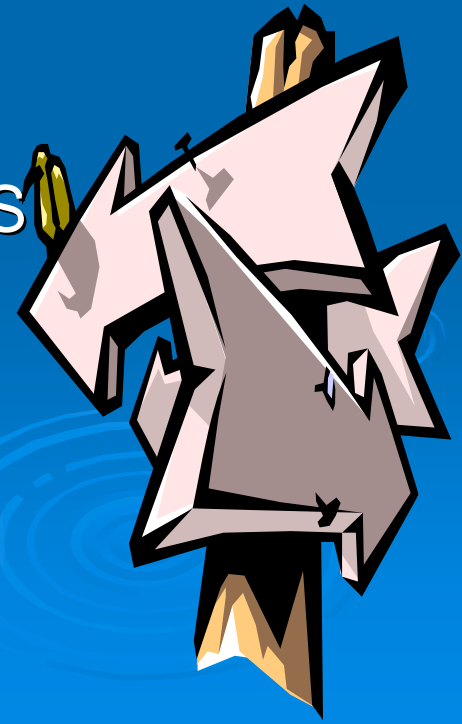
STANDARDS AND CONSISTENCY

TRANSPARENCY AND ACCESS TO
INFORMATION

NIMBLENESS AND RESPONSIVENESS
TO CQI

MORE EFFECTIVE RISK
COMMUNICATION (& BENEFIT)

RISKMAP POLICY AND OVERSIGHT



FINAL PANEL: ACTIONABLE STEPS

INFORMATICS AGENDA:

CLINICAL DECISION SUPPORT
SYSTEMS

LAMPS FOR SECTOR MONITORING,
EXPOSURE, OUTCOMES,
UTILIZATION (INCL. 'OFF LABEL' OR
OFF PROGRAM) , SENTINELS

WEB—BASED COMMUNICATIONS
AND KNOWLEDGE MANAGEMENT

HOT LINKS

HIGH TECH and HIGH TOUCH



FINAL PANEL: ACTIONABLE STEPS

BENEFIT TO RISK BALANCE:

METHODOLOGY

RESEARCH AGENDA

THINK TANKS

CONSENSUS CONFERENCE

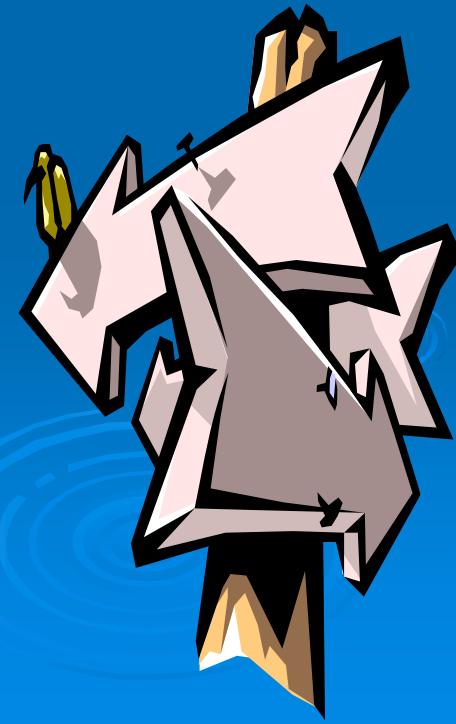
BEST PRACTICES

(REMEMBER CIOMS IV)

Quality of Life

And how to balance the whole benefit with the
whole harms

And how to talk about it



RISK MANAGEMENT DILEMMA

- IN THE BALANCE REMEMBER BENEFITS AND NOT JUST HARMS



FINAL PANEL: ACTIONABLE STEPS

BENEFIT TO RISK BALANCE:
METHODOLOGY
COMMUNICATION
EFFECTIVENESS
COMPARATIVE
EFFECTIVENESS



FINAL PANEL: ACTIONABLE STEPS

Training of an effective workforce

The Pharmacoepidemiologist full
employment act

Competencies

Curriculum

Core faculty

Centers

AND the training of the profes-
sional world in therapeutics



FINAL PANEL: ACTIONABLE STEPS

RISKMAP METHODS:
STANDARDS AND TOOLS
VETTING/DEVOLVING
GOOD RM PRACTICES in lieu
of
MICRO-MANAGEMENT



FINAL PANEL: ACTIONABLE STEPS

KEEPING THE TORCH BURNING:

WEBSITE/WEB FORUM

CONVENER

SAFE HAVEN

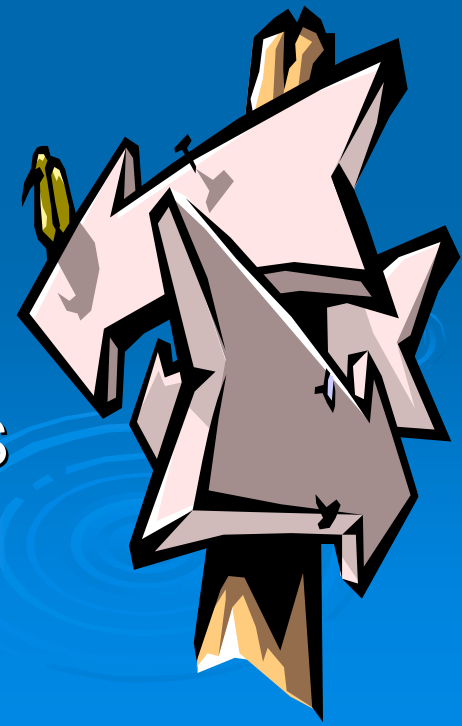
TRUSTED NATIONAL RESOURCES

CONSULTATION

PUBLICATION

SECTOR ENGAGEMENT: AFFERENT
AND EFFERENT ARMS

A FOLLOW-UP OF THESE TWO DAYS



FINAL PANEL: ACTIONABLE STEPS

Definable framework for REMS

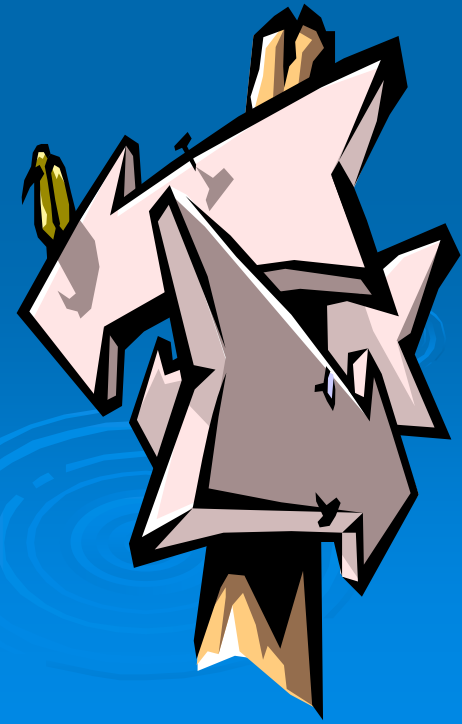
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Criteria for a RiskMAP

Systematic should not be
robotic

It's the ACCESS stupid

Systematic evaluation tools



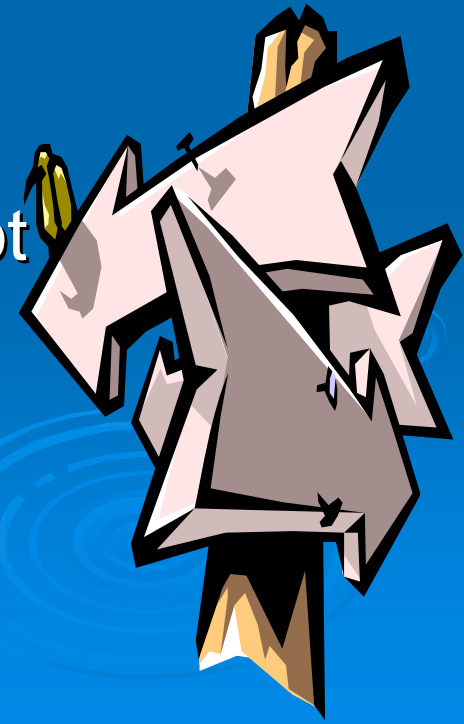
FINAL PANEL: ACTIONABLE STEPS

FDA ... more systematic at the policy level ... centralize ... and 'go to' staff

RiskMAPs with the "end" in mind.
FDA's role? What's the goal? I don't want the FDA to be my doctor.

Don't want doctors not to think ..not yet artificial intelligence

Culture(s) of SAFETY in Industry
(AND elsewhere)



RiskMAPPING THE WAY
FORWARD
--FDA CHANGES
--INFORMATICS
--EFFECTIVENESS
--RISKMAP METHODS
--KEEPING THE TORCH
BURNING
TASKING!!



FINAL PANEL: ACTION AGENTS

FDA

AHRQ

OTHER GOV. AGENCIES

SPONSORS/INDUSTRY

PROVIDERS/PROFESSIONAL
SOCIETIES

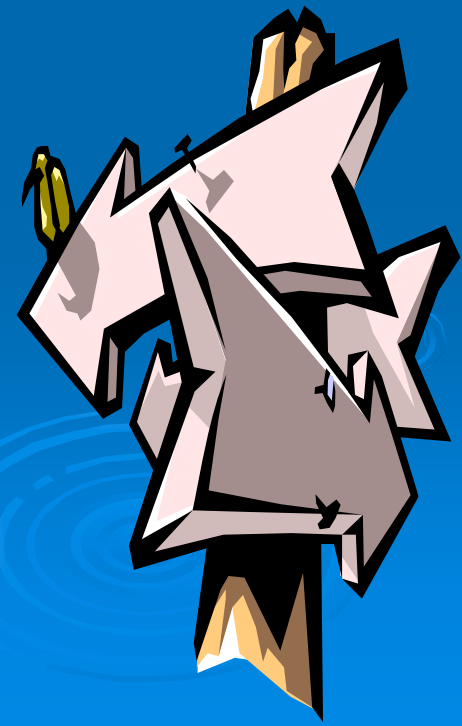
TRADE ASSOCIATIONS

PATIENT GROUPS

OTHER KEY STAKEHOLDERS

CERTS/ACADEMIA

CONGRESS



FINAL PANEL: ACTION AGENTS

FDA

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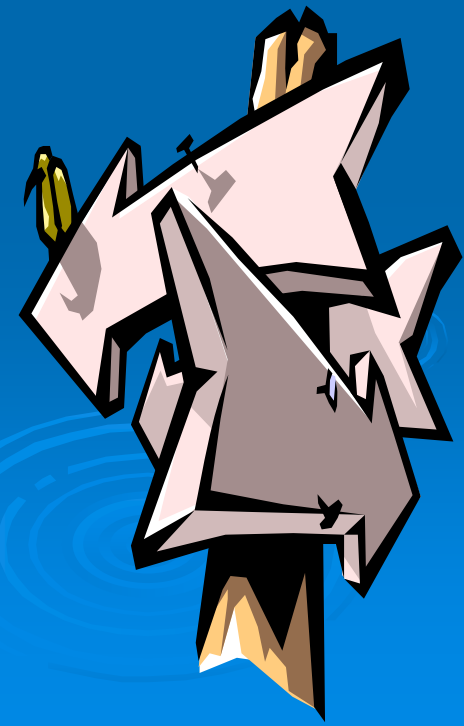
PATIENT GROUPS

OTHER KEY STAKEHOLDERS

CERTS/ACADEMIA

CONGRESS

YOU



VARIATIONS ON THE THEME OF M.A.P



VARIATIONS ON THE THEME OF M.A.P:

--Making RMP drugs ACCESSIBLE to (the
right) PATIENTS

--Making RMPs ACCCEPTABLE to
PROVIDERS

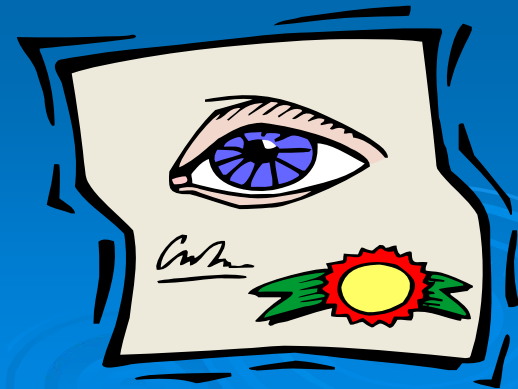
--Making RMPs AFFORDABLE to PAYERS
and the PRICE-WEARY

--Making RMPs ATOMATABLE for
PROGRAMMERS



VARIATIONS ON THE THEME OF M.A.P:

- Making RMPs AMENABLE to PRVACY concerns and requirements
- Making RMPs ARTICULABLE to the PRESS



VARIATIONS ON THE THEME OF M.A.P.:

- Making RMPs ACHIEVABLE for the
PRODUCER/Sponsor
- Making RMPs ACCOUNTABLE for the
PBUBLIC



IMPLEMENTATION OF RISK MAPS: LOOK IN THE MIRROR:

➤ YOU ARE ON THE MAP!

