



U.S. Food and Drug Administration

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DDMAC Research Update



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Upcoming Studies



Upcoming Studies

- Additional study of format of brief summary
- Investigation of online DTC advertising
- Effects of disease awareness information in branded pieces



Upcoming Studies

- Investigation of the toll-free statement for reporting negative side effects in TV DTC ads
- Effect of adding quantitative benefit information to DTC ads



Toll-Free Statement

- FDAAA (Public Law 110-85): Title IX
- Printed DTC ads must include the following statement:

“You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.”



Toll-Free Statement

- FDAAA (Public Law 110-85): Title IX
- FDA shall conduct a study to determine whether this statement is appropriate for DTC television ads.
- Will the statement detract from risk information?



Toll-Free Statement

FDA research question:

- How can this statement be placed to **minimize** interference with risk information AND **maximize** comprehension of the statement?



Toll-Free Statement

Four main questions:

- Duration
- Placement
- Prominence
- Wording



Toll-Free Statement

How long is the statement on the screen?

- Short duration
- Long duration
- During the whole ad
- No statement (Control)



Toll-Free Statement

Where is the statement placed in the ad?

- Before the major statement of risks
- During the major statement of risks
- After the major statement of risks
- During the whole ad
- No statement (Control)



Toll-Free Statement

How prominent is the statement?

- On screen after the major statement of risks
- On screen after the major statement of risks and spoken in the audio



Toll-Free Statement

What wording is used in the statement?

- “You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.” (*FDAAA*)
- “Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.”



Toll-Free Statement

Protocol

- Internet – Knowledge Networks
- Each participant randomly assigned to view only one test ad



Toll-Free Statement

Protocol

- Test ad will be embedded in an advertising pod:
 - Two filler ads
 - Unrelated DTC ad with statement
 - Test ad– high blood pressure



Toll-Free Statement



You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088



Toll-Free Statement

Study Sample

- internet panel members
- Two samples:
 - High blood pressure sufferers
 - General population



Toll-Free Statement

Key Dependent Variables

- Comprehension of risk information
- Comprehension of benefit information
- Recall of toll-free statement



Toll-Free Statement

Timeline

- OMB-approved
- US Census moratorium in place
- Data collection will start in September
- Preliminary results expected by end of 2010



Quantitative Information



Quantitative Information

FDA research questions:

- Will the addition of quantitative benefit information help consumers?
- What are the best ways to present quantitative information about product benefits in DTC print and television ads?



Quantitative Information

What statistical format maximizes consumer understanding of the information?



Quantitative Information

No Quantitative Info

- Votrea reduces bad cholesterol for people with several common risk factors for heart disease



Quantitative Information

Absolute Frequency

- Votrea reduces bad cholesterol for people with several common risk factors for heart disease
- With Votrea, **65 out of 100** people lowered their bad cholesterol to normal levels versus **2 out of 100** people with no treatment.



Quantitative Information

Percent

- Votrea reduces bad cholesterol for people with several common risk factors for heart disease
- With Votrea, **65%** of people lowered their bad cholesterol to normal levels versus **2%** of people with no treatment.



Quantitative Information

Absolute Frequency & Percent

- Votrea reduces bad cholesterol for people with several common risk factors for heart disease
- With Votrea, **65 out of 100 (65%)** people lowered their bad cholesterol to normal levels versus **2 out of 100 (2%)** people with no treatment.



Quantitative Information

Relative Frequency

- Votrea reduces bad cholesterol for people with several common risk factors for heart disease
- With Votrea, people were **33 times** more likely to lower their bad cholesterol to normal levels, compared to no treatment



Quantitative Information

Relative Frequency & Percent

- Votrea reduces bad cholesterol for people with several common risk factors for heart disease
- With Votrea, **65%** of people lowered their bad cholesterol to normal levels versus **2%** of people with no treatment—that's **33 times** more effective

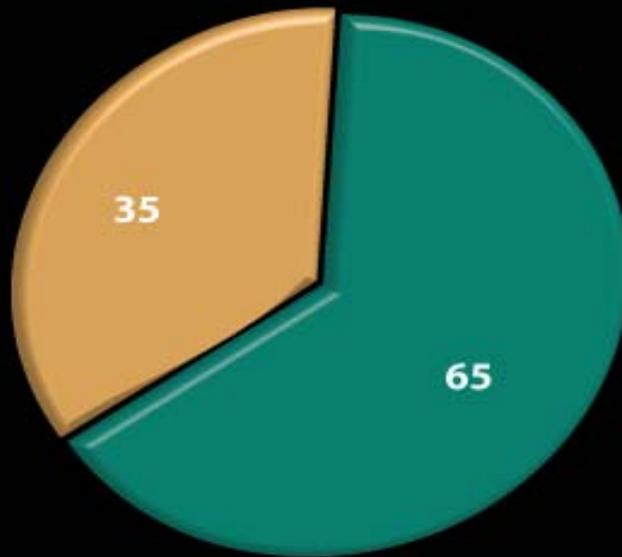


Quantitative Information

What visual display best helps consumers understand statistical information?



Votrea



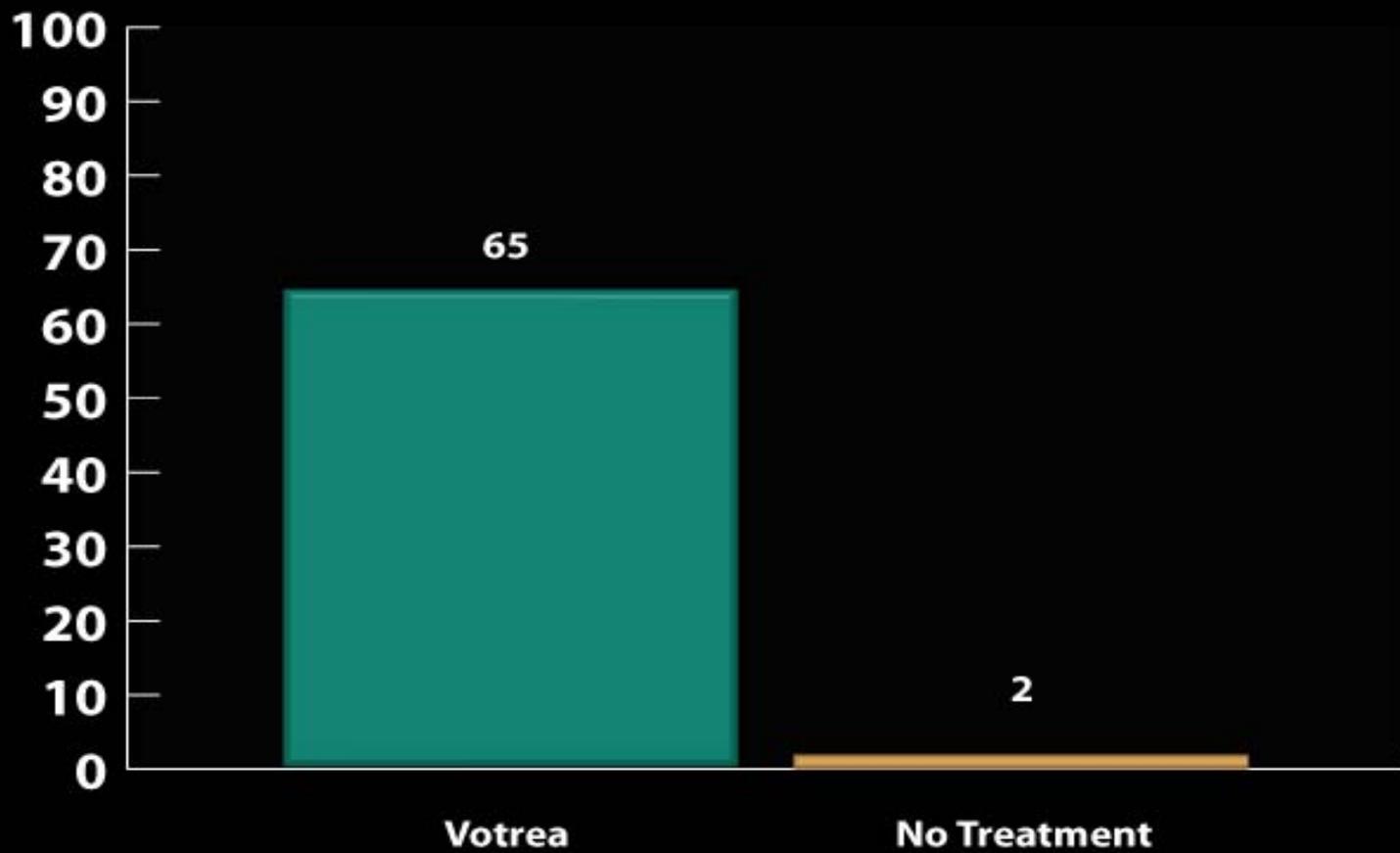
No Treatment



Not Final

RTI International





Not Final

RTI International



Clinical Trial Results to Lower Cholesterol By 50 Points

	Votrea	No Treatment
Yes	65	2
No	35	98
Total Patients	100	100

Not Final

RTI International



Votrea

No Treatment



Not Final

RTI International



Quantitative Information

Protocol

- Internet – Knowledge Networks
- Print or TV ad; questions are same
- Each participant randomly assigned to view only one test ad



Quantitative Information

Study Sample

- internet panel members
- High cholesterol sufferers



Quantitative Information

Key Measures

- Perceived efficacy
- Benefit recall
- Specific benefit accuracy
- Perceived risk
- Risk recall



Quantitative Information

Timeline

- OMB-approved
- US Census moratorium in place
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Contact Information

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- DDMAC website:

[http://www.fda.gov/AboutFDA/CentersOffices/
CDER/ucm090142.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm)

