

Rafting and paddling on the Statistical Programming river

The value of a leadership culture, within your organization, to overcome obstacles and taming the rivers temper

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Inspired by **patients.**
Driven by **science.**



Agenda



- 01** Statistical Programming is water rafting
- 02** The river temper
- 03** The boat
- 04** Leadership and Culture
- 05** Reflections

Water rafting is Statistical Programming



Statistical Programming is most of the time a **team effort** (development and validation)

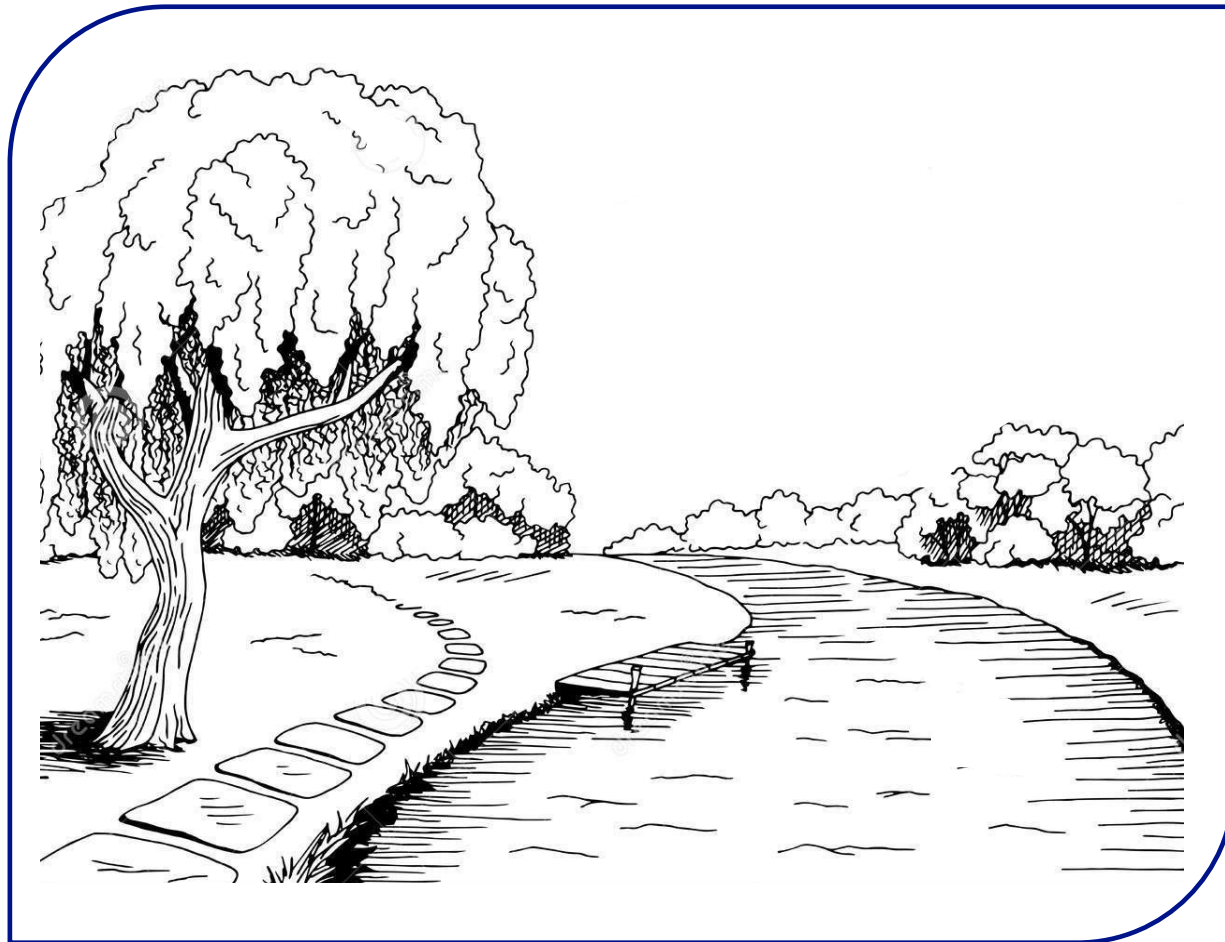
No (or minimal) **control over the river** strength and directions



Skipper is important to determine paths (leadership) but **Team** (Culture) equally important to navigate through and work synchronized

The river temper...

few years ago...



- **Global Standards** still in transition (FDA/PMDA transitioning to CDISC with exceptions)
- **Biotechnology market** in the early stage
- Drug development process following a **sequential model** (Phase I → II → III)

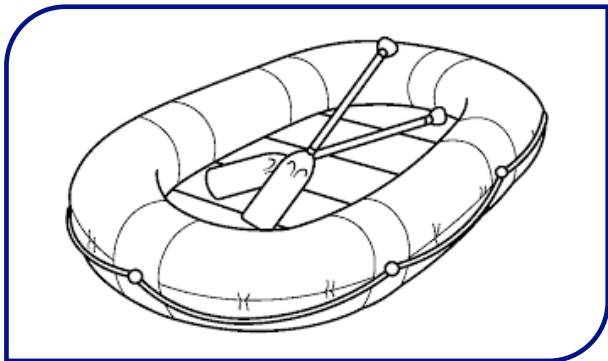
The river temper...

nowadays

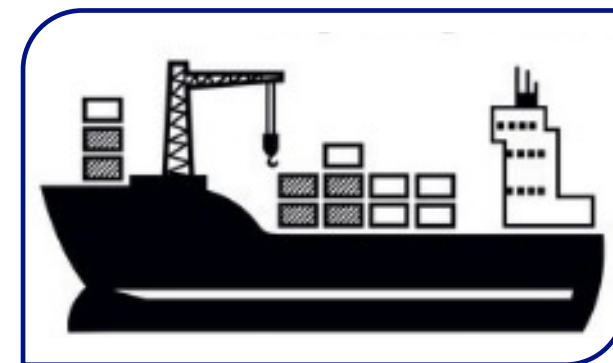


- **Data Standards (CDISC)** are the **required** by several Health Agencies
- **New technologies in drug development** (ex. gene/cell therapies, proteomics, genomics)
- **New technologies supporting the data collection** (devices, wearables, AI/NLP, RWE)
- More **partnerships** between pharma industries and **across business areas** (ex. Google, Microsoft, etc.)
- **Increasing competitive markets** and more focus on costs reduction from countries

The boat



- **New data sources and collection techniques** (ex. real world data, wearables, devices, etc.)
- Moving from a “**dualistic**” **biometric model** with data collection and data analysis to a crowded space with multiple stakeholders on the data side (Analytics, Data Scientists, Digital Health experts, RWE)
- Increased use of **nontraditional analysis** (estimands) **and software** (open source)
- **Mutated global landscape** after two-year pandemic-induced hiatus
- Evolving **acquisitions and partnerships** biotech/pharma/universities with spin offs



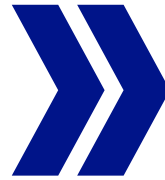
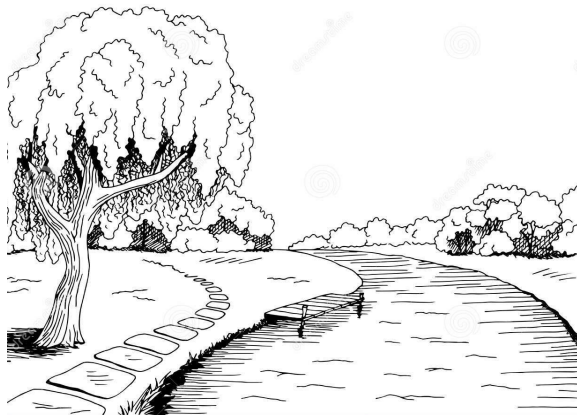
Leadership and Culture

Leadership is the **ability to inspire a team** to achieve a certain goal.

Leadership is to influence, inspire and **help others become their best selves, building their skills** and achieving goals along the way.

Leadership is **empowering others to become effective leaders** as well.

Great leadership – quality leadership – is servant leadership.
Servant leadership refers to someone who wants to influence others to serve the greater good.



Culture as the **accumulated shared learning** of a given group, covering **behavioral, emotional, and cognitive elements** of the group members

For such shared learning to occur, there must be a **history of shared experience** that, in turn, implies **some stability of membership in the group**.

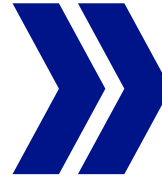
*Given such **stability** and a **shared history**, the various shared elements form into **patterns that eventually can be called a culture**.

*Cit. (E. Schein, Organizational culture and Leadership, 4th edition).

Leadership and Culture II

Strategy

- Transparent/discussed/understood
- Visible in the company context
- Opportunities of engagement across levels and roles within organization



The Team

- Revised in relation a new landscape (more flexibility and remote work)
- Bringing junior roles/interns with new skills into organization
 - Development opportunities
 - Rotating programs



The Team Interactions

- Extend the line function network with other stakeholders
- Solid extended LTs to manage the organization
- Create network of leaders within our groups (irrespective role)
- New areas within company where bring value



The Boat

- Up to date Technologies, Tools and Systems
- Revised Processes
- New skills/areas identified
- Evolving languages

Reflections

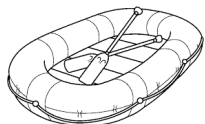
Increased Environmental complexity



from the creek to a rocky river



Increased Organization's complexity



from inflatable boat to a sophisticated tank



Evolve from Leadership to Culture



Leadership is the kick fire.
Culture is integrating multiple elements and tying at a deeper level





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Thanks for your attention