MAGI's 2008 Clinical Trial Agreements, Budgets & Regulatory Conference

Managing Currency Risks in International Clinical Trials

How to manage financial exposures to currency fluctuations risks

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The Problem:

- More and more, studies are conducted globally at international sites
- Most companies budget for studies at the start as part of investment capital allocation to complete development
- The source of money is defined in certain currency, USD or Euro
- However, cash outflows are paid in other currencies

The Problem: case study

- Multi site, international study, across five countries: France, Poland, Russia, Bulgaria and Romania
- Study negotiated in late 2006 and client capital is in USD, therefore, the budget is established in USD
- More than 90% of expenses and operational cash outflows are in other currencies

Countries' Currencies

Romania - LEI

France - EURO

Bulgaria - LEVA

Poland - Zlotych

Russia - Roubles

Type of contracts typical for each country

France - Contract currency can be EURO.

Romania - Contract currency can be in EURO, USD or RON. However, payments are paid in RON, at the exchange rate of the date of invoicing

Russia - Contract currency can be in EURO, USD or Rubles. Payments are paid in Roubles, at the exchange rate of the date of invoicing

Poland - Contract currency can be EURO, USD or Zlotych. Payments are paid in Zlotych, at the exchange rate of the date of invoicing

Bulgaria - Contract currency can be in EURO, USD or Leva. Payments are paid in Leva, at the exchange rate of the date of invoicing

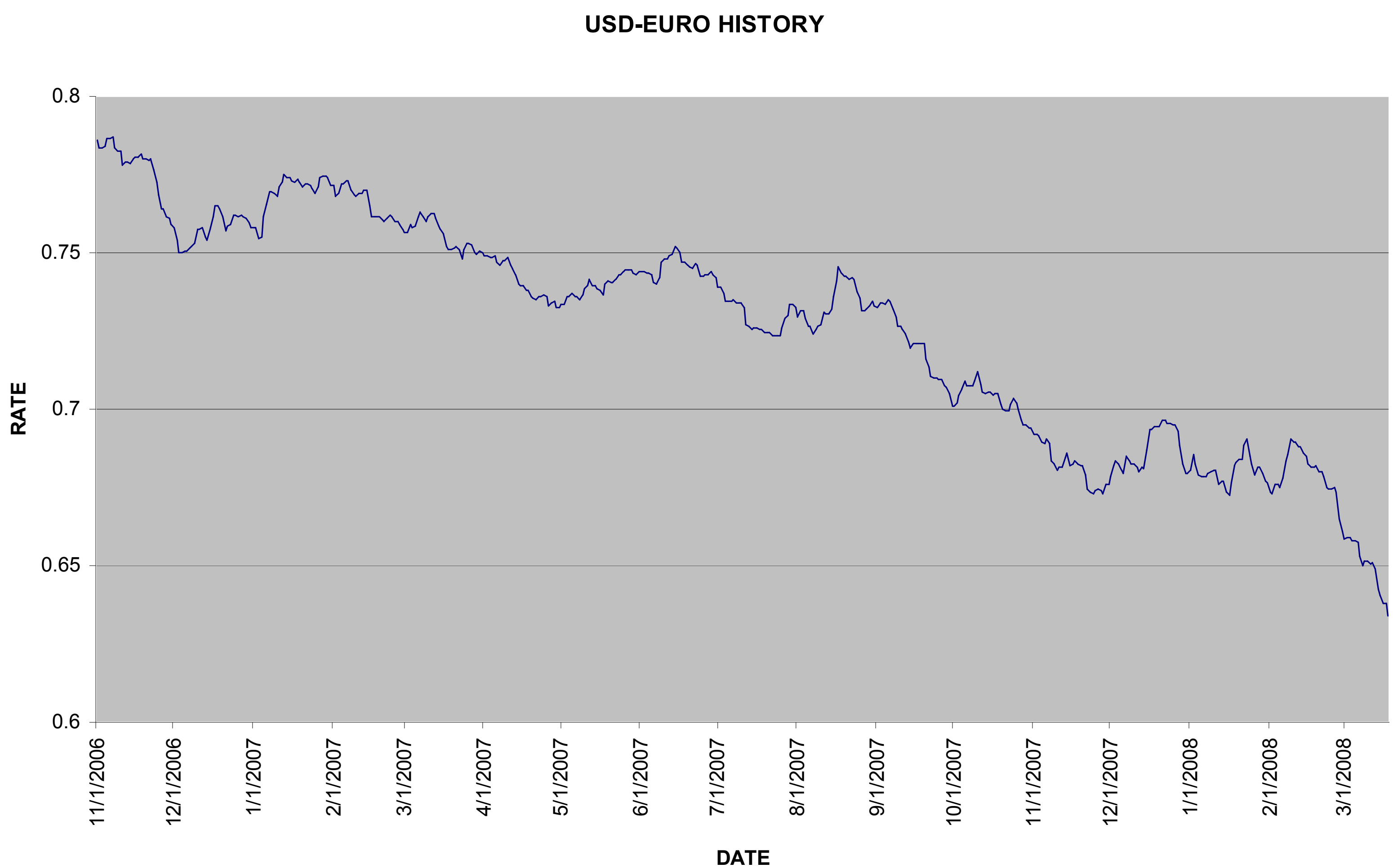
Break–down of standard clinical trials cash flows

- Investigator & Clinical Research Team fees – 25%
- Lab – equipment usage, kits & staffing – 30%
- Biostatistics & Pharmacokinetics fees – 10%
- Facility usage (patient accessibility & recruitment) – 5%
- QC - Monitoring & Auditing – 10%
- Regulatory Affairs – 10%
- Administrative & Consumables – 10%

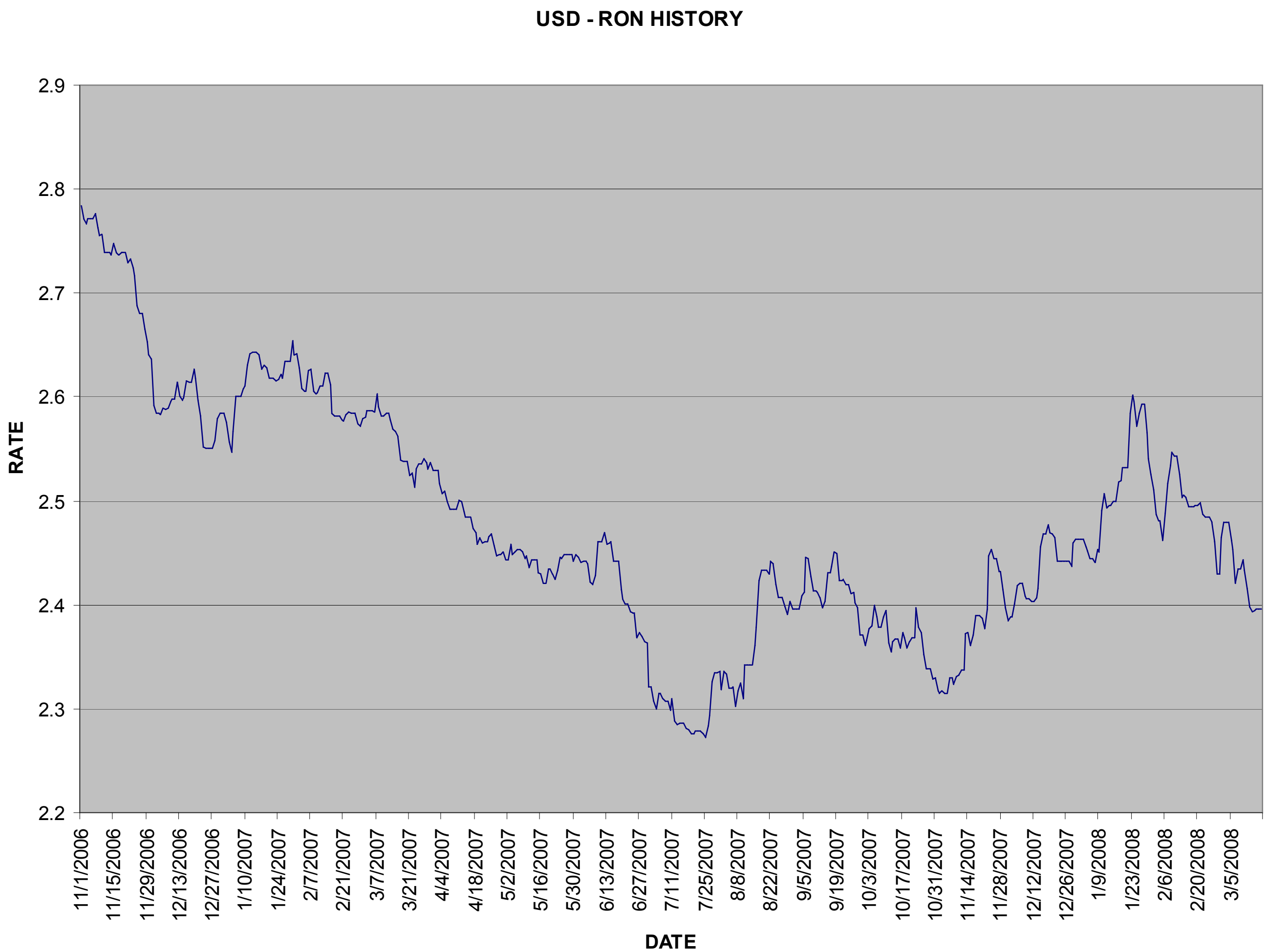
Step one: evaluate currency exposure

- The first step in managing currency risk is to evaluate exposure
- In multi sites studies, that could be straight forward when all study design and planning are set
- Evaluate when payments are made and at what currency
- Consolidate payments as possible in fewer nos. of currencies

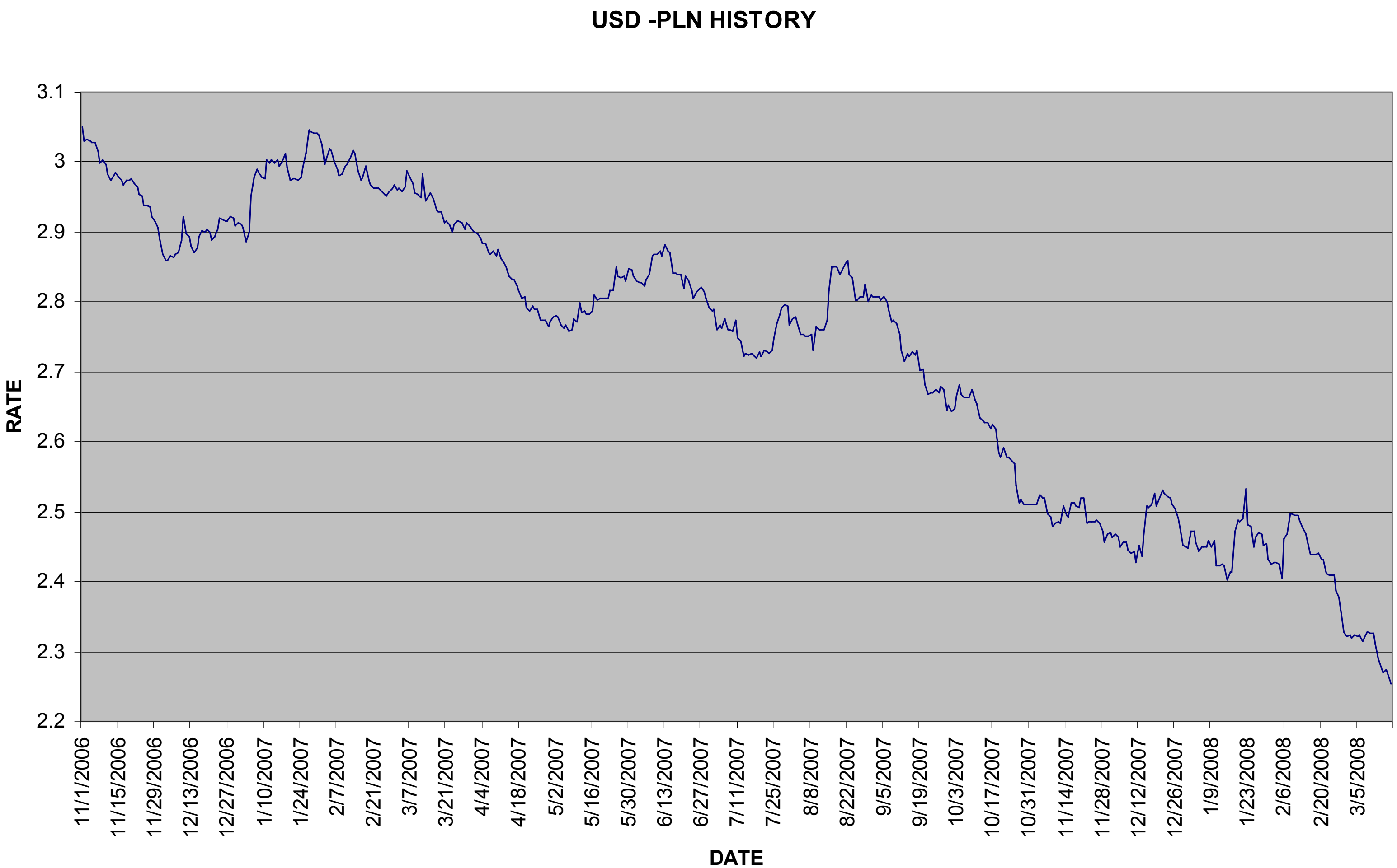
French operation: measuring risks: 17%



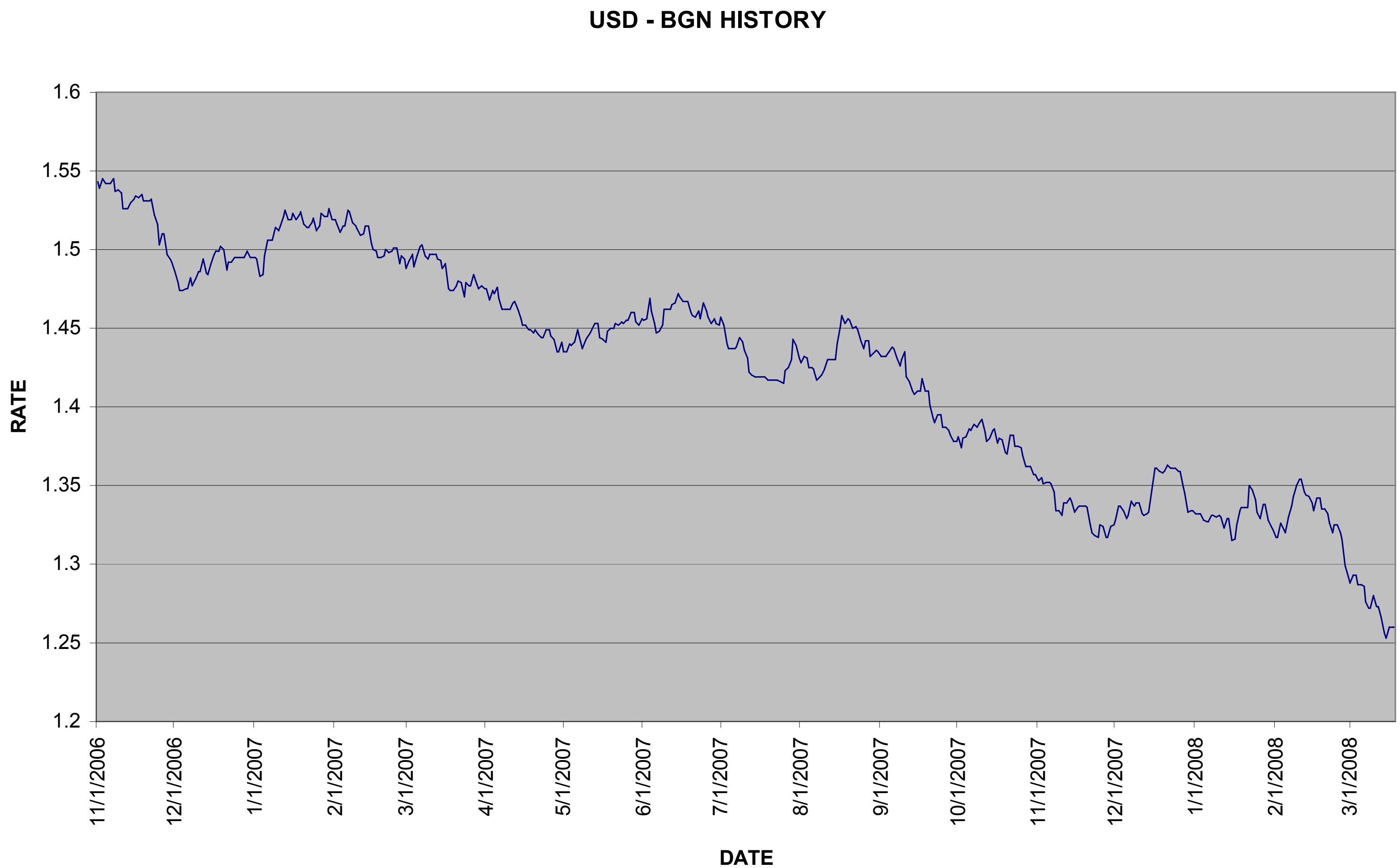
Romania operation: risk, 14%



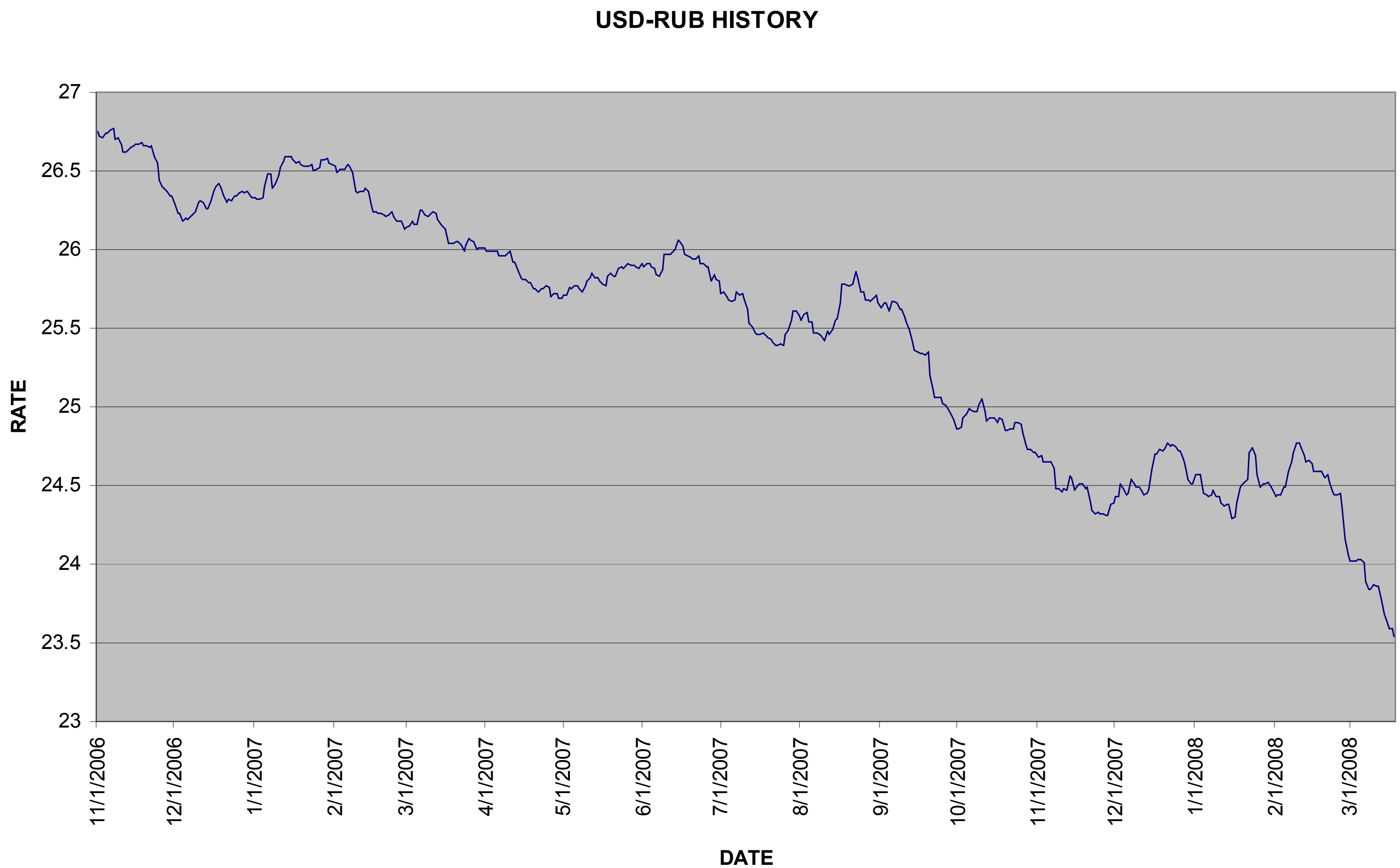
Poland operation: risks, 22%



Bulgaria operation: risks, 21%



Russia operation: risks, 15%



Second step: Value at Risk budgeting

- Investment institutions need clear budgets
- Value at risk provides an excellent tool
- Value at risk is a financial management concept that determines value of assets with some level of certainty of risk exposure
- E.g. we are x% sure that the cost of the study will be $1m. And that we will not exceed 50k

Third Step: Management options

- After value at risk is determined and at different levels of probabilities, then the planner has a better understanding of risks
- If the risk is small and acceptable, then no need to do anything until new value at risks are evaluated during the conduct of the study that reflect new changes
- If the risk is high, then management options should be considered

Currency Risks Management options

- Forward Rate Agreements
- Currency Options
- Currency Futures
- Natural Hedging
- Swaps
- Diversification

Forward Rate Agreement (FRA)

- Forward Rate Agreement is the simplest and easiest tool
- FRA is a contract with a bank or finanical institution that the delivery of a currency will be at a specified rate in certain time in the future
- The currency amount and the rates are fixed per contract

FRA for Clinical trials: Advantages & Disadvantages

- Advantages:
  - Simple and straight forward
  - When future payments are known, then fluctuation is less and cost of hedging (FRA) is less
  - FRA fits into large payments to labs and medical centers when services are completed at certain milestones
- Disadvantages:
  - Can not re-negotiate terms if study changes
  - Not available for some currencies

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Currency Options

- Options are contracts that provide the right to buy (call) or to sell (put) an asset (stock, currency) at a certain price within or at a certain time; at exercise price
- American options: can exercise anytime before maturity
- European options: should exercise on maturity
- Main attractive feature: the right but not obligation to exercise, and therefore alleviate FRA disadvantage for clinical trials contracts

Currency Futures CF

- Futures are contracts to buy or sell assets at a specified time in the future and at certain price
- To use this management option, one will buy currency future buy or sell contract for a standard price or premium, which is a small fraction of the face value, plus a margin fee that changes based on currency fluctuation (margin cover)
- Futures could be canceled anytime (close out) by entering a reverse contract

Advantages and disadvantages of CF

- Advantages:
  - Could be canceled out anytime
  - Low cost (commitment of funds) to acquire future rights for currency exchnge
  - The market of future is deep (active) and liquid
- Disadvantages:
  - Exposure to margin calls and its costs

Natural Hedging

- If financial instruments are expensive or complicated, natural hedging provide simple solutions
- Natural hedging refer to wiping out the currency risk factors from one (cost) stream by the risk factors from another stream (revenue)
- E.g. borrow money in local currencies
- However, do not borrow only to natual hedge
- Very common in clinical trials where companies have several currencies streams from different studies, and naturally hedge them

Natural Hedging w. clients cash streams

- To naturally hedge, projects planners may explore naturally hedging their revenues stream with their clients and even with their providers
- However, strong attention should be exercised on contractual implications to changes in these contracts

Swaps,

- Applied for large transactions of currencies
- Swap emerged by specialized firms that arrange swap of debts contracts
- In the currency market, the fiancial company (swap) the terms of contracts currency for certain costs.
- Swap may provide a cost effective way of managing risks when swapping debts into another currency offset the streams risks from this currency

Diversification

- Driven by portfolio theory, diversification is the most straight forward tool to avoid currency risks
- For payments dues in monthly cycles, it will be wise to diversify holding of currencies
- If no other instruments are chosen, diversification will be the safer and least expensive way to avoid currency risk

Thank you!

For questions:

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