

Gaoyang LI, Happy Life Technology

Beyond
data visualization:
Let's tell a visual
analysis story

李高扬，开心生活，统计编程负责人

高扬微信

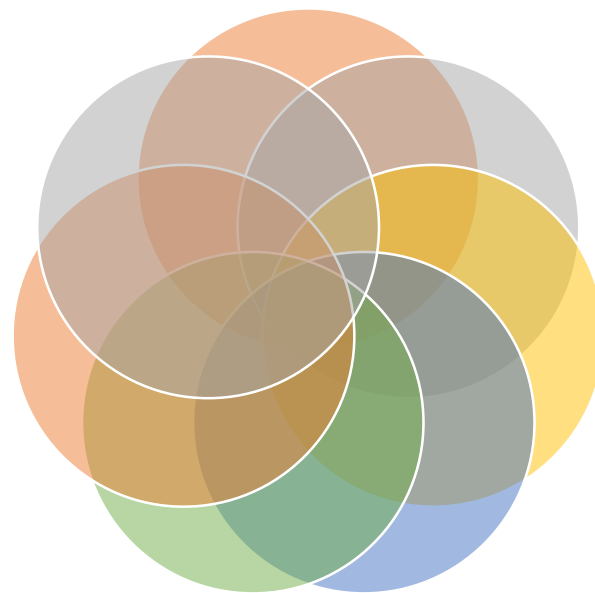


DIA青年顾问团
成员

羽毛球亚军

户外爱好者

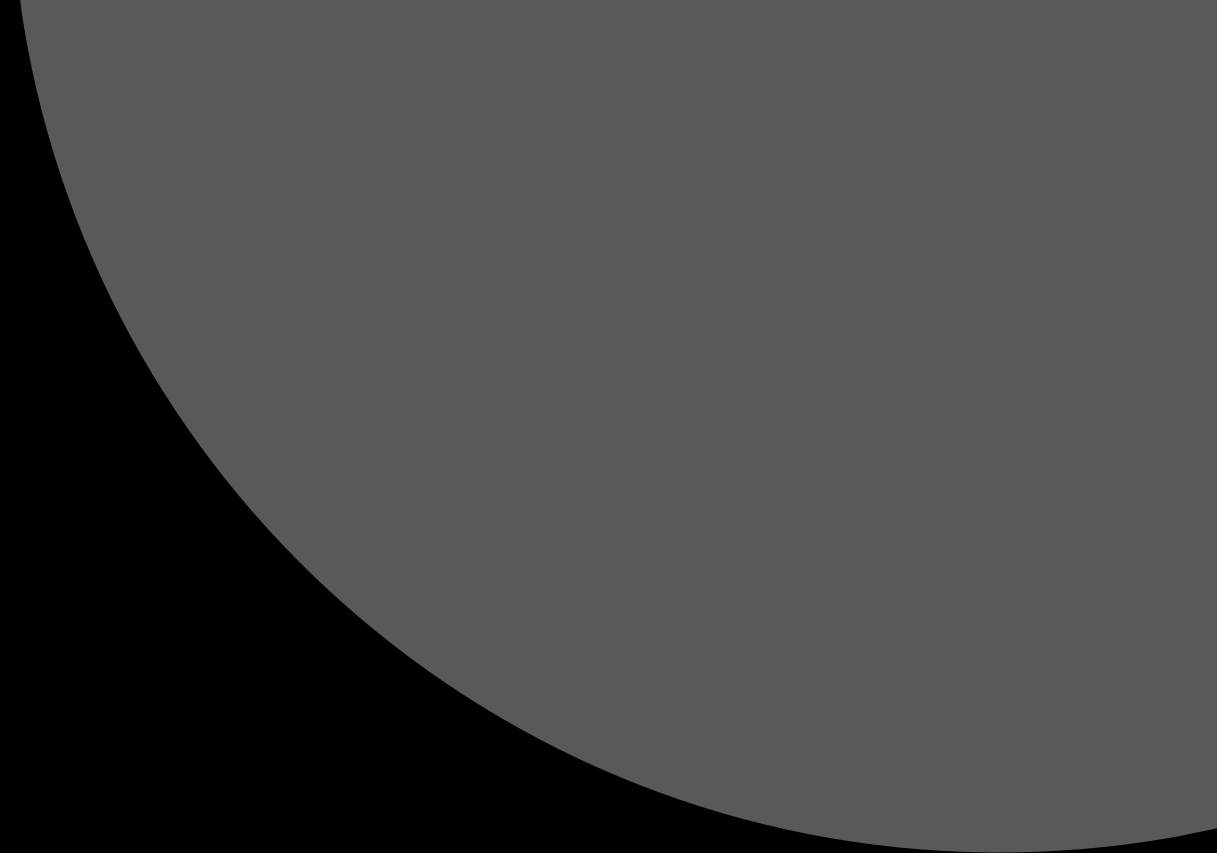
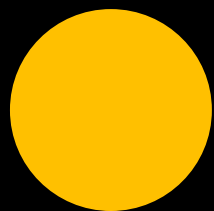
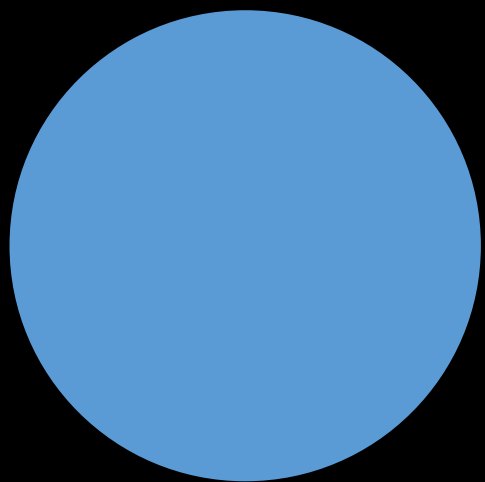
航拍小达人，群主



数字健康社区，
群主

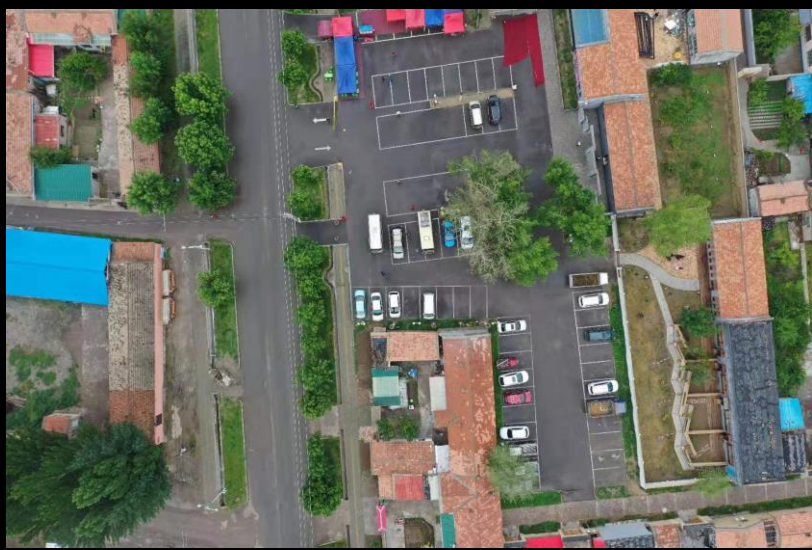
临床研究交互
式分析，群主

流程自动化初级



Is this a Whole Picture

@xinjiang, by Gaoyang



FDA Town Hall CDER Update

Patrizia Cavazzoni, M.D.

Deputy Director for Operations
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Global DIA
June 27, 2019



DV is required

Framework for Evaluating RWD/RWE for Use in Regulatory Decisions



Demonstration projects underway
addressing RWD sources and RWE
methods and new projects addressing
data standards for FDA submission.

- FDA-Catalyst
 - Claims linkage to the RELIANCE trial.
 - FDA MyStudies App support for LimitUIA trial and Crohn's and Colitis Foundation registry.
 - IMPACT Afib trial
- Duke Harmony trial vs. RWD comparison.
- One Source EHR optimization.
- Duplication of Clinical Trials with RWE from Observational Studies.



Facilitating consistency and
knowledge exchange across the
Center/Agency with review of RWE
submissions.



Stakeholder engagement –
meetings on RWE Study Designs
and Regulatory Considerations,
Data Standards, and RWD curation.

6

Incorporating Technological Innovations in Regulatory Processes



Cloud-based Data Management Systems

- FDA involved in multiple efforts to explore the use of cloud-based systems to enable secure external collaborations.
- Benefits include:
 - Controlled access to data in real-time.
 - Enhanced and more facile advanced analytic capabilities.
 - Facilitating and simplifying collaborations and communication.
 - Ability to transfer large files while safeguarding data integrity.

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Incorporating Technological Innovations in Regulatory Processes

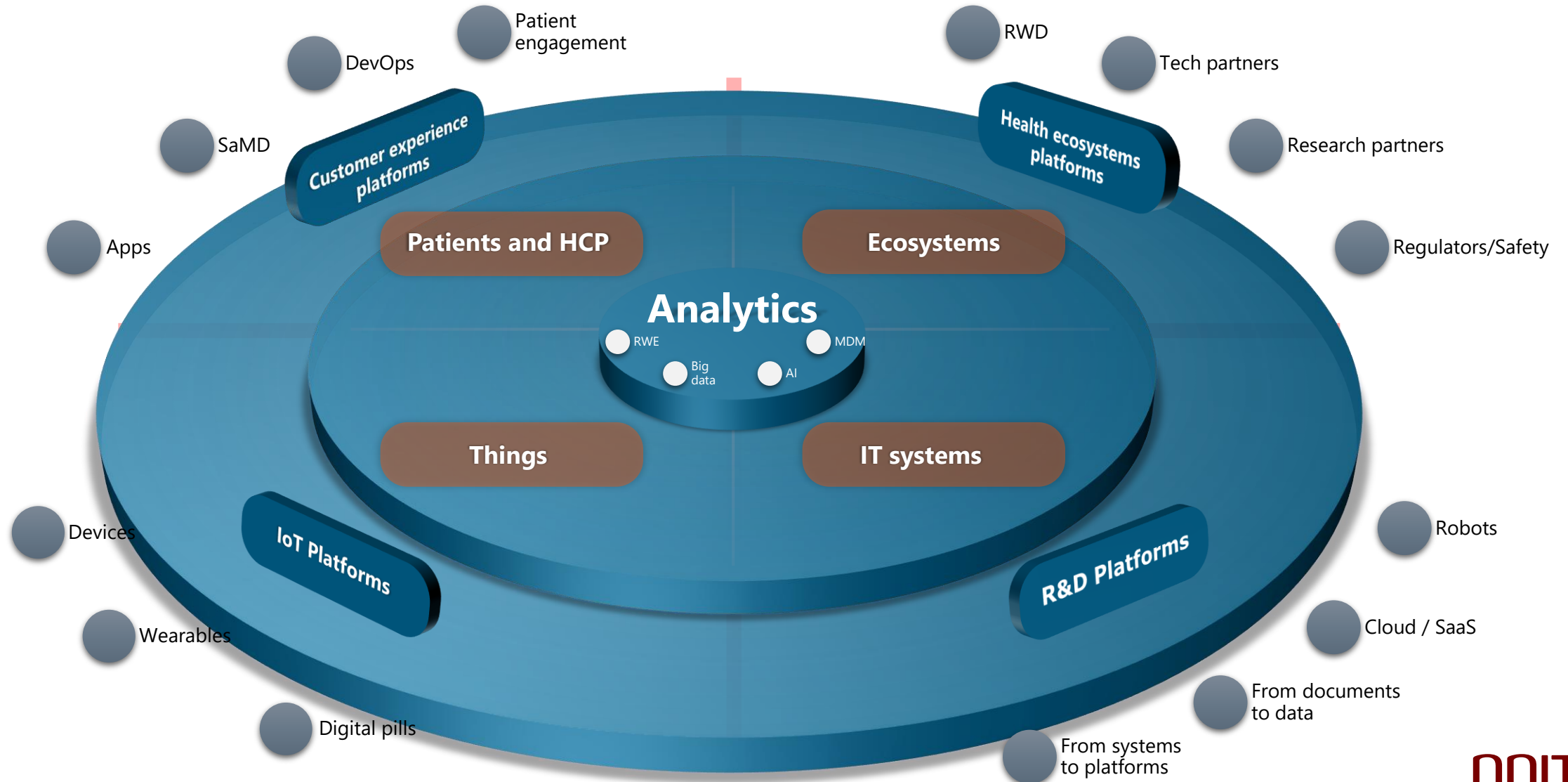


Artificial Intelligence (AI)

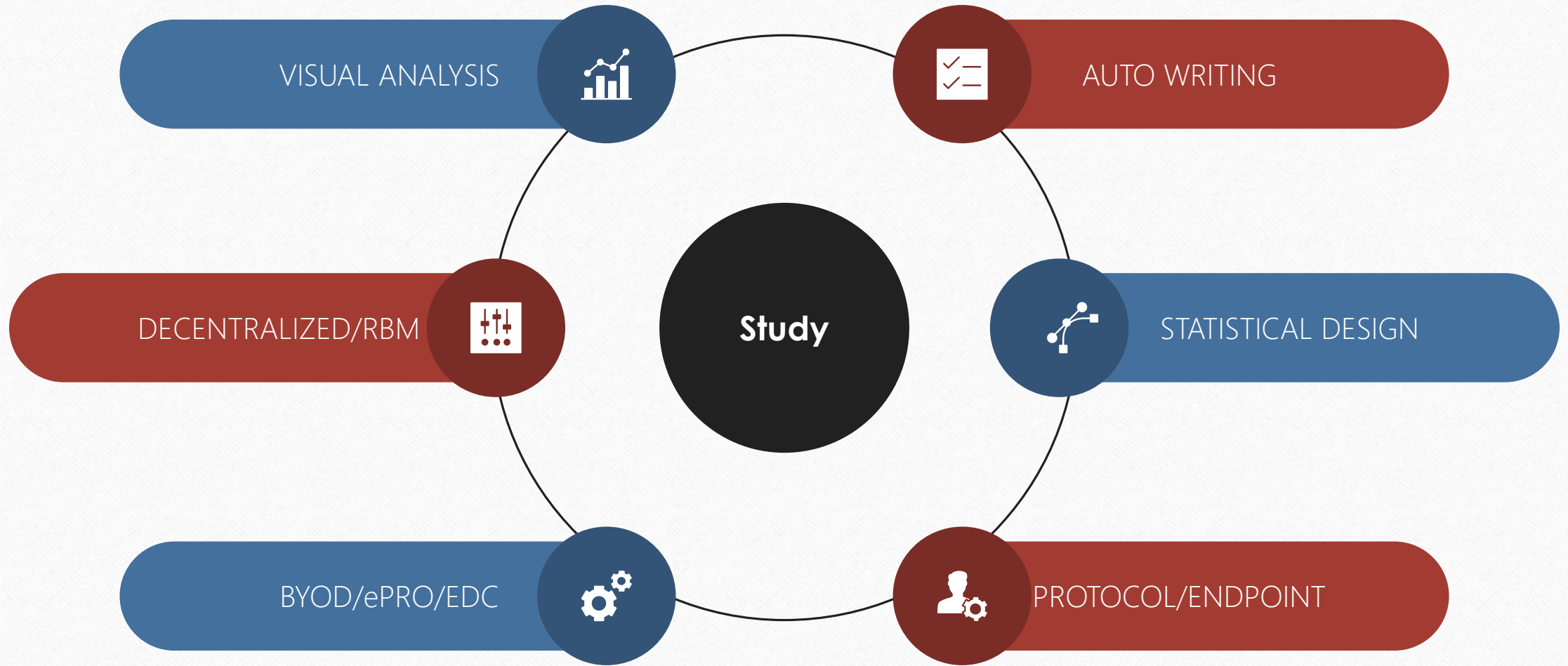
- FDA has multiple concurrent efforts focused on anticipating and understanding the use of AI in drug and device development.
- The agency is also exploring the potential for AI systems to enhance regulatory processes.
 - Exploring the use of AI is a part of the agency's commitment to incorporate innovative technology in its processes, and to ensure robust handling of such tools when used to support drug applications.
 - AI systems are increasingly utilized across the drug development continuum (e.g., target identification, drug design, enhancing clinical trial design).
 - AI may prove very useful in helping us make sense of real-world data (RWD).

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DV is for visual analysis



DV is part of automation



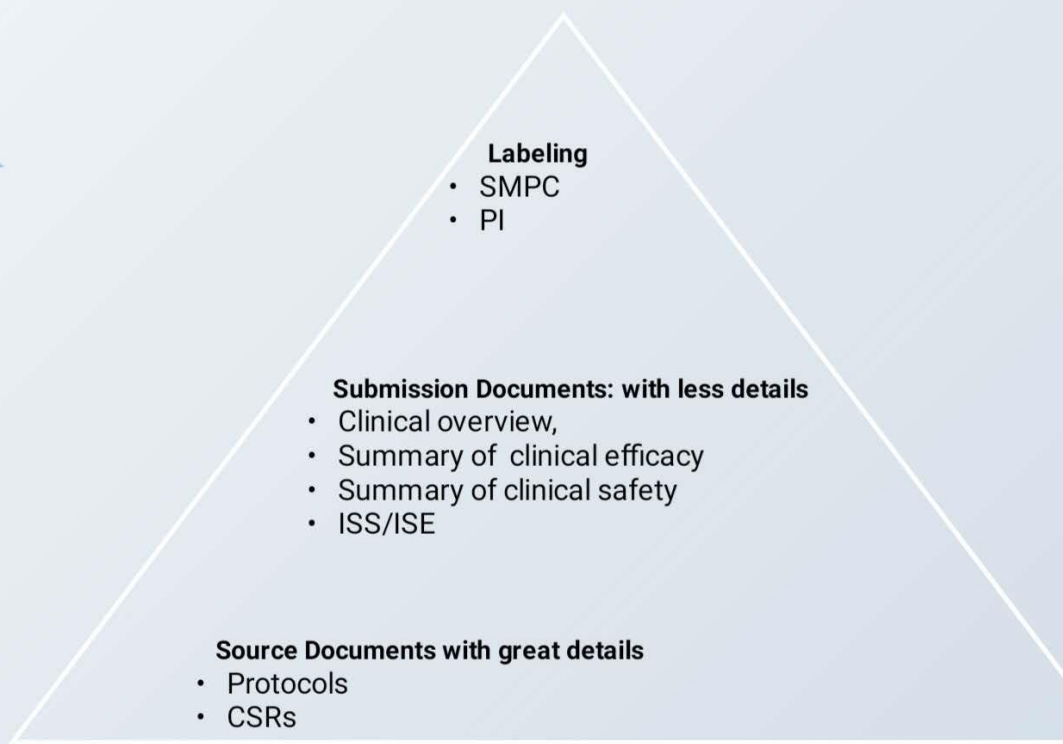
DV tools is of Business Intelligence



传统医药研发数据分析从提出数据分析需求到获得分析结果周期漫长，流程复杂，医学专业人士严重依赖静态分析报告，无法直接从数据获取洞察。在数字化时代，医药大数据源源不断，真实世界数据维度无穷，AI技术广泛应用，传统医药研发数据分析模式不再适宜，自助式分析崛起。

文件关系

逐步总结升华得出结论



- 以终为始，以TLF为目标
- 图表一体，表是一种图
- 天下武功，唯快不破
- 早期研发，Go or no-go
- 系统上线，go live or go die

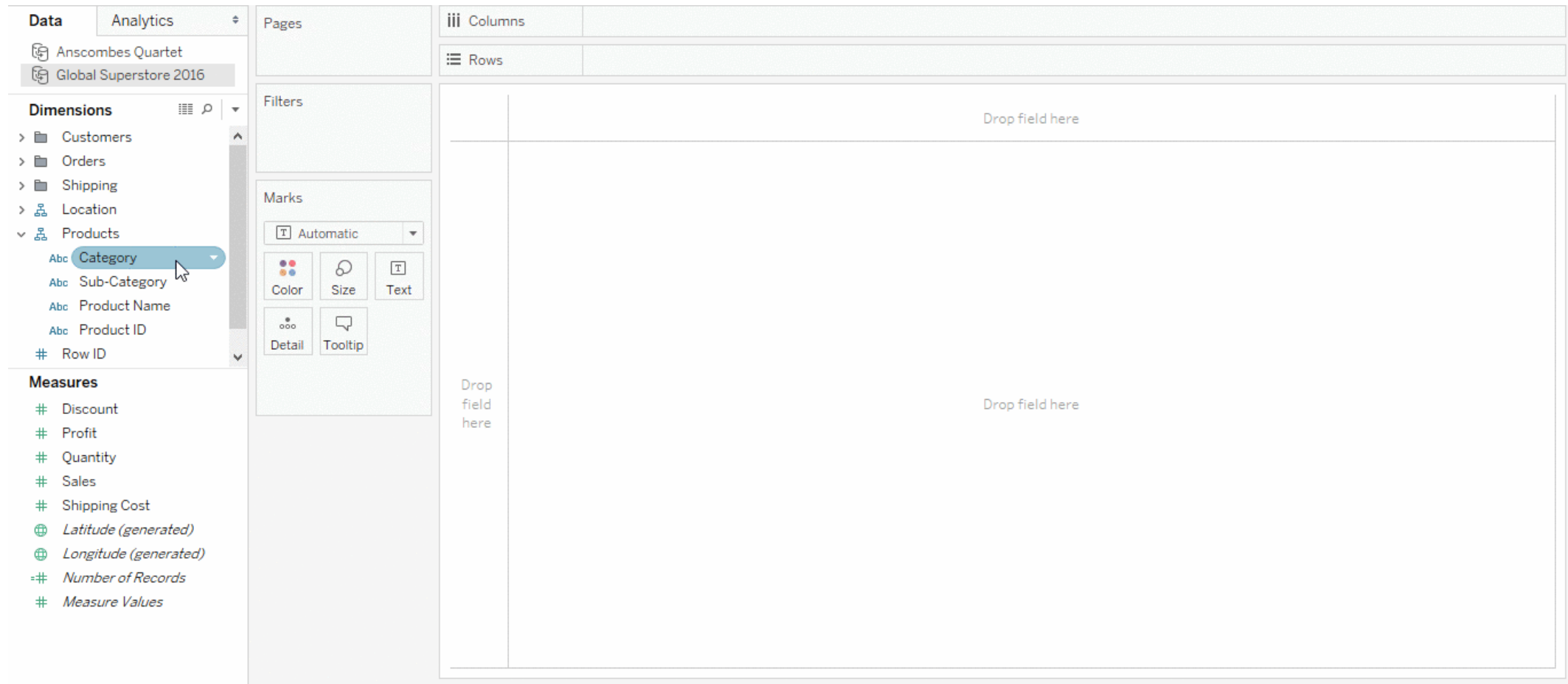
DV tools is for Insights



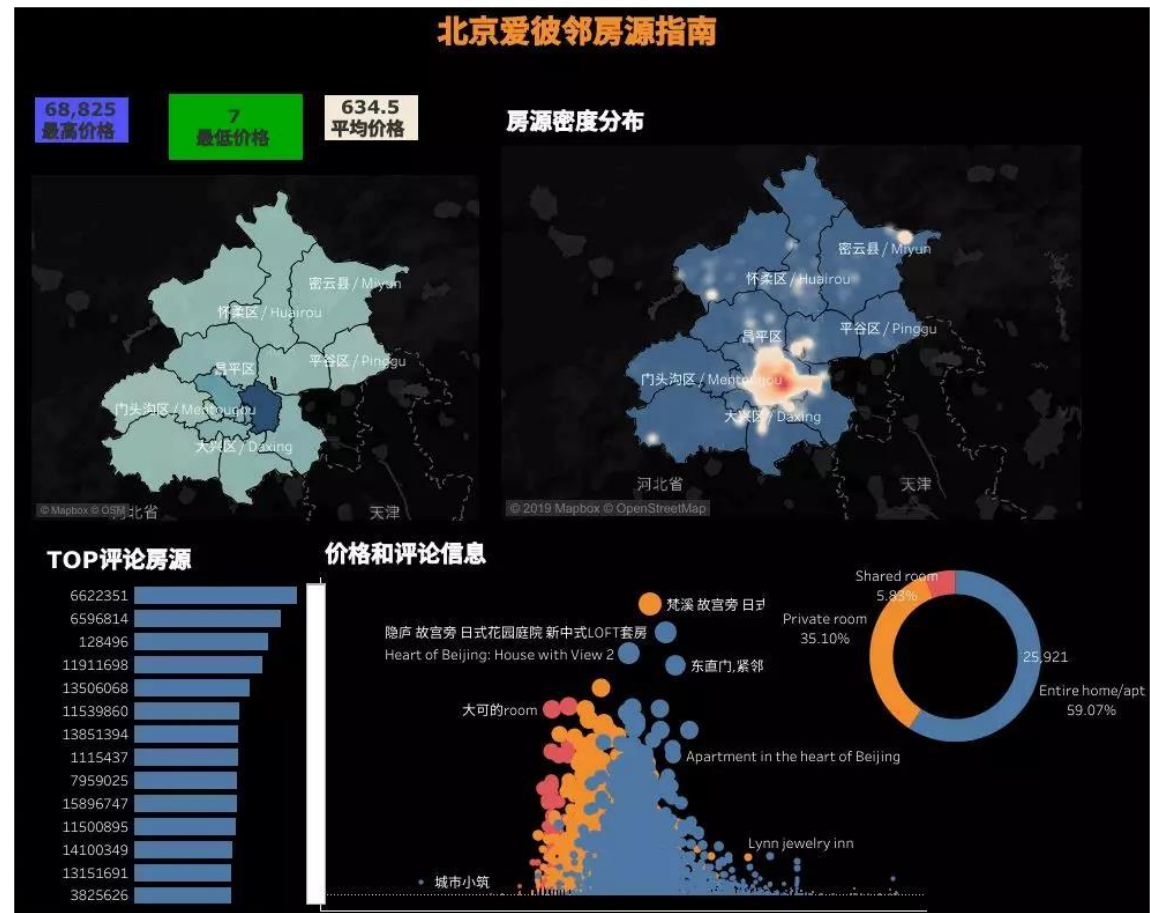
How to tell a visual analysis story

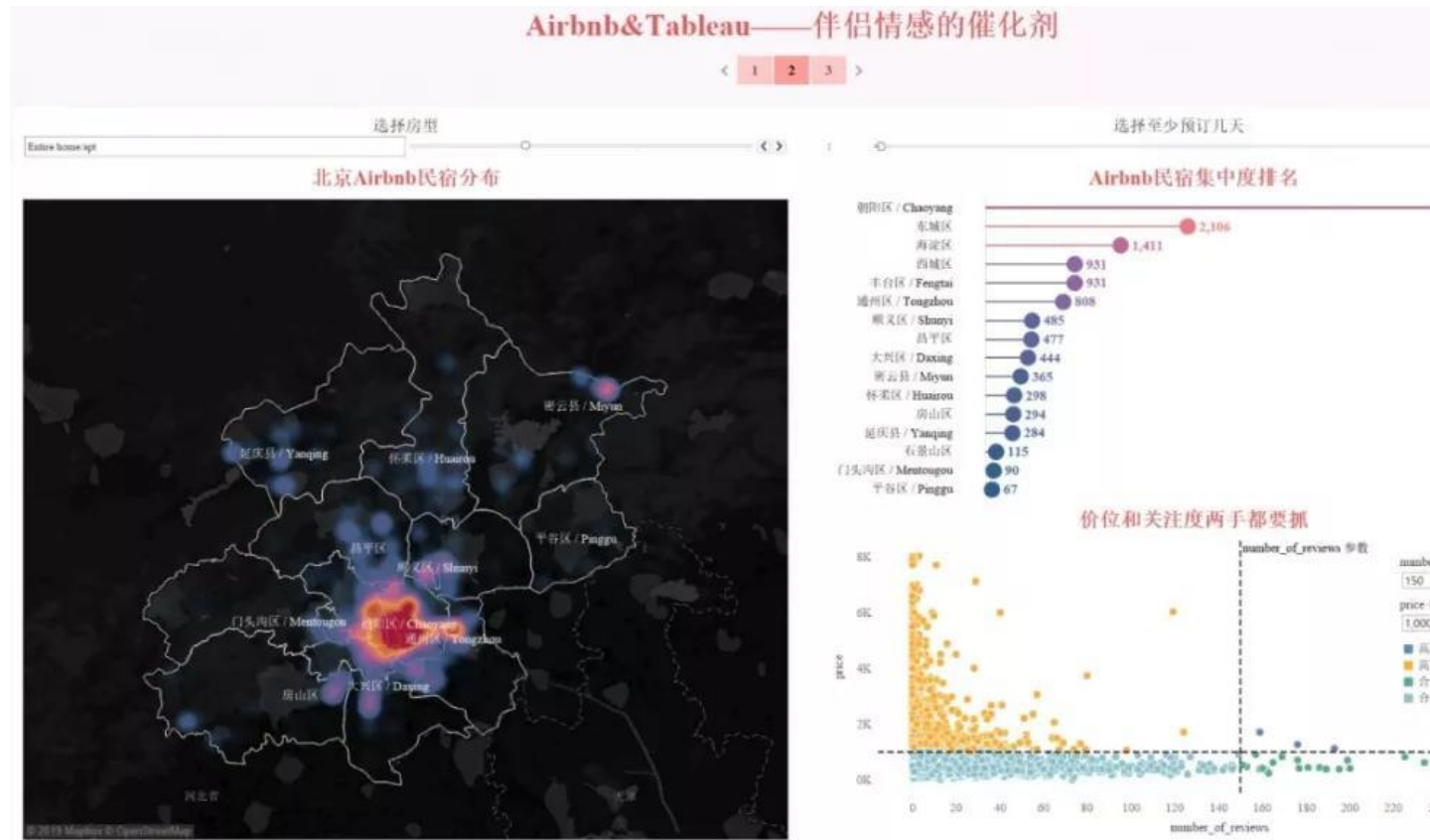
8 criteria

1. Choose a tool with Simple operation



2. Clear goal, Clear Display





3. What is your **Key** points

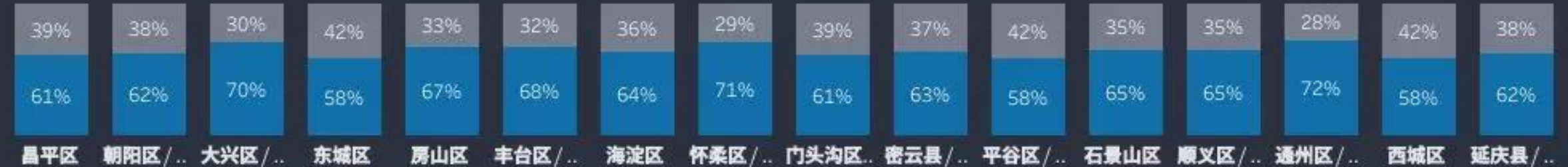
"老炮儿"带您聊民宿

4. What is the important facts?

消费洞察

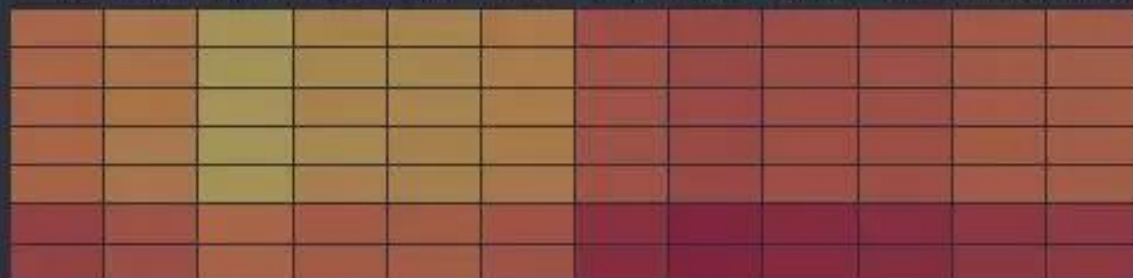


2019民宿攻略



星期日
星期一
星期二
星期三
星期四
星期五
星期六

一月 二月 三月 四月 五月 六月 七月 八月 九月 十月 十一月 十二月



小贴士:
假日安排胸中了
节日哪里都别跑
来京错开高峰月
京郊预定要提早

5. Live data, Live connection

- Live connection to statistical file video

6. Dynamic plot, **dynamic** view

- Dynamic dashboard video

7. Evils are in the details

- Drill down video

The Data Journey Begins...

8. Is this a **true** story?



总结/Summary

简

- Simple

操作简单

明

- Clear

显示明确

扼

- Key

关键信息

要

- Important

重点突出

- Live

实时连接

- Dynamic

动态交互

- Details

详细追溯

- True

实事求是

生

动

详

实

谢谢/Thank you

